## **Network Notifications**

New Hampshire



Date: August 31, 2022 Number: 74

To: All WellSense Providers

From: WellSense Health Plan

Subject: August Medical Policy Network Notifications

Product: 

⊠ NH Medicaid 
⊠ NH Medicare Advantage

## **August Network Notifications**

The following WellSense Health Plan medical policies will be updated with revisions to clinical review criteria and/or applicable coding included in the medical policies (excluding industry-wide code updates and/or codes that do not require prior authorization). The revised medical policies will be effective on November 1, 2022:

- Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies, OCA 3.573
- 2. Clinical Review Criteria, OCA 3.201
- 3. Complementary and Alternative Medicine, OCA 3.194
- 4. Facet Joint Nerve Injections, OCA 3.9641
- 5. Gender Affirmation Services, OCA 3.11
- 6. Genetic/Genomic Testing and Pharmacogenetics, OCA 3.727
- 7. Genetic Testing for Fragile X-Associated Disorders, OCA 3.571
- 8. Genetic Testing for Hereditary Thrombophilia, OCA 3.728
- 9. Minimally Invasive Procedures to Treat Back Pain, OCA 3.713
- 10. Non-Emergency Transportation Services, OCA 3.191
- 11. Occupational Therapy in the Outpatient Setting, OCA 3.543
- 12. Osteochondral Treatments for Defects of the Knee, Talus or Other Joints, OCA 3.965

## **Network Notifications**

New Hampshire



- 13. Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder, OCA 3.561
- 14. Physical Therapy in the Outpatient Setting, OCA 3.544
- 15. Posterior Tibial Nerve Stimulation, 3.562
- 16. Sacroiliac Joint Injections, OCA 3.9642
- 17. Speech Therapy, OCA 3.542
- 18. Temporomandibular Joint Disorders, OCA 3.968

#### **General Information**

All WellSense Health Plan medical policies are located on the Provider's page at <a href="https://www.wellsense.org/providers/nh/policies">https://www.wellsense.org/providers/nh/policies</a> under the Policies link. If you do not have Web access, you may contact your provider relations representative for a copy of the policies. The updated policies listed above will be posted on the website and available from your provider relations representative on September 1, 2022.

### Questions?

If you have any questions about this Network Notification, please contact your dedicated provider relations consultant or call the Provider Line at 877-957-1300, option 3 (for NH Medicaid) or 866-808-3833 (for Medicare Advantage). WellSense Health Plan Network Notifications and Reimbursement Policies are available online at wellsense.org.



Medical Policy - Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 11/01/22

# Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies

**Policy Number**: OCA 3.573

Version Number: 20

Policy Retired Date: 11/01/22

#### **Impacted Products**

- ⋈ NH Medicaid
- ⋈ NH Medicare Advantage
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

## **Policy Summary**

Genetic testing using chromosomal microarray analysis (CMA) is considered medically necessary for the diagnosis of an adult or pediatric member with unexplained intellectual disability, developmental delay, symptoms or findings consistent with an autism spectrum disorder, and/or multiple congenital anomalies when AIM clinical appropriateness guidelines are met. Prior authorization from AIM Specialty Health is required for genetic testing.

#### Clinical Criteria

No medical policy criteria.

#### **Limitations and Exclusions**

None.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage

determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 190.3 includes guidelines for the use of cytogenetic studies. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for genetic testing, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT/HCPCS Codes	Code Description
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., Bacterial Artificial Chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81349	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis
S3870	Comparative genomic hybridization (CGD) microarray testing for developmental delay, autism spectrum disorder and/or intellectual disability
	Plan note: Code is NOT payable for the Senior Care Options and NH Medicare Advantage HMO products.

#### References

Allach El Khattabi L, Heide S, Caberg JH, Andrieux J, Doco Fenzy M, Vincent-Delorme C, Callier P, Chantot-Bastaraud S, Afenjar A, Boute-Benejean O, Cordier MP, Faivre L, Francannet C, Gerard M, Goldenberg A, Masurel-Paulet A, Mosca-Boidron AL, Marle N, Moncla A, Le Meur N, Mathieu-Dramard M, Plessis G, Lesca G, Rossi M, Edery P, Delahaye-Duriez A, De Pontual L, Tabet AC, Lebbar A, Suiro L, loos C, Natiq A, Chafai Elalaoui S, Missirian C, Receveur A, François-Fiquet C, Garnier P, Yardin C, Laroche C, Vago P, Sanlaville D, Dupont JM, Benzacken B, Pipiras E. 16p13.11 microduplication in 45

new patients: refined clinical significance and genotype-phenotype correlations. J Med Genet. 2018 Oct 4. pii: jmedgenet-2018-105389. doi: 10.1136/jmedgenet-2018-105389. [Epub ahead of print]. PMID: 30287593.

American Academy of Neurology (AAN) and Child Neurology Society (CNS). AAN and CNS Guideline Summary for Clinicians. Screening and Diagnosis for Autism.

American Academy of Neurology (AAN) and Child Neurology Society (CNS). Shevell M, Ashwal S, Donley D, Flint J, Gingold M, Hirtz D, Majnemer A, Noetzel M, Sheth RD; Quality Standards Subcommittee of the AAN; Practice Committee of the CNS. Practice parameter: evaluation of the child with global developmental delay: report of the Quality Standards Subcommittee of the American Academy of Neurology and The Practice Committee of the Child Neurology Society. Neurology. 2003 Feb 11;60(3):367-80.

American Academy of Neurology (AAN). Policy & Guidelines.

American Academy of Pediatrics (AAP). Guideline Summaries.

American Academy of Pediatrics (AAP). Hyman SL, Levy SE, Myers SM, Council on Children with Disabilities, Section on Development and Behavioral Pediatrics. Pediatrics. 2020 Jan; 145(1):e20193447. doi: https://doi.org/10.1542/peds.2019-3447.

American Academy of Pediatrics (AAP). Moeschler JB, Shevell M, and Committee on Genetics. Clinical Report: Comprehensive Evaluation of the Child with Intellectual Disability or Global Developmental Delays. Pediatrics. 2014 Sep;134(3):e903-18. doi: 10.1542/peds.2014-1839. PMID: 25157020.

American College of Medical Genetics and Genomics (ACMG). ACMG Board of Directors. Direct-to-consumer genetic testing: a revised position statement of the ACMGC. Genet Med. 2016 Feb;18(2):207-8. doi: 10.1038/gim.2015.190. Epub 2015 Dec 17. PMID: 26681314.

American College of Medical Genetics and Genomics (ACMG). Kearney HM, Thorland EC, Brown KK, Quintero-Rivera F, South ST; Working Group of the ACMG Laboratory Quality Assurance Committee. ACMG standards and guidelines for interpretation and reporting of postnatal constitutional copy number variants. Genet Med. 2011;13(7):680-5. doi: 10.1097/GIM.0b013e3182217a3a. PMID: 21681106.

American College of Medical Genetics and Genomics (ACMG). Manning M, Hudgins L; Professional Practice and Guidelines Committee ACMG. Array based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. Genet Med. 2010 Nov;12(11):742-5. doi: 10.1097/GIM.0b013e3181f8baad. PMID: 20962661.

American College of Medical Genetics and Genomics (ACMG). Monaghan KG, Lyon E, Spector EB; ACMG. ACMG Standards and Guidelines for fragile X testing: a revision to the disease-specific

supplements to the Standards and Guidelines for Clinical Genetics Laboratories of the American College of Medical Genetics and Genomics. Genet Med. 2013 Jul; 15(7):575-86. doi: 10.1038/gim.2013.61. Epub 2013 Jun 13. PMID: 23765048.

American College of Medical Genetics and Genomics (ACMG). Practice Guidelines.

American College of Medical Genetics and Genomics (ACMG). Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. Genet Med. 2013 May;15(5):399-407. doi: 10.1038/gim.2013.32. Epub 2013 Mar 21. Erratum in: Genet Med. 2013. Aug; 15(8):669. PMID: 23519317.

American College of Medical Genetics and Genomics (ACMG). South ST, Lee C, Lamb AN, Higgins AW, Kearney HM; Working Group for the ACMG Laboratory Quality Assurance Committee. ACMG Standards and Guidelines for constitutional cytogenomic microarray analysis, including postnatal and prenatal applications: revision 2013. Genet Med. 2013 Nov;15(11):901–9. doi: 10.1038/gim.2013.129. Epub 2013 Sep 26. PMID: 24071793.

American College of Medical Genetics and Genomics (ACMG). Waggoner D, Wain KE, Dubuc AM, Conlin L, Hickey SE, Lamb AN, Martin CL, Morton CC, Rasmussen K, Schuette JL, Schwartz S, Miller DT; ACMG Professional Practice and Guidelines Committee. Yield of additional genetic testing after chromosomal microarray for diagnosis of neurodevelopmental disability and congenital anomalies: a clinical practice resource of the ACMG. Genet Med. 2018 Oct;20(10):1105-1113. doi: 10.1038/s41436-018-0040-6. Epub 2018 Jun 18. PMID: 29915380.

The American College of Obstetricians and Gynecologists (ACOG). ACOG's Clinical Guidelines.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Carrier Screening in the Age of Genomic Medicine. Number 690. 2017 Mar.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Carrier Screening for Genetic Conditions. Number 691. 2017 Mar. Reaffirmed 2019.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Counseling About Genetic Testing and Communication of Genetic Test Results. Number 693. 2017 April.

The American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal–Fetal Medicine (SMFM). ACOG Committee on Genetics and Society for Maternal–Fetal Medicine Publication Committee. Microarrays and Next–Generation Sequencing Technology: The Use of Advanced Genetic Diagnostic Tools in Obstetrics and Gynecology. ACOG Committee Opinion. Number 682. 2016 Dec.

Babkina N, Graham JM Jr. New genetic testing in prenatal diagnosis. Semin Fetal Neonatal Med. 2014 Jun;19(3):214-9. doi: 10.1016/j.siny.2013.10.005. Epub 2013 Dec 4. PMID: 24315623.

Battaglia A, Doccini V, Bernardini L, Novelli A, Loddo S, Capalbo A, Filippi T, Carey JC. Confirmation of chromosomal microarray as a first-tier clinical diagnostic test for individuals with developmental delay, intellectual disability, autism spectrum disorders and dysmorphic features. Eur J Paediatr Neurol. 2013 Nov;17(6):589-99. doi: 10.1016/j.ejpn.2013.04.010. Epub 2013 May 24. PMID: 23711909.

Bi W, Borgan C, Pursley AN, Hixson P, Shaw CA, Bacino CA, Lalani SR, Patel A, Stankiewicz P, Lupski JR, Beaudet AL, Cheung SW. Comparison of chromosome analysis and chromosomal microarray analysis: what is the value of chromosome analysis in today's genomic array era? Genet Med. 2013 Jun;15(6):450-7. doi: 10.1038/gim.2012.152. Epub 2012 Dec 13. PMID: 23238528.

Bug S, Solfrank B, Schmitz F, Pricelius J, Stecher M, Craig A, Botcherby M, Nevinny-Stickel-Hinzpeter C. Diagnostic utility of novel combined arrays for genome-wide simultaneous detection of aneuploidy and uniparental isodisomy in losses of pregnancy. Mol Cytogenet. 2014 Jun 24;7:43. doi: 10.1186/1755-8166-7-43. eCollection 2014. PMID: 25013457.

Centers for Disease Control and Prevention (CDC). Autism Spectrum Disorder (ASD).

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Cytogenetic Studies (190.3). Version 1. 1998 Jul 16.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Centers for Medicare & Medicaid Services (CMS). Update on Mapping the Landscape of Genetic Tests for Non-Cancer Diseases/Conditions. Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. Final Report. 2012 May 22.

Change Healthcare. InterQual® Overview.

Child Neurology Society (CNS). Practice Parameters.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Cooper GD, Coe BP, Girirajan S, Rosenfeld JA, Vu TH, Baker C, Williams C, Stalker H, Hamid R, Hannig V, Abdel-Hamid H, Bader P, McCracken E, Niyazov D, Leppig K, Thiese H, Hummel M, Alexander N, Gorski J, Kussmann J, Shashi V, Johnson K, Rehder C, Ballif BC, Shaffer LG, Eichler EE. A copy number variation morbidity map of developmental delay. Nat Genet. 2011;43(9):883-46. doi: 10.1038/ng.909. PMID: 21841781.

Coulter ME, Miller DT, Harris DJ, Hawley P, Picker J, Roberts AE, Sobeih MM, Irons M. Chromosomal microarray testing influences medical management. Genet Med. 2011;13(9):770-6. doi: 10.1097/GIM.0b013e31821dd54a. PMID: 21716121.

Ellison JW, Ravnan JB, Rosenfeld JA, Morton SA, Neil NJ, Williams MS, Lewis J, Torchia BS, Walker C, Traylor RN, Moles K, Miller E, Lantz J, Valentin C, Minier SL, Leiser K, Powell BR, Wilks TM, Shaffer LG. Clinical Utility of Chromosomal Microarray Analysis. Pediatrics. 2012 Nov;130(5):e1085-95. doi: 10.1542/peds.2012-0568. Epub 2012 Oct 15. PMID: 23071206.

Emy Dorfman L, Leite JC, Giugliani R, Riegel M. Microarray-based comparative genomic hybridization analysis in neonates with congenital anomalies: detection of chromosomal imbalances. J Pediatr (Rio J). 2015 Jan-Feb;91(1):59-67. doi: 10.1016/j.jped.2014.05.007. Epub 2014 Sep 6. PMID: 25203518.

Friedman J, Adam S, Arbour L, Armstrong L, Baross A, Birch P, Boerkoel C, Chan S, Chai D, Delaney AD, Flibotte S, Gibson WT, Langlois S, Lemyre E, Li HI, MacLeod P, Mathers J, Michaud JL, McGillivray BC, Patel MS, Qian H, Rouleau GA, Van Allen MI, Yong SL, Zahir FR, Eydoux P, Marra MA. Detection of pathogenic copy number variants in children with idiopathic intellectual disability using 500 K SNP array genomic hybridization. BMC Genomics. 2009 Nov 16;10:526. doi: 10.1186/1471-2164-10-526. PMID: 19917086.

Grünblatt E, Oneda B, Ekici AB, Ball J, Geissler J, Uebe S, Romanos M, Rauch A, Walitza S. High resolution chromosomal microarray analysis in paediatric obsessive-compulsive disorder. BMC Med Genomics. 2017 Nov 28;10(1):68. doi: 10.1186/s12920-017-0299-5. PMID: 29179725.

Haga SB, Burke W, Agans R. Primary-care physicians' access to genetic specialists: an impediment to the routine use of genomic medicine? Genet Med. 2013 Jul;15(7):513-4. doi: 10.1038/gim.2012.168. Epub 2013 Jan 10. PMID: 23306802.

Hayes. Clinical Utility Evaluation. Clinical Utility of Genetic Testing to Aid in the Evaluation of Idiopathic Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Aug 22. Annual Review 2021 Aug 09.

Hayes. Clinical Utility Evaluation. Dallas, TX: Hayes; 2018 Aug 22. Annual Review 2021 Aug 09.

Hayes. Clinical Utility Evaluation. Clinical Utility of Genetic Testing for Primary Diagnosis of Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Jun 29. Annual Review 2021 Aug 09.

Hayes. Clinical Utility Evaluation. Clinical Utility of Prenatal Genetic Testing for Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Sep 28. Annual Review 2021 Aug 20.

Hayes. Laboratory Test Insights. Autism Spectrum Disorders: Tier 1 – Cytogenetics and Molecular Only. Dallas, TX: Hayes; 2018 Dec 11.

Hayes. Laboratory Test Insights. Autism Spectrum Disorders: Tier 1 Cytogenetic and Molecular Panel. Dallas, TX: Hayes; 2018 Dec 12.

Hayes. Precision Medicine Insights. Expanded Carrier Screening. Dallas, TX: Hayes; 2020 Aug 17.

Hayes. Precision Medicine Research Brief. Comprehensive Non-Specific Intellectual Disability Panel. Dallas, TX: Hayes; 2015 Dec 23.

Henderson LB, Applegate CD, Wohler E, Sheridan MB, Hoover-Fong J, Batista D. The impact of chromosomal microarray on clinical management: a retrospective analysis. Genet Med. 2014 Sep;16(9):657-64. doi: 10.1038/gim.2014.18. Epub 2014 Mar 13. PMID: 24625444.

Hersh JH, Saul RA; Committee on Genetics. Health supervision for children with fragile X syndrome. Pediatrics. 2011 May; 127(5):994-1006. doi: 10.1542/peds.2010-3500. Epub 2011 Apr 25. PMID: 21518720.

Hillman SC, McMullan DJ, Hall G, Togneri FS, James N, Maher EJ, Meller CH, Williams D, Wapner RJ, Maher ER, Kilby MD. Use of prenatal chromosomal microarray: prospective cohort study and systematic review and meta-analysis. Ultrasound Obstet Gynecol. 2013 Jun;41(6):610-20. doi: 10.1002/uog.12464. Epub 2013 May 7. PMID: 23512800.

International Society of Psychiatric Genetics (ISPG). Genetic Testing and Psyschiatric Disorders. 2019 Mar 11.

Levy B, Sigurjonsson S, Pettersen B, Maisenbacher MK, Hall MP, Demko Z, Lathi RB, Tao R, Aggarwal V, Rabinowitz M. Genomic imbalance in products of conception: single-nucleotide polymorphism chromosomal microarray analysis. Obstet Gynecol. 2014 Aug;124(2 Pt 1):202-9. doi: 10.1097/AOG.000000000000325. PMID: 25004334.

Levy RJ, Xu B, Gogos JA, Karayiorgou M. Copy number variation and psychiatric disease risk. Methods Mol Biol. 2012;838:97-113. doi: 10.1007/978-1-61779-507-7\_4. PMID: 22228008.

Lo JO, Shaffer BL, Feist CD, Caughey AB. Chromosomal microarray analysis and prenatal diagnosis. Obstet Gynecol Surv. 2014 Oct; 69(10):613-21. doi: 10.1097/OGX.000000000000119. PMID: 25336071.

Lowther C, Costain G, Baribeau DA, Bassett AS. Genomic Disorders in Psychiatry-What Does the Clinician Need to Know? Curr Psychiatry Rep. 2017 Sep 20;19(11):82. doi: 10.1007/s11920-017-0831-5. PMID: 28929285

Maortua H, Martínez-Bouzas C, García-Ribes A, Martínez MJ, Guillen E, Domingo MR, Calvo MT, Guitart M, Gabau E, Botella MP, Gener B, Rubio I, López-Aríztegui MA, Tejada MI. MECP2 gene study in a large cohort: testing of 240 female patients and 861 healthy controls (519 females and 342 males). J Mol Diagn. 2013 Sep;15(5):723-9. doi: 10.1016/j.jmoldx.2013.05.002. Epub 2013 Jun 26. PMID: 23810759.

McGrew SG, Peters BR, Crittendon JA, Veenstra-Vanderweele J. Diagnostic yield of chromosomal microarray analysis in an autism primary care practice: which guidelines to implement? J Autism Dev Disord. 2012 Aug;42(8):1582-91. doi: 10.1007/s10803-011-1398-3. PMID: 22089167.

Miller DT, Adam MP, Aradhya S, Biesecker LG, Brothman AR, Carter NP, Church DM, Crolla JA, Eichler EE, Epstein CJ, Faucett A, Feuk L, Friedman JM, Hamosh A, Jackson L, Kaminsky EB, Kok K, Krantz ID, Kuhn RM, Lee C, Ostell JM, Rosenberg C, Scherer SW, Spinner NB, Stavropoulos DJ, Tepperberg JH, Thorland EC, Vermeesch JR, Waggoner DJ, Watson MS, Martin CL, and Ledbetter DH. Consensus Statement: Chromosomal Microarray Is a First-Tier Clinical Diagnostic Test for Individuals with Developmental Disabilities or Congenital Anomalies. Am J Hum Genet. 2010 May 14;86(5):749-64. doi: 10.1016/j.ajhg.2010.04.006. PMID: 20466091.

Moeschler JB, Shevell M; Committee on Genetics. Comprehensive evaluation of the child with intellectual disability or global developmental delays. Pediatrics. 2014 Sep;134(3):e903-18. doi: 10.1542/peds.2014-1839. PMID: 25157020.

National Human Genome Research Institute. National Institutes of Health. Genetic Testing FAQ. 2019 Feb 13.

National Human Genome Research Institute. National Institutes of Health. Genomic Education Websites.

National Human Genome Research Institute. National Institutes of Health. Health Professional Genetics Resources Online.

National Institute for Health and Care Excellence (NICE). Autism spectrum disorder in under 19s: recognition, referral and diagnosis. CG128. 2011 Sep. Last Updated 2017 Dec 20. National Society of Genetic Counselors (NSGC). NSGC Practice Guidelines.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Reddy UM, Page GP, Saade GR, Silver RM, Thorsten VR, Parker CB, Pinar H, Willinger M, Stoll BJ, Heim-Hall J, Varner MW, Goldenberg RL, Bukowski R, Wapner RJ, Drews-Botsch CD, O'Brien BM, Dudley DJ, Levy B; NICHD Stillbirth Collaborative Research Network. Karyotype versus microarray testing for genetic abnormalities after stillbirth. N Engl J Med. 2012 Dec 6;367(23):2185-93. doi: 10.1056/NEJMoa1201569. PMID: 23215556.

Resta N. Memo L. Chromosomal microarray (CMA) analysis in infants with congenital anomalies: when is it really helpful? J Matern Fetal Neonatal Med. 2012 Oct;25 Suppl 4:124-6. doi: 10.3109/14767058.2012.715004. PMID: 22958042.

Riggs ER, Wain KE, Riethmaier D, Smith-Packard B, Faucett WA, Hoppman N, Thorland EC, Patel VC, Miller DT. Chromosomal microarray impacts clinical management. Clin Genet. 2014 Feb;85(2):147-53. doi: 10.1111/cge.12107. Epub 2013 Feb 21. PMID: 23347240.

Rosenfeld JA, Ballif BC, Torchia BS, Sahoo T, Ravnan JB, Schultz R, Lamb A, Bejjani BA, Shaffer LG. Copy number variations associated with autism spectrum disorders contribute to a spectrum of neurodevelopmental disorders. Genet Med. 2010 Nov;12(11):694-702. doi: 10.1097/GIM.0b013e3181f0c5f3. PMID: 20808228.

Shen Y, Dies KA, Holm IA, Bridgemohan C, Sobeih MM, Caronna EB, Miller KJ, Frazier JA, Silverstein I, Picker J, Weissman L, Raffalli P, Jeste S, Demmer LA, Peters HK, Brewster SJ, Kowalczyk SJ, Rosen-Sheidley B, McGowan C, Duda AW 3rd, Lincoln SA, Lowe KR, Schonwald A, Robbins M, Hisama F, Wolff R, Becker R, Nasir R, Urion DK, Milunsky JM, Rappaport L, Gusella JF, Walsh CA, Wu BL, Miller DT; Autism Consortium Clinical Genetics/DNA Diagnostics Collaboration. Clinical genetic testing for patients with autism spectrum disorders. Pediatrics. 2010 Apr;125(4):e727-35. doi: 10.1542/peds.2009-1684. Epub 2010 Mar 15. PMID: 20231187.

Vlaskamp DRM, Callenbach PMC, Rump P, Giannini LAA, Dijkhuizen T, Brouwer OF, van Ravenswaaij-Arts CMA. Copy number variation in a hospital-based cohort of children with epilepsy. Epilepsia Open. 2017 May 8;2(2):244-54. doi: 10.1002/epi4.12057. eCollection 2017 Jun. PMID: 29588953.

Wapner RJ, Martin CL, Levy B, Ballif BC, Eng CM, Zachary JM, Savage M, Platt LD, Saltzman D, Grobman WA, Klugman S, Scholl T, Simpson JL, McCall K, Aggarwal VS, Bunke B, Nahum O, Patel A, Lamb AN, Thom EA, Beaudet AL, Ledbetter DH, Shaffer LG, Jackson L. Chromosomal microarray

versus karyotyping for prenatal diagnosis. N Engl J Med. 2012;367(23):2175-84. doi: 10.1056/NEJMoa1203382. PMID: 23215555.

Webb BD, Scharf RJ, Spear EA, Edelmann LJ, Stroustrup A. Evaluation of the Affymetrix CytoScan(\*) Dx Assay for developmental delay. Expert Rev Mol Diagn. 2015 Feb;15(2):185-92. doi: 10.1586/14737159.2015.975213. Epub 2014 Oct 28. PMID: 25350348.

Wu XL, Li R, Fu F, Pan M, Han J, Yang X, Zhang YL, Li FT, Liao C. Chromosome microarray analysis in the investigation of children with congenital heart disease. BMC Pediatr. 2017 May 4;17(1):117. doi: 10.1186/s12887-017-0863-3. PMID: 28472932.

Xu M, Ji Y, Zhang T, Jiang X, Fan Y, Geng J, Li F. Clinical Application of Chromosome Microarray Analysis in Han Chinese Children with Neurodevelopmental Disorders. Neurosci Bull. 2018 Dec;34(6):981-91. doi: 10.1007/s12264-018-0238-2. Epub 2018 Jun 9. PMID: 29948840.

#### **Next Review Date**

Not applicable

#### **Retired Date**

11/01/22

## **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity;

Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies

utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.	

## **Appendix: Policy History**

Original	Original Effective	Policy Owner	Original Policy
Approval Date	Date* and Version		Approved by
Regulatory Approval: N/A  Internal Approval: 11/20/13: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 12/19/13: Quality Improvement Committee (QIC)	03/01/14 Version 1	Director of Medical Policy as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	MPCTAC and QIC

- \* Effective date for QHP Commercial product: 01/01/12
- \* Effective date for New Hampshire Medicaid product: 01/01/13
- \* Effective date for Senior Care Options product: 01/01/16
- \* Effective date for New Hampshire Medicare Advantage HMO product: 01/01/22

Note: Effective 03/01/14 to 04/30/16, the policy title was Cytogenomic Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies. Effective 05/01/16, policy renamed Chromosomal Microarray Analysis for Unexplained Intellectual Disabilities and/or Multiple Congenital Anomalies. Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
01/30/14	Off cycle review for effective date 04/01/14. Added ICD10 diagnosis code equivalents of existing ICD9 diagnosis codes.	04/01/14 Version 2	01/27/14: MPCTAC 01/30/14: QIC
11/01/14	Review for effective date 03/01/15. Revised criteria in the Medical Policy Statement and Limitations sections. Updated the Summary, Description of Item or Service, Definitions, and Clinical Background Information sections. Revised review calendar.	03/01/15 Version 3	11/19/14: MPCTAC 12/10/14: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.	01/01/16 Version 4	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC

01/01/16	Review for effective date 05/01/16. Revised	05/01/16	01/20/16: MPCTAC
e, e, ie	language in the Applicable Coding section and updated the list of waived pregnancy diagnosis codes and corresponding procedure codes.  Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised title. Revised criteria in the Medical Policy Statement and Limitations sections.	Version 5	02/10/16: QIC
09/28/16	Review for effective date 11/01/16. Administrative changes to clarify language related to gender.	11/01/16 Version 6	09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
01/01/17	Review for effective date 05/01/17. Revised ICD-10 pregnancy diagnosis codes in the Applicable Coding section. Updated Summary, Definitions, References, and Reference to Applicable Laws and Regulations sections. Updated criteria in the Medical Policy Statement section.	05/01/17 Version 7	01/18/17: MPCTAC 02/08/17: QIC
01/01/18	Review for effective date 02/01/18. Updated Summary, Description of Item or Service, Definitions, References, and Reference to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement and Applicable Coding sections.	02/01/18 Version 8	01/17/18: MPCTAC
01/01/19	Review for effective date 04/01/19. Administrative changes made to the Policy Summary, Definitions, Applicable Coding, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections.	04/01/19 Version 9	01/16/19: MCPTAC
02/01/19	Review fore effective date 04/01/19. Administrative changes made to the Medical Policy Statement section to clarify guidelines. Updated Plan notes in the Applicable Coding section (without revising the applicable code list). Revised the Policy Summary and Other Applicable Policies sections.	04/01/19 Version 10	02/20/19: MPCTAC
06/01/19	Review for effective date 07/01/19. Revised language in the Policy Summary, Medical Policy Statement, and Applicable Coding section to clarify that the prior authorization waiver for the specified primary pregnancy diagnosis codes	07/01/19 Version 11	06/19/19: MPCTAC

	only applies to genetic tests ordered, administered, and processed by participating providers and participating laboratories.		
07/01/19	Review for effective date 10/01/19. Medical policy criteria retired and InterQual® criteria adopted. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, and Other Applicable Policies sections. Updated Plan notes in the Applicable Coding section. Maintained guidelines for testing with CMA and Fragile X testing. Maintained diagnosis code list for prior authorization pregnancy waiver and updated corresponding procedure code list.	10/01/19 Version 12	07/17/19: MPCTAC
09/01/19	Review for effective date 12/01/19. Added high-risk diagnosis code in the Applicable Coding section.	12/01/19 Version 13	09/18/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Applicable Coding, and Definitions sections.	01/01/20 Version 14	12/18/19: MPCTAC
01/01/20	Review for effective date 02/01/20. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	02/01/20 Version 15	01/15/20: MPCTAC
02/01/21	Review for effective date 03/01/21. Updated the Policy Statement and References sections. Administrative changes made to the Applicable Coding section.	03/01/21 Version 16	02/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 17	11/17/21: MPCTAC
12/01/21	Review for effective date 01/01/22. Industry-wide code revision made to the Applicable Coding section.	01/01/22 Version 18	Not applicable because industry-wide code revision; 12/15/21: MPCTAC review

01/01/22	Review for effective date 02/01/22.	02/01/22	01/19/22: MPCTAC
	Administrative changes made to the Policy	Version 19	
	Summary, Clinical Criteria, Limitations and		
	Exclusions, and References sections.		
08/01/22	Review for policy retired date 11/01/22. Revised	11/01/22	08/26/22: MPCTAC
	the Policy Summary, Clinical Criteria,	Version 27	(electronic vote)
	Limitations and Exclusions, and Applicable		
	Coding sections. InterQual medical necessity		
	criteria and medical policy retired on 11/01/22.		
	Plan prior authorization waivers removed after		
	10/31/22. AIM medical necessity criteria		
	adopted for genetic testing on 11/01/22. Plan		
	prior authorization waivers removed after		
	10/31/22. AIM prior authorization is required for		
	genetic testing as of 11/01/22, even when		
	applicable codes are not listed in this Plan		
	policy.		



#### Administrative Policy

#### **Clinical Review Criteria**

Policy Number: OCA 3.201

**Version Number**: 29

**Version Effective Date**: 11/01/22

#### **Impacted Products**

#### 

- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

## **Policy Summary**

This policy defines the Plan's process for making utilization review decisions using written clinical review criteria based on sound and current clinical evidence. The Plan conducts all utilization review activities in accordance with applicable policies and procedures and the Plan's Utilization Management (UM) Program. Plan-adopted written clinical review criteria are used to determine the medical necessity of services that require utilization review, including medical services, surgical treatment, pharmacotherapy and pharmacy services, behavioral health services, radiological services, dental services, and durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). In addition, clinical review criteria are used to determine the most clinically appropriate level of care and intensity of services to ensure the provision of medically necessary services. Plan-adopted written clinical review criteria include the Plan's internally developed medical and pharmacy policies, InterQual® criteria, and clinical guidelines established by delegated management partners (for related services provided to Plan members for applicable Plan products). All Plan-adopted written clinical review criteria are reviewed at least annually and are developed in accordance with contractual requirements, state and federal regulations, and guidelines from accrediting organizations, including National Committee for Quality Assurance (NCQA). Review the Plan's Prior Authorization/Notification Requirements Matrix, Code Look-up Tools, medical and pharmacy policies, and the Plan's pharmacy formulary (available via the drug search tool or the formulary quidebook) to determine if prior authorization is required.

The Plan's clinical coverage criteria and UM decision tools are applied equitably across the Plan's membership. However, the Plan's Office of Clinical Affairs (OCA) UM staff (or the delegated clinical vendor's professional staff when the management of services is delegated to the vendor) will take into account the member's individual needs, circumstances, and healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services, as well as assessing the local healthcare delivery system's ability to meet the member's healthcare needs, when determining the medical necessity of services. Plan guidelines (including but not limited to appeals and/or clinical reconsiderations) comply with all applicable Plan contract terms with providers, employers, governmental agencies, and other contracting entities.

The Plan complies with coverage guidelines for all applicable state and federally-mandated benefits. Plan authorizations, as well as authorizations by each of the Plan's delegated clinical vendors conducting utilization management, are based on a comprehensive and individualized needs assessment that addresses all member needs, including but not limited to social determinants of health and a subsequent person-centered planning process. Plan prior authorization requirements (and those of each of the Plan's delegated clinical vendors) comply with parity in mental health and substance use disorders. The Plan and the Plan's delegated clinical vendors conducting utilization management do NOT discriminate, arbitrarily deny, or impose stricter requirements by reducing the amount, duration, or scope of required and medically necessary services for ANY Plan member based on the member's diagnosis, type of illness, health status or condition, sex, gender identity or dysphoria, or sexual orientation.

See the member's product-specific handbook on the Plan's website for benefit coverage guidelines and a summary of member rights and responsibilities, as well as the Plan's process for receiving and promptly resolving inquires, grievances, or appeals from a member (or an authorized representative acting on behalf of the member). Member appeals may be related to issues that include but are not limited to benefit coverage, the evaluation of clinical technology (including new technology and a new indication for an established technology), and/or the application of the Plan's clinical review criteria for the member's requested indication for treatment.

The Plan's Cosmetic, Reconstructive, and Restorative Services medical policy, policy number OCA 3.69, includes the product-specific definitions of cosmetic services and reconstructive surgery and procedures. The product-specific definitions of experimental or investigational treatment are listed in the Plan's Experimental and Investigational Treatment medical policy, policy number OCA 3.12. Product-specific definitions for medically necessary services (i.e., medical necessity) are listed in the Plan's Medically Necessary medical policy, policy number OCA 3.14. The Clinical Technology Evaluation administrative policy, policy number OCA 3.13, outlines the Plan's process for evaluating new technology and new clinical application(s) of existing technology. Review the Plan's applicable reimbursement policy for payment guidelines related to clinical trials.

## **Policy Statement**

When the Plan conducts utilization review (UR), appropriate professional utilization management (UM) Plan staff consistently apply current, Plan-adopted written clinical review criteria, including the Plan's

internally developed criteria specified in internal medical policies and Plan pharmacy policies, InterQual® criteria, and clinical guidelines established by delegated management partners (for related services provided Plan members for applicable Plan products). Plan staff (including but not limited to representatives from the Plan's Accreditation, Utilization Management, Pharmacy, and Vendor Management Departments) routinely collects and reviews documentation to verify that quality standards are met by clinical vendors who are delegated to conduct utilization management on behalf of Plan members, including but not limited to contractual obligations and the guidelines specified in the Delegated Management section of this policy. When national clinical guidelines (e.g., InterQual® criteria) are not available or not adopted by the Plan, Plan-specific criteria may be established and documented in internally developed medical and pharmacy policies.

The development and review of the Plan's internal clinical criteria include input from participating practitioners and consultant specialists in the related specialties that may include but are not limited to licensed pharmacists, community-based providers, behavioral health clinicians, and physician specialists in neonatology, pediatrics, family medicine, internal medicine, medical/pediatric/surgical subspecialties, and geriatrics. Practitioners with professional expertise and relevant credentials in the clinical area being reviewed have the opportunity to advise or comment on the development, adoption, and implementation of all UM criteria utilized by the Plan; this includes feedback from qualified practitioners on staff at the Plan or delegated clinical vendors, outside physician consultants, provider reviewers, participating providers in the Plan's network, and practitioners treating Plan members. The Plan-adopted written clinical review criteria (i.e., the Plan's internal medical policies and pharmacy policies, InterQual® criteria, and clinical guidelines implemented by the Plan's delegated management partners for related services provided Plan members by Plan product type) are objective, scientifically derived, and evidence-based for the requested service(s) and indication(s) for treatment and are compliant with applicable legal obligations , regulatory requirements, and national accreditation organization standards.

The Plan's clinical coverage criteria and UM decision tools are applied equitably across the Plan's membership. All Plan-adopted written clinical review criteria (including criteria specified in the Plan's internal medical policies and pharmacy policies, InterQual® criteria, and clinical guidelines developed and implemented by the Plan's delegated management partners for related services provided Plan members by Plan product type) are clinically reviewed at least annually to verify that these clinical guidelines are developed and implemented in accordance with generally accepted standards of medical/clinical practice which are based on objective and credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying on controlled clinical trials. On at least an annual basis, Plan staff confirm that all clinical review criteria utilized by the Plan (including all of the Plan's internal medical and pharmacy policies, InterQual® criteria, and clinical guidelines implemented by the Plan's delegated management partners for related services provided Plan members by Plan product type) have had an annual clinical review and the procedures for applying those clinical review criteria are documented.

Updates to clinical review criteria are implemented as new treatments, applications, and technologies are adopted and become components of generally accepted professional practice for behavioral health, medical/surgical services, dental services, and/or pharmacotherapy. The Plan's Office of

Clinical Affairs (OCA) UM staff applies the clinical review criteria consistently; however, OCA UM staff also takes into account the member's individual needs and circumstances. The Plan's Medical Directors and/or licensed Plan pharmacists consider member-specific factors when applying clinical criteria to a request for services. When clinical review criteria are not met for a requested treatment such that medical necessity cannot be established for the member's condition or indication for treatment, OCA UM staff engages in discussions with licensed Plan pharmacists, OCA UM clinicians, and/or Plan Medical Directors to determine if the clinical review criteria are appropriate for the member's circumstances or local delivery system (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment). If the clinical review criteria are not appropriate, OCA UM staff may make the utilization determination based on the member's condition and other unique circumstances. The Delegated Management section of this policy includes delegated management guidelines applicable for the Plan's partner clinical vendors, including Plan oversight and the development, review, and application of the clinical vendors' clinical review criteria.

Change Health staff analyze over 3,000 medical literature sources daily to review and update current InterQual® clinical review criteria and to develop criteria for new technologies and new application(s) of existing technologies. InterQual® criteria are developed and implemented in accordance with generally accepted standards of medical/clinical practice which are based on objective and credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying on controlled clinical trials. In addition, InterQual® criteria are evaluated by an independent clinical review panel drawn from more than 900 experts for authoritative peer review, utilizing providers with expertise and appropriate credentials in the applicable clinical area under consideration. Inter-rater reliability testing is conducted annually by the Plan using the Plan-adopted InterQual® criteria sets. InterQual® criteria are revised, as necessary, throughout the year (at least annually but may occur quarterly).

## **Delegated Management**

The Plan's delegated clinical vendors conduct utilization management for behavioral health services, radiology services, pharmacy services, dental services, and durable medical equipment, prosthetics, orthotics and supplies on behalf of Plan members (when applicable for the Plan product). Practitioners with clinical expertise in the area being reviewed have the opportunity to advise or comment on the development, adoption, and implementation of utilization management criteria established by the Plan's delegated management partners; this includes feedback from qualified practitioners on staff at the Plan or delegated clinical vendors, outside physician consultants, provider reviewers, participating providers in the Plan's network, and practitioners treating Plan members.

All Plan-adopted written clinical review criteria, including clinical guidelines established by delegated management partners, are reviewed at least annually (or more frequently when policy revisions require more immediate implementation). Clinical review criteria utilized by the Plan's delegated clinical vendors are develop with oversight by the clinical vendor's Medical Director who is an actively practicing physician and who is responsible for the oversight of the clinical vendor's utilization management program. Proposed new and revised clinical guidelines are evaluated by the clinical vendor's expert panel, all of whom are practicing clinicians and acknowledged experts in the relevant

fields and pertinent specialties. All clinical review criteria are developed in accordance with applicable state and federal requirements and guidelines from applicable national accreditation organizations.

The clinical review criteria and UM decision tools from each of the Plan's delegated clinical vendors are applied equitably across the Plan's membership. However, the delegated clinical vendor's professional staff (when the management of services is delegated to the clinical vendor) will take into account the member's individual needs, circumstances, and healthcare services requested and/or currently provided to the member to integrate healthcare for continuity, coordination, and collaboration of services, as well as assessing the local healthcare delivery system's ability to meet the member's healthcare needs, when determining the medical necessity of services. Inter-rater reliability testing is utilized by the Plan's delegated clinical vendors to assess the consistency and adherence to clinical review criteria. At least quarterly, the consistency with which the healthcare professionals involved in prior authorization apply criteria in decision making is evaluated by the delegated clinical vendors using a variety of mechanisms. The application of medical necessity criteria by Medical Directors and non-physician reviewers are assessed to ensure consistency and accuracy in the application of the clinical review criteria. Results are reported to the Plan.

Below are delegated management guidelines applicable for the Plan's partner clinical vendors, including Plan oversight and the development, review, and application of the clinical vendors' clinical review criteria, as specified below in items 1 through 3:

#### 1. Plan's Delegated Services and Partner Clinical Vendors:

When applicable for the Plan product, the following services are managed by a delegated clinical vendor for a Plan member, as stated in items a through f:

a. Behavioral Health Services (Beacon Health Strategies, LLC):

Effective March 1, 2010, the Plan delegated management of behavioral health services to an NCQA-accredited managed behavioral health organization (MBHO), Beacon Health Strategies, LLC. The MBHO has its own clinical criteria policy which has been approved as part of delegation oversight.

b. Dental Services (DentaQuest for Senior Care Options Members):

Effective June 18, 2015, the Plan delegated dental services to Dental Service of Massachusetts, Inc. (DSM) for DentaQuest to administer the Senior Care Options (SCO) dental benefit. This clinical vendor establishes policies for communicating criteria to providers and the vendor has its own clinical criteria policy and procedure which has been approved as part of delegation oversight.

c. Dental Services (Delta Dental for Qualified Health Plan Pediatric Members):

Effective November 23, 2016, the Plan delegated dental services to Dental Service of Massachusetts, Inc. (DSM) for Delta Dental to administer the Qualified Health Plans (QHP) pediatric dental benefit. This clinical vendor establishes policies for communicating criteria to providers and DSM has its own clinical criteria policy and procedures which have been approved as part of delegation oversight.

d. Durable Medical Equipment, Prosthetics, Orthotics and Supplies (Northwood, Inc.):

Effective April 1, 2011, the Plan delegated management of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to a URAC-accredited DMEPOS clinical vendor, Northwood, Inc. The Plan has retained the management of medical necessity denial decisions and notifications. This clinical vendor has its own clinical criteria policy and procedure which has been approved as part of delegation oversight.

e. Pharmacy Benefits Manager (Express Scripts):

Effective January 1, 2021, Express Scripts is the Plan's pharmacy benefits manager for the Plan's products. Express Scripts adopts the guidelines included in this Plan's *Clinical Review Criteria* administrative policy and adheres to the Plan's administrative UM policies and clinical policy criteria, unless specifically delegated such as the Plan's Medicare product lines. Policies delegated to Express Scripts have been approved as part of delegation oversight. Effective December 1, 2019, the Plan's pharmacy mail order company for all of the Plan's Massachusetts and New Hampshire products is Cornerstone Health Solutions.

f. Radiology Services, Musculoskeletal Services, Genetic Testing, and Outpatient Rehabilitation Services (AIM Specialty Health):

Effective November 1, 2022, the Plan delegated the management of radiology services, musculoskeletal services (i.e., spine surgeries, joint surgeries, and interventional pain management treatments), genetic testing, and outpatient rehabilitation services (i.e., physical therapy, occupational therapy, and speech therapy after the initial evaluation) to an NCQA-accredited managed care clinical vendor, AIM Specialty Health. AIM develops and utilizes criteria to make utilization management decisions for requested services, establishes policies for communicating those criteria to providers and members, and evaluates consistency in the application of those criteria through inter-rater reliability testing when determining medical necessity for these delegated services.

#### 2. Clinical Vendor Clinical Review:

a. Review and Application of Clinical Vendor's Established Clinical Review Criteria:

The Plan's Clinical Vendor Oversight Committee conducts an annual review of each clinical vendor that conducts delegated management for Plan members to ensure that all of the following guidelines are met: each clinical vendor conducts an annual review of its clinical

criteria, approving and implementing criteria that are objective, scientifically-derived, and evidence-based for the requested service(s) and indication(s) for treatment and compliant with applicable legal obligations; each clinical vendor completes an annual review and approval of policies and procedures developed to ensure that the clinical vendor's clinical criteria are consistently applied to Plan members for a requested service. The service may include a treatment, procedure, supply, device, biologic, or drug that will be used to prevent, diagnose, stabilize, or treat a disease, condition, or disorder that results in health impairment or disability, or the service allows the member to attain, maintain, or regain functional capacity. The clinical vendor will also consider member-specific factors impacting the member's individual healthcare needs when applying clinical review criteria to determine if the service is medically necessary for the requested indication. Individual consideration includes an assessment of any member-specific factor impacting care, including one or more of the following:

- (1) Member's condition;
- (2) Member's comorbidities;
- (3) Member's age, including the assessment of the member's age-appropriate growth, development, and competencies, as well as evaluation of age-related and conditionspecific healthcare needs and associated issues;
- (4) Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history;
- (5) Complications;
- (6) Progression of the member's condition, illness, or injury;
- (7) Diagnostic test results;
- (8) Treatment outcomes;
- (9) Treatment options;
- (10) Psychosocial circumstances;
- (11) Home and environmental factors impacting member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood);
- (12) Other healthcare services requested and/or provided to the member to integrate healthcare for continuity, coordination, and collaboration of services;
- (13) Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition;

- (14) Member's reasonable accessibility to a qualified provider with appropriate credentials, licensure, clinical expertise and/or resources in the applicable clinical area necessary to adequately manage the member's condition (including but not limited to pharmacotherapy, behavioral health services, dental services, radiology services, and/or durable medical equipment, prosthetics, orthotics and supplies);
- (15) Other factors related to the member's plan of care or health outcomes; AND/OR
- (16) If applicable, verification that the requested device, therapeutic, biologic, or drug is being prescribed/requested and will be utilized according to its FDA-approved or compendia indication and guideline information, including intended use for the member's age and medical condition.
- b. Clinical Vendor Review of Requested Service Without Written Clinical Review Criteria:

If written clinical review criteria have not been established for the requested service (for the specified indication) by the Plan's delegated management clinical vendors, these clinical vendors will use published and applicable generally accepted, scientifically-based standards of care and objective and credible scientific evidence published in peer-reviewed medical/clinical literature, and/or reviewing observational studies for a request for services for a Plan member to make medical necessity determination. If scientifically-based standards of care are not available, observational studies from more than one (1) institution that suggest a causal relationship between the service or treatment and health outcomes may be used by the delegated utilization management clinical vendor to make medical necessity determinations if these observational studies are clinically appropriate with respect to the member's clinical presentation. The Plan's delegated management clinical vendors will also consider member-specific factors impacting the member's individual healthcare needs to determine if the service is medically necessary for the requested indication. The service may include a treatment, procedure, supply, device, biologic, or drug and will be used to prevent, diagnose, stabilize, and/or treat a disease, condition, and/or disorder that results in health impairment and/or disability, and/or the service allows the member to attain, maintain, or regain functional capacity. Individual consideration includes an assessment of any member-specific factors impacting care, including one or more of the following:

- (1) Member's condition;
- (2) Member's comorbidities;
- (3) Member's age, including the assessment of the member's age-appropriate growth, development, and competencies, as well as evaluation of age-related and conditionspecific healthcare needs and associated issues;

- (4) Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history;
- (5) Complications;
- (6) Progression of the member's condition, illness, or injury;
- (7) Diagnostic test results;
- (8) Treatment outcomes;
- (9) Treatment options;
- (10) Psychosocial circumstances;
- (11) Home and environmental factors impacting member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood);
- (12) Other healthcare services requested and/or provided to the member to integrate healthcare for continuity, coordination, and collaboration of services;
- (13) Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition;
- (14) Member's reasonable accessibility to a qualified provider with appropriate credentials, licensure, clinical expertise or resources in the applicable clinical area necessary to adequately manage the member's condition, including but not limited to pharmacotherapy, behavioral health services, dental services, radiology services, or durable medical equipment (prosthetics, orthotics and supplies);
- (15) Other factors related to the member's plan of care or health outcomes; AND/OR
- (16) If applicable, verification that the requested device, system, biologic, or drug is being prescribed/requested and will be utilized according to its FDA-approved or compendia indication and guideline information, including intended use for the member's age and medical condition.
- c. Clinical Vendor Evaluation of New Technology:

The Plan's partner clinical vendors evaluate new technology and new application(s) of an established technology to develop new clinical review criteria or revise established clinical review criteria when clinically appropriate. The Plan's partner clinical vendor will use published and applicable generally accepted, scientifically-based standards of care and objective and credible scientific evidence published in peer-reviewed medical/clinical literature, and/or reviewing observational studies for the new technology or new

application(s) of an existing technology to establish written clinical review criteria that will be used to make medical necessity determinations (in addition to individual consideration of the member's status and healthcare needs). When a requested service that does not have established, applicable clinical review criteria, the medical necessity of the service is determined on a case-by-case basis for individual consideration, as specified above in the Clinical Vendor Review of Requested Service Without Written Clinical Review Criteria section.

#### d. Out-of-Network Providers:

The clinical vendor will authorize a member's care from an out-of-network provider when, as determined by the clinical vendor, the care and necessary resources are needed by the member are not available or are not reasonably accessible to the member.

#### e. Input from Practicing Practitioners:

Actively practicing practitioners with appropriate credentials and clinical expertise in the applicable clinical area have the opportunity to submit comments on clinical review criteria utilized by clinical vendors who are delegated to conduct utilization management on behalf of Plan members (with feedback related to the development, ongoing management, and/or application of those criteria). Practitioners may submit feedback through the Plan's Provider Information Mailbox available at Provider.Info@BMCHP-wellsense.org.

If the practitioner would like to provide input on a clinical vendor's clinical review criteria and have those comments considered during the criteria's next annual review, supporting documentation must be provided that includes position statements developed or endorsed by nationally recognized professional associations, consensus reports or guidelines from specialty societies, and/or standards adopted by governmental agencies (e.g., National Institutes of Health, Agency for HealthCare Research and Quality, Center for Medicare & Medicaid Services, Massachusetts Executive Office of Health and Human Services, or New Hampshire Department of Health and Human Services). Published scientific evidence from additional reputable sources may also be submitted for consideration.

Issues related to clinical review criteria that must be addressed before each clinical vendor's annual review will be evaluated immediately during a prior authorization request for services; clinical vendors conducting delegated utilization will engage in individual case discussions with qualified clinicians applicable for the member's condition and requested treatment to determine if the clinical review criteria are appropriate for the member's circumstances or care provided by a local delivery system according to the guidelines specified below in the Application of the Plan's Clinical Review Criteria section of this policy.

#### f. Access to Clinical Review Criteria:

The Plan makes all of its clinical review criteria available to practitioners and members upon oral or written request. Providers and member may call or fax the Plan with a request for a copy of the specific criteria, as stated in writing in the provider manual on the Plan's website. This access to clinical review criteria includes applicable copyrighted commercial criteria used by the Plan's partner delegated clinical vendors. Participating providers are notified at least 60 calendar days before the implement of substantive revisions to applicable coding (excluding industry-wide code updates) and/or clinical review criteria (i.e., implementation of new medical necessity guidelines and/or revised clinical review criteria) used by the Plan's partner delegated clinical vendors. The current version of clinical review criteria is available to all providers, members, and the general public on the Plan's extranet site.

#### 3. Plan Oversight:

Plan staff (including but not limited to representatives from the Plan's Accreditation, Utilization Management, Pharmacy, and Vendor Management Departments) routinely collects and reviews documentation to verify that quality standards are met by clinical vendors who are delegated to conduct utilization management on behalf of Plan members. In addition, an annual review of each clinical vendor is completed by the Plan's Clinical Vendor Oversight Committee to ensure that each clinical vendor complies with delegated utilization management requirements, including but not limited to contractual obligations and the guidelines specified in this section of this policy related to the development, review, and application of objective, scientificallyderived, and evidence-based clinical review criteria, with individual consideration of the member's status (when appropriate). If established quality standards are not met, the delegated utilization management clinical vendor develops and implements a targeted and measurable corrective action plan that is monitored by the Plan. For services managed by clinical vendors with whom the Plan has delegated utilization management, the Plan evaluates member access to treating facilities and availability of qualified providers (including care from an out-of-network provider when clinically appropriate), member satisfaction, provider satisfaction, member and provider timely access to applicable clinical review criteria, and the vendor's process for evaluating recommended revisions to clinical review criteria submitted by actively practicing practitioners with appropriate credentials and clinical expertise.

#### **Procedure**

The Plan-adopted clinical review criteria are developed and implemented in accordance with generally accepted standards of medical/clinical practice which are based on objective and credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying on controlled clinical trials. Practitioners with clinical expertise in the area being reviewed have the opportunity to advise or comment on the development, adoption, and implementation of all UM criteria utilized by the Plan; this includes feedback from qualified practitioners on staff at the Plan or delegated clinical vendors, outside physician consultants, provider reviewers, participating providers in the Plan's network, and practitioners treating Plan members.

See the Policy Summary and the Delegated Management sections of this policy for guidelines related to applicable clinical review criteria and services managed by partner clinical vendors with whom the Plan has delegated utilization management (by Plan product), including behavioral health services, radiology services, pharmacy benefits administration, and durable medical equipment, prosthetics, orthotics and supplies. Review the *Clinical Technology Evaluation* administrative policy, policy number OCA 3.13, for a description of the Plan's process for evaluating new technology and the new application of existing technology.

#### 1. Development and Review of the Plan's Internal Clinical Review Criteria:

The Plan's internal clinical review criteria are specified in the Plan's medical policies or pharmacy policies. Internal clinical review criteria are developed, reviewed at least annually, and updated as necessary, utilizing the following resources (as applicable) to evaluate the clinical services, treatments, and technologies for the specified indications and the application of medical necessity criteria, as stated below in items a through I:

- a. In consultation with the Plan's Medical Director(s) and other Plan staff, as appropriate; AND
- b. With input from actively practicing specialists and/or professionals or serving as consultants who have expertise and appropriate credentials in the applicable clinical area under consideration, as appropriate; e.g., criteria review by board-certified physician experts in the Plan's service area, feedback from participants of the local network-based Provider Advisory Committee, and/or independent medical criteria review from board-certified physician consultants from Advanced Medical Reviews (AMR). Consultants may include but are not limited to pharmacists, community-based providers, behavioral health clinicians, dentists, and/or board-certified physicians actively practicing in specialties that include neonatology, pediatrics, family medicine, internal medicine, medical/surgical subspecialties, and/or geriatrics; AND
- c. In accordance with the Plan's definition of medical necessity (as specified in the *Medically Necessary* medical policy, policy number OCA 3.14), the Plan's definition of experimental and investigational services (as stated in the *Experimental and Investigational Treatment* medical policy, policy number OCA 3.12), and the Plan's definition of cosmetic and reconstructive or restorative services (as documented in the *Cosmetic, Reconstructive, and Restorative Services* medical policy, policy number OCA 3.69); AND
- d. Review of unbiased, evidence-based assessments of health technologies, clinical programs, and/or healthcare services to determine the impact of intervention(s) on patient safety and clinical outcomes; AND
- e. Review of position papers and guidelines established or endorsed by nationally recognized medical associations, specialty societies, dental organizations, or governmental agencies, including but not limited to practice guidelines adopted by the Plan; AND

- f. Clinical studies published in peer-reviewed scientific literature evaluating the use of the clinical service as an alternative treatment strategy to established interventions considered the standard of care for the specified indication (considering the patient's medical condition, age, comorbidities, and other factors applicable to the health outcomes of the clinical technology) to determine if the service improves the net health outcome, is cost-effective compared to the standard of care, and if the clinical outcomes outweigh any harmful effects; AND
- g. The documented, favorable health outcomes are reasonably expected to be attainable outside of the investigational settings (i.e., in a standard clinical setting) to a degree comparable in the published, scientifically derived and evidence-based investigations; AND
- h. When applicable, the clinical technology, including drugs, biologics, devices, or other products requiring final approval to market, has final approval for the specified indication from the appropriate governmental body(ies) with the authority to regulate the clinical technology (e.g., the U.S. Food and Drug Administration); AND
- i. Policies, position statements, consensus reports, and standards adopted by governmental agencies which may include but are not limited to the National Institutes of Health (NIH), Agency for HealthCare Research and Quality (AHRQ), U.S. Center for Disease Control and Prevention (CDC), Center for Medicare & Medicaid Services (CMS), Massachusetts Executive Office of Health and Human Services, or New Hampshire Department of Health and Human Services (e.g., U.S. Preventive Services Task Force, AAP Bright Futures); AND
- j. Published scientific evidence from additional reputable sources concerning the safety and effectiveness of the clinical treatment on health outcomes (i.e., proven benefit, unproven benefit, insufficient evidence to determine effect, or documented harm) such as industry-standard, evidence-based guidelines and recommendations (such as those established by InterQual®, National Institute for Health and Care Excellences, National Comprehensive Cancer Network); AND
- k. Other sources deemed necessary to evaluate the clinical technology for the specified clinical indication and to develop the Plan's clinical coverage criteria; AND
- I. With input from actively practicing practitioners with appropriate credentials and clinical expertise in the applicable clinical area who have the opportunity to submit comments on clinical review criteria utilized for Plan members (with feedback related to the development, ongoing management, and/or application of those criteria). Practitioners may submit feedback at any time through the Plan's Provider Information Mailbox available at <a href="mailto:Provider.Info@BMCHP-wellsense.org">Provider.Info@BMCHP-wellsense.org</a>. The Plan will thoroughly research recommendations and comments submitted from providers.

On at least an annual basis, Plan staff review all clinical review criteria utilized by the Plan and the procedures for applying those clinical review criteria; the Plan will evaluate provider feedback submitted by practicing practitioners when evaluating applicable clinical review criteria. If the practitioner would like to provide input on clinical review criteria that will be considered during the internal policy's next annual review, it is recommended that comments and supporting references be submitted to the Plan a few months before the applicable policy's scheduled annual review date (as specified in the Next Review Date section at the end of each internal policy). Supporting documentation must include position statements developed or endorsed by nationally recognized professional associations, consensus reports or guidelines from specialty societies, or standards adopted by governmental agencies (e.g., National Institutes of Health, Agency for HealthCare Research and Quality, Center for Medicare & Medicaid Services, Massachusetts Executive Office of Health and Human Services, or New Hampshire Department of Health and Human Services). Published scientific evidence from additional reputable sources may also be submitted for consideration.

Issues related to clinical review criteria that must be addressed before the policy's annual review date will be evaluated immediately during a prior authorization request for services; OCA UM staff will engage in individual case discussions with licensed Plan pharmacists, OCA UM clinicians, and/or Plan Medical Directors (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment) to determine if the clinical review criteria are appropriate for the member's circumstances or care provided by a local delivery system according to the guidelines specified below in the Application of the Plan's Clinical Review Criteria section of this policy.

Providers may email feedback on the Plan's internal medical policies to the Medical Policy Mailbox at <a href="medical.policy@bmchp-wellsense.org">medical.policy@bmchp-wellsense.org</a>. It is important to include the medical policy title and policy number with the comments so Plan staff can thoroughly research the issue. An integral component of the Plan's annual medical policy review process is to evaluate provider comments and recommendations.

## 2. Application of Plan's Internal Clinical Review Criteria and Plan-Adopted InterQual® Criteria

Review the Policy Summary and the Delegated Management sections (rather than this section of the policy) for guidelines related to clinical review criteria and services managed by partner clinical vendors with whom the Plan has delegated utilization management by Plan product. Application of the Plan's clinical review criteria (including internal clinical review criteria and InterQual® criteria) follows the procedure specified below in items a through q:

a. The Plan's Office of Clinical Affairs (OCA) includes OCA UM staff, Plan licensed pharmacists, and Plan Medical Directors who apply applicable Plan clinical review criteria consistently when determining the medical necessity of healthcare services. The Plan's OCA UM staff includes both the Pharmacy UM staff and UM staff. Reporting to the Director of Pharmacy, the Pharmacy UM staff reviews requests for pharmacotherapy or directs requests to a partner clinical vendor for delegated utilization management. Reporting to the Directors of Utilization Management, UM staff reviews medical/surgical/behavioral health requests for service or

directs requests to a partner clinical vendor for delegated utilization management according to guidelines in both item (1) and item (2):

- (1) The Plan's OCA UM staff applies clinical review criteria consistently for all Plan members according to the standards specified in this policy (e.g., requests for transplant services), as well as complying with the Plan's out-of-network guidelines and product-specific requirements outlined in the Out-of-Network Services medical policy, policy number OCA 3.18. When standard clinical criteria are not met, qualified OCA UM staff also considers member-specific factors impacting the member's individual healthcare needs to determine if the service is medically necessary for the requested indication. The service may include a treatment, procedure, supply, device, biologic, or drug and will be used to prevent, diagnose, stabilize, and/or treat a disease, condition, and/or disorder that results in health impairment and/or disability, and/or the service allows the member to attain, maintain, or regain functional capacity. Individual consideration includes an assessment of any member-specific factors impacting care, including one or more of the following:
  - (a) Member's condition;
  - (b) Member's comorbidities;
  - (c) Member's age, including the assessment of the member's age-appropriate growth, development, and competencies, as well as evaluation of age-related and conditionspecific healthcare needs and associated issues;
  - (d) Relevant past medical/surgical/behavioral health/dental/pharmacotherapy history;
  - (e) Complications;
  - (f) Progression of the member's condition, illness, or injury;
  - (g) Diagnostic test results;
  - (h) Treatment outcomes;
  - (i) Treatment options;
  - (i) Psychosocial circumstances;
  - (k) Home and environmental factors impacting member's clinical condition (e.g., homelessness, employment status, poverty, neighborhood);
  - (l) Other healthcare services requested and/or provided to the member to integrate healthcare for continuity, coordination, and collaboration of services;

- (m) Local healthcare delivery system's ability to meet the healthcare needs of the member's specific condition;
- (n) Member's reasonable accessibility to a qualified provider with appropriate credentials, licensure, clinical expertise or resources in the applicable clinical area necessary to adequately manage the member's condition, including but not limited to pharmacotherapy, behavioral health services, dental services, radiology services, or durable medical equipment (prosthetics, orthotics and supplies);
- (o) Other factors related to the member's plan of care or health outcomes; AND/OR
- (p) If applicable, verification that the requested device, system, biologic, or drug is being prescribed/requested and will be utilized according to its FDA-approved or compendia indication and guideline information, including intended use for the member's age and medical condition; AND
- (2) When clinical review criteria are NOT met for a specified service such that medical necessity cannot be established, OCA UM staff will engage in individual case discussions with licensed Plan pharmacists, OCA UM clinicians, and/or Plan Medical Directors (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment) to determine if the clinical review criteria are appropriate for the member's circumstances or care provided by a local delivery system. If the clinical review criteria are not appropriate, OCA UM staff may make the utilization determination based on the member's condition and other unique circumstances; AND
- b. OCA UM staff considers the following characteristics of the healthcare delivery system listed in items (1) through (4) to assess the local healthcare delivery system's ability to meet the member's healthcare needs when applying clinical review criteria to each request:
  - (1) Availability and member access to acute and subacute care facilities, including but not limited to acute care inpatient hospitals (with access to inpatient and outpatient specialty hospital services such as major burn care, transplantation, specialty pediatric care, specialty outpatient centers for HIV/AIDS, sickle cell disease, hemophilia, craniofacial and congenital anomalies), surgi-centers, rehabilitation facilities, transitional care facilities, skilled nursing facilities (SNF), home health agencies, and hospice programs, as applicable for the member's clinical needs; AND
  - (2) Member's reasonable accessibility to a qualified provider with appropriate credentials and clinical expertise in the applicable clinical area necessary to adequately treat the member's condition; AND

Note: The Plan will authorize a member's care from an out-of-network provider when, as determined by the Plan, the care needed by the member is not available or is not reasonably accessible to the member.

- (3) Covered benefits for acute and subacute care facilities, including but not limited to acute care inpatient hospitals, surgi-centers, rehabilitation facilities, transitional care facilities, SNF, or home health agencies, as applicable for the member's clinical needs; AND
- (4) The ability of acute and subacute care facilities, including but not limited to acute care inpatient hospitals, surgi-centers, rehabilitation facilities, transitional care facilities, SNF, or home health agencies, to provide the following services, as specified below in BOTH items (a) and (b):
  - (a) Provide the recommended medically necessary services to the member within the estimated amount, frequency, and duration of treatment (including the estimated length of stay, when applicable); medically necessary services required by the member and provided by the facility/treating provider may include routine medical/surgical services, highly specialized healthcare services (such as transplant services or cancer care), rehabilitative care, habilitative services, and/or support services after hospital discharge; AND
  - (b) Provide the medically necessary clinical support to the Plan member after the member's hospital discharge and/or transition to a less intense clinical setting or to home, as applicable for the member's treatment plan; AND
- c. When an OCA UM staff member is unable to authorize care by establishing medical necessity, the OCA UM staff will forward the request and documentation to the appropriate Medical Director or licensed Plan pharmacist for a determination (utilizing qualified Plan clinicians applicable for the member's condition and requested treatment); AND
- d. When medical necessity cannot be established through existing clinical review criteria, the Plan's Medical Directors and/or licensed Plan pharmacists consider alternate methods of determining medical necessity, as defined in the Medically Necessary medical policy, policy number OCA 3.14. If Plan-adopted written clinical review criteria have not been established for the requested service for the specified indication, the Plan's Medical Directors and/or licensed Plan pharmacists will use published and applicable generally accepted, scientifically-based standards of care to determine medical necessity. If scientifically-based standards of care are not available, observational studies from more than one (1) institution that suggest a causal relationship between the service or treatment and health outcomes may be used by the Plan's Medical Directors and/or licensed Plan pharmacists to make medical necessity determinations if these observational studies are clinically appropriate with respect to the member's clinical presentation. The Plan's Medical Directors and/or licensed Plan pharmacists also consider member-specific factors when applying clinical criteria, evaluating standards of care and credible scientific evidence published in peer-reviewed medical/clinical literature, and/or reviewing observational studies for a request for services for a Plan member to make medical necessity determinations; AND

- e. The Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC), Pharmacy and Therapeutics (P&T) Committee, Utilization Management Committee (UMC), and other applicable committees meet annually or more frequently as needed to review and/or and authorize all clinical review criteria used by the Plan along with the policies and procedures for application; AND
- f. OCA UM staff training and annual inter-rater reliability testing are conducted to review the application of internal clinical review criteria (including criteria in the Plan's internal medical policies and internal pharmacy policies) and Plan-adopted InterQual® criteria to ensure the consistency of medical necessity determinations among the OCA UM staff, Plan pharmacists, and Plan Medical Directors (according to the definitions of inter-rater reliability, OCA Staff, and OCA UM Staff in the Definitions section of this policy); AND
- g. The Plan makes all of its clinical review criteria available to practitioners, members, regulatory agencies, and accreditation organizations, upon oral or written request. Providers and member may call or fax the Plan with a request for a copy of the specific criteria, as stated in writing in the Plan's provider manual and Plan's website. This access to clinical review criteria includes applicable copyrighted commercial criteria such as those used by the Plan's partner delegated clinical vendors and Plan-adopted InterQual® criteria.

The current version of clinical review criteria included in the Plan's internal medical policies and internal pharmacy policies are available to all providers, members, and the general public on the Plan's extranet site. Participating providers receive network notifications via email at least 60 calendar days before the effective date of material changes to internal clinical review criteria and/or coding (excluding industry-wide code updates and administrative changes) or when new versions of InterQual® criteria are adopted by the Plan. Copies of internal medical policies with material changes to clinical review criteria and/or coding are included these provider network notifications (sent at least 60 calendar days before the effective date); updated internal medical policies will be available at the Plan's website on the effective date of the revisions. Providers may email feedback on the Plan's medical policies to the Medical Policy Mailbox at medical.policy@bmchp-wellsense.org. It is important to include the medical policy title and policy number with the comments so Plan staff can thoroughly research the issue. An integral component of the Plan's annual medical policy review process is to evaluate provider comments and recommendations.

The Plan will submit material revisions to its medical necessity guidelines, including clinical review criteria and related utilization management protocols, to the Massachusetts Office of Patient Protection, Massachusetts Executive Office of Health and Human Services (EOHHS), New Hampshire Department of Health and Human Services (DHHS), and the Centers for Medicare & Medicaid Services (CMS) at least 60 calendar days before the effective date of these material revisions (or another timeframe specified by the organization) when these changes may impact services provided to the organization's enrollees; a designated contact person must be provided in writing to the Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) by the organization or its designee.

Internal pharmacy policy revisions are communicated to providers 60 calendar days before the effective date of the revisions. Pharmacy policies for the Plan's NH Medicaid product are submitted to DHHS for review and approval prior to implementation. Once approved, pharmacy policies are available on the Plan's website 30 calendar days before the effective date. For Medicaid and commercial lines of business, providers may email feedback on the Plan's pharmacy policies at <a href="mailto:pharmacym@bmchp-wellsense.org">pharmacy policies at pharmacym@bmchp-wellsense.org</a>, or provide feedback as part of the UM process during Peer to Peer discussions with the Plan's clinical staff. During the annual pharmacy policies for Medicaid and commercial products are approved by the Plan's Pharmacy & Therapeutics (P&T) Committee. For MA Senior Care Options (SCO) and NH Medicare Advantage products, the pharmacy policies are approved by the Centers for Medicare & Medicaid Services. Pharmacy utilization management functions and the P&T Committee responsibilities are delegated to the Pharmacy Benefit Manager for MA SCO and NH Medicare Advantage products.

## Responsibility and Accountability

See the Policy Summary and Delegated Management sections of this policy for guidelines related to clinical review criteria and services managed by clinical vendors with whom the Plan has delegated utilization management (by Plan product), including behavioral health services, radiology services, dental services, pharmacy benefits administration, and durable medical equipment, prosthetics, orthotics and supplies. Responsibility and accountability related to the development, implementation, and monitoring of the Plan's internal clinical review criteria (included in the Plan's medical policies and internal pharmacy policies) are specified below in items 1 through 4:

- 1. The Utilization Management Committee (UMC), chaired by the Director of UM Program Oversight and Member Appeals and Grievances, oversees and is accountable for the adoption, development, review, update, and implementation of the Plan's clinical review criteria. Generally, the Plan adopts nationally developed and accepted criteria (e.g., InterQual®). When national criteria are not available or not utilized by the Plan, Plan-specific criteria may be developed that are objective, scientifically derived, and evidence-based, with input from participating practitioners and consistent with applicable legal, regulatory, and national accreditation organization standards.
- 2. The Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) is responsible for developing and approving medical policies, and the Pharmacy and Therapeutics (P&T) Committee is responsible for developing and approving pharmaceutical coverage policies.
- 3. The Directors of OCA (including but not limited to the Directors of Utilization Management and the Director of Pharmacy), Chief Medical Officer, Plan Medical Directors, Plan pharmacists, and other OCA UM staff use the Plan's clinical review criteria in accordance with applicable Plan policies and procedures.

4. The Directors of OCA, including but not limited to the Directors of Utilization Management and the Director of Pharmacy, or their designee(s) are responsible for ensuring OCA UM staff training, evaluating, and monitoring. The Chief Medical Officer or designee is responsible for ensuring Medical Director training, evaluation, and monitoring to ensure consistent application of clinical review criteria and medical necessity determinations.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

### **Definitions**

### Clinical Review Criteria (Definition for MassHealth and Senior Care Options Products):

Criteria used to determine the most clinically appropriate and necessary level of care and intensity of services to ensure the provision of medically necessary services. Medical necessity guidelines established by the Plan will be no more restrictive than the applicable contractual MassHealth ACO and MCO definition of Medically Necessary or Medical Necessity and the same services furnished to members under MassHealth fee-for-service, as specified in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. Any new or amended pre-authorization requirement or restriction shall NOT be implemented unless the Plan's and/or partner clinical vendor's respective website has been updated to clearly reflect the new or amended requirement or restriction.

Clinical Review Criteria (Definition for Qualified Health Plans/ConnectorCare/Employer Choice Direct Definition Products): In accordance with 958 CMR 3.020, clinical review criteria are the written screening procedures, decisions, abstracts, clinical protocols and/or practice guidelines used by the Plan to determine the medical necessity and appropriateness of health care services. Utilization review criteria shall be up to date and applied consistently by the Plan or the Plan's partner clinical vendor and made easily accessible to members, providers, and the general public on the Plan's website; or, in the alternative, on the Plan's partner clinical vendor's website so long as the Plan provides a link on its website to the vendor's website; provided, however, that the Plan shall not be required to disclose licensed, proprietary criteria purchased by the Plan or partner clinical vendor on its website, but must disclose such criteria to a provider or subscriber upon request. Review the Plan's Medically Necessary medical policy, policy number OCA 3.14, for the product-specific definition of medically necessary treatment. Any new or amended pre-authorization requirement or restriction shall NOT be implemented unless the Plan's and/or partner clinical vendor's respective website has been updated to clearly reflect the new or amended requirement or restriction.

Clinical Review Criteria (Definition for New Hampshire Medicaid Product): A set of medical decision standards employed in the utilization review process in order to ensure members receive

appropriate care, at an appropriate time, in an appropriate setting by an appropriate provider and at an appropriate level of care. Criteria are consistent with an efficient and effective utilization of resources available to recipients. Medical necessity guidelines established by the Plan will be no more restrictive than the contractual definition of Medically Necessary for the New Hampshire Department of Health and Human Services (DHHS) and the same services furnished in the New Hampshire DHHS fee-for-service Medicaid program, as specified in the Plan's *Medically Necessary* medical policy, policy number OCA 3.14. Any new or amended pre-authorization requirement or restriction shall NOT be implemented unless the Plan's and/or partner clinical vendor's respective website has been updated to clearly reflect the new or amended requirement or restriction.

**Inter-Rater Reliability (IRR):** A performance measurement tool used to compare and evaluate the level of consistency in healthcare determinations between two (2) or more medical and behavioral health utilization management (UM) clinicians. The tool is used to minimize variation in the application of clinical review criteria and identify potentially avoidable utilization target areas that need improvement and evaluate the ability to identify quality of care issues.

Office of Clinical Affairs (OCA) Staff: Plan staff members within the OCA that include but are not limited to OCA Utilization Management (UM) staff, Plan licensed pharmacists, Plan Medical Directors, and the Chief Medical Officer. The Directors of OCA, including the Directors of Utilization Management and the Director of Pharmacy, or their designees are responsible for ensuring OCA UM staff training, evaluating, and monitoring. The Plan's OCA UM staff, Plan licensed pharmacists, and Plan Medical Directors consistently use applicable Plan clinical review criteria when determining the medical necessity of healthcare services. The Chief Medical Officer or designee is responsible for ensuring Medical Director training, evaluation, and monitoring to ensure consistent application of clinical review criteria and medical necessity determinations.

Office of Clinical Affairs (OCA) Utilization Management (UM) Staff: The Plan's OCA UM staff includes both the Pharmacy UM staff and UM staff. Reporting to the Director of Pharmacy, the Pharmacy UM staff reviews requests for pharmacotherapy or directs requests to a partner clinical vendor for delegated utilization management. Reporting to the Directors of Utilization Management, appropriately qualified UM staff reviews medical, surgical, behavioral health, and/or dental requests for service or directs requests to a partner clinical vendor for delegated utilization management.

**Plan-Adopted Clinical Review Criteria:** Written clinical review criteria used to determine medical necessity, including internally developed criteria specified in Plan medical policies and Plan pharmacy policies, InterQual® criteria utilized by the Plan, and clinical guidelines established by delegated management partners (for related services provided Plan members for applicable Plan products).

Practitioner (Definition for the Qualified Health Plans, ConnectorCare, and Employer Choice Direct): A professional who provides healthcare services. Practitioners are usually required to be licensed as defined by law.

**Utilization Review (UR):** A set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, healthcare services, procedures, or

settings. Such techniques may include, but are not limited to, ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, and/or retrospective review.

### References

American Society for Reproductive Medicine (ASRM). Practice Committee of ASRM. Definition of experimental procedures: a committee opinion. Fertil Steril. 2013.

Centers for Medicare & Medicaid Services (CMS). EPSDT - A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents. 2014 Jun.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicaid. Early and Periodic Screening, Diagnosis, and Treatment. Medicaid.gov.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Change Healthcare. InterQual® Overview.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Contract between the Commonwealth Health Insurance Connector Authority and Plan.

Contract between the Executive Office of Health and Human Services (EOHHS) and the Plan to Serve as an Accountable Care Partnership Plan for the Accountable Care Organization (ACO) Program.

Contract between the Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan.

Contract between the New Hampshire Department of Health and Human Services (DHHS) and Plan.

Hayes, a symplr Company.

Levenson JL. Psychological factors affecting other medical conditions: Clinical features, assessment, and diagnosis. UpToDate. 2020 Nov 2.

Medicaid.gov. Early and Periodic Screening, Diagnostic, and Treatment. Centers for Medicare & Medicaid Services.

National Committee for Quality Assurance (NCQA). HEDIS® & Performance Measurement.

National Committee for Quality Assurance (NCQA). Utilization Management Accreditation.

National Institute for Health and Care Excellence (NICE). NICE guidance.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Senior Care Options Contract between the Massachusetts Executive Office of Health and Human Services (EOHHS) and Plan and Medicare Advantage Special Needs Plan Contract between the Centers for Medicare & Medicaid Services (CMS) and the Plan.

- U. S. Food and Drug Administration (FDA). Device Labeling.
- U. S. Food and Drug Administration (FDA). Drug Approvals and Databases.
- U. S. Food and Drug Administration (FDA). Medical Device Databases.

### **Next Review Date**

06/01/23

# **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

### **Other Applicable Policies**

Administrative Policy - Clinical Technology Evaluation, policy number OCA 3.13

Administrative Policy - Inter Rater Reliability, policy number OCA 3.216

Medical Policy - Clinical Trials, policy number OCA 3.192

Medical Policy - Cosmetic, Reconstructive, and Restorative Services, policy number OCA 3.69

Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12

Medical Policy - Medically Necessary, policy number OCA 3.14

Medical Policy - Out-of-Network Services, policy number OCA 3.18

Reimbursement Policy - Clinical Trials, policy number 4.134

Reimbursement Policy - Clinical Trials, policy number SCO 4.134

Reimbursement Policy - Clinical Trials, policy number WS 4.12

Reimbursement Policy - Early Intervention, policy number 4.3

Reimbursement Policy - Early and Periodic Screening, Diagnosis and Treatment (EPSDT), policy number WS 4.15

Reimbursement Policy - General Billing and Coding Guidelines, policy number 4.31

Reimbursement Policy - General Billing and Coding Guidelines, policy number SCO 4.31

Reimbursement Policy - General Billing and Coding Guidelines, policy number WS 4.17

Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number 4.108

Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number SCO 4.108

Reimbursement Policy - General Clinical Editing and Payment Accuracy Review Guidelines, policy number WS 4.18

Reimbursement Policy - Hospital, policy number WS 4.21

Reimbursement Policy - Inpatient Hospital, policy number 4.110

Reimbursement Policy - Inpatient Hospital, policy number SCO 4.110

Reimbursement Policy - Non-Participating Provider, policy number WS 4.5

Reimbursement Policy - Non-Reimbursed Codes, policy number 4.38

Reimbursement Policy - Non-Reimbursed Codes, policy number WS 4.38

Reimbursement Policy - Outpatient Hospital, policy number 4.17

Reimbursement Policy - Outpatient Hospital, policy number SCO 4.17

Reimbursement Policy - Physician and Non-Physician Practitioner Services, policy number 4.608

Reimbursement Policy - Physician and Non-Physician Practitioner Services, policy number SCO 4.608

Reimbursement Policy - Physician and Non-Physician Practitioner Services, policy number WS 4.28

Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number 4.610

Reimbursement Policy - Provider Preventable Conditions and Serious Reportable Events, policy number SCO 4.610

Reimbursement Policy - *Provider Preventable Conditions and Serious Reportable Events*, policy number WS 4.29

### Reference to Applicable Laws and Regulations

42 CFR 405.1060. Code of Federal Regulations. Applicability of National Coverage Determinations.

42 CFR 422.205. Code of Federal Regulations. Public Health, Centers for Medicare & Medicaid Services. Medicare Advantage Program. Provider Antidiscrimination Rules.

42 CFR 438.100. Code of Federal Regulations. Public Health, Centers for Medicare & Medicaid Services. Managed Care. Enrollee Rights and Protections. Enroll Rights.

42 CFR §438.210. Code of Federal Regulations. Public Health. Centers for Medicare & Medicaid Services. Medical Assistance Programs. Managed Care. Coverage and Authorization of Services.

42 CFR Parts 438, 440, 456, and 457. Code of Federal Register. Vol. 81. No. 61. Medicaid and Children's Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; the Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans. Centers for Medicare & Medicaid Services (CMS). 2016 Mar 30.

42 CFR §440.210. Code of Federal Regulations. Public Health. Centers for Medicare & Medicaid Services. Medical Assistance Programs. Medical Assistance Programs. Required Services for the Categorically Needy.

42 CFR §441.56. Code of Federal Regulations. Public Health. Centers for Medicare & Medicaid Services. Medical Assistance Programs. Medical Assistance Programs. Requirements and Limits Applicable to Specific Services. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21. Required Activities.

42 USC § 18001, United States Code, Patient Protection and Affordable Care Act. 2010.

42 USC § 18001, United States Code, Patient Protection and Affordable Care Act, 2010.

78 FR 48164-69. Federal Register. Centers for Medicare & Medicaid Services (CMS). Medicare Program. Revised Process for Making National Coverage Determinations. 2013 Aug 7.

114.3 CMR 17.00. Code of Massachusetts Regulations. Division of Health Care Finance and Policy. Medicine.

130 CMR. Code of Massachusetts Regulations. Division of Medical Assistance.

130 CMR 410.00. Code of Massachusetts Regulations. Division of Medical Assistance. Outpatient Hospital Services.

130 CMR 415.000. Code of Massachusetts Regulations. Division of Medical Assistance. Acute Inpatient Hospital Services.

130 CMR 433.00. Code of Massachusetts Regulations. Division of Medical Assistance. Physician Services.

130 CMR 440.00. Division of Medical Assistance. Code of Massachusetts Regulations. Early Intervention Program Services.

130 CMR 450.000. Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations.

130 CMR 450.117(J). Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations. Managed Care Participation. Compliance with Mental Health Parity Law.

130 CMR 450.204. Code of Massachusetts Regulations. Division of Medical Assistance. Administrative and Billing Regulations. Medically Necessary.

211 CMR 52.00. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers.

211 CMR 52.02. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers. Definitions. Clinical Review Criteria.

211 CMR 52.02. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers. Definitions. Medical Necessity or Medically Necessary.

211 CMR 52.02. Code of Massachusetts Regulations. Division of Insurance. Managed Care Consumer Protections and Accreditation of Carriers. Definitions. Utilization Review.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Clinical Review Criteria.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Utilization Review.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Medical Necessity or Medically Necessary.

958 CMR 3.020. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Utilization Review.

958 CMR 3.101. Code of Massachusetts Regulations. Health Insurance Consumer Protection. Definitions. Carrier's Medical Necessity Guidelines.

958 CMR 3.400. Code of Massachusetts Regulations. Health Insurance Consumer Protection. External Review.

Commonwealth of Massachusetts. Chapter 207 of the Acts of 2010 - An Act Relative to Insurance Coverage for Autism.

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation.

Commonwealth of Massachusetts. Massachusetts General Laws Mandating that Certain Health Benefits Be Provided By Commercial Insurers, Blue Cross and Blue Shield and Health Maintenance Organizations. Regulatory Citations. 2017 Oct 24.

Commonwealth of Massachusetts. MassHealth Provider Regulations.

He-W 500. New Hampshire Code of Administrative Rules. Medical Assistance.

He-W 530. New Hampshire Code of Administrative Rules. Medical Assistance. Service Limits, Co-Payments, and Non-Covered Services.

He-W 530.01(e). New Hampshire Code of Administrative Rules. Medical Assistance. Service Limits, Co-Payments, and Non-Covered Services. Definitions. Medically Necessary.

He-W 530.05(b)(4). New Hampshire Code of Administrative Rules. Medical Assistance. Non-Covered Services. Experimental or Investigational Procedures.

He-W 531. New Hampshire Code of Administrative Rules. Medical Assistance. Physician Services.

He-W 531.01(a). New Hampshire Code of Administrative Rules. Medical Assistance. Physician Services. Cosmetic Purpose.

He-W 543. New Hampshire Code of Administrative Rules. Medical Assistance. Hospital Services.

He-W 546. New Hampshire Code of Administrative Rules. Medical Assistance. Early and Periodic Screening, Diagnosis and Treatment Service.

MGL c 233. Massachusetts General Laws. An Act Relative to HIV-Associated Lipodystrophy Syndrome Treatment.

MGL c 1760. Massachusetts General Laws. Health Insurance Consumer Protections.

The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). The Center for Consumer Information & Insurance Oversight. Centers for Medicare and Medicaid Services (CMS).

Newborns' and Mothers Health Protection Act of 1996 (NMHPA). The Center for Consumer Information & Insurance Oversight. Centers for Medicare and Medicaid Services (CMS).

New Hampshire Department of Health and Human Services (DHHS). Certified Administrative Rules. RSA 417-D:2-b. New Hampshire Revised Statutes Annotated. Women's Health Care. Reconstructive Surgery.

RSA Chapter 420-E. New Hampshire Revised Statutes. Insurance. Licensure of Medical Utilization Review Entitles.

Social Security Act. Title XIX. 1902(a)(43), 1905(a)(4)(B), 1905(r). Grants to States for Medical Assistance Programs. Early and Periodic Screening, Diagnosis, and Treatment (EPSDT).

Social Security Act. Title XXI. State Children's Health Insurance Program.

U.S. Women's Health and Cancer Right Act of 1998.

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval:	08/13/07	Director of Medical Policy as	Utilization
08/01/08	Version 1	Chair of Medical Policy,	Management
MH Review: 02/19/10		Criteria, and Technology	Committee (UMC)
		Assessment Committee	
Internal Approval:		(MPCTAC)	
07/24/07 and 08/13/07			

<sup>\*</sup>Effective date for MA QHP commercial product: 01/01/12

Note: Policy title was *Clinical Criteria* until 07/31/17. Policy title changed to *Clinical Review Criteria* as of 08/01/17.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
04/22/08	Typos and formatting corrected. Removed bullet stating Chief Medical Officer conducts review on all criteria annually.	Version 2	04/22/08: UMC
05/07/08	Added authority for plan pharmacists to render pharmacy denials.	Version 3	05/20/08: UMC 06/19/08: Quality Improvement Committee (QIC)
08/20/09	Changed titles within Health Services, minor typos and formatting, updated references, changed definition for clinical criteria.	Version 4	09/22/09: UMC 09/23/09: QIC
07/21/10	Updated names, departments and references, extra definition for medically necessary was removed.	Version 5	07/21/10: MPCTAC 08/25/10: QIC
07/01/11	Added medically necessary definition and language for Commercial product.	Version 6	07/22/11: MPCTAC 08/24/11: QIC
07/01/12	References updated, moved Purpose section of policy to the beginning of the document and added reference for the Plan's Prior Authorization/ Notification Requirements matrix. Referenced the Plan's Medically Necessary policy for a definition of medically necessary for each member type and deleted	Version 7	07/18/12: MPCTAC 08/15/12: MPCTAC

<sup>\*</sup>Effective date for New Hampshire Medicaid product: 01/01/13

<sup>\*</sup>Effective date for MA Senior Care Options product: 01/01/16

<sup>\*</sup>Effective date for New Hampshire Medicare Advantage HMO product: 01/01/22

	medically necessary definitions from this		
	policy. Added language regarding delegated		
	management in Policy Statement section.		
	Added reference to Physician Reviewers in		
	policy. Changed definition title from "Clinical		
	Criteria" to "Clinical Review Criteria."		
08/15/12	Off cycle review for New Hampshire Medicaid	Version 8	08/17/12: MPCTAC
33/13/12	product. Revised the Purpose, Definitions,		09/13/12: QIC
	Policy Statement, reformatted Procedure,		03/13/12. Q10
	updated references for all Plan products.		
9/01/12	Added language to clarify the Plan's UR	Version 9	09/19/12: MPCTAC
9/01/12		version 9	
	process that includes the evaluation of		09/26/12: QIC
	member's circumstances and local delivery		
2 2 1 2 1 1 2	system, when clinically appropriate.	2= 42 42	
06/01/13	Review for effective date 07/18/13. Revised	07/18/13	06/19/13: MPCTAC
	title of chair for the Utilization Management	Version 10	07/18/13: QIC
	Committee.		
06/01/14	Review for effective date 10/01/14. Updated	10/01/14	06/09/14: MPCTAC
	Purpose, Policy Statement, Delegated	Version 11	07/09/14: QIC
	Management, Procedure, Responsibility and		
	Accountability, Definitions, and References		
	sections.		
06/01/15	Review for effective date 07/08/15.	07/08/15	06/17/15: MPCTAC
	Removed Commonwealth Care,	Version 12	07/08/15: QIC
	Commonwealth Choice, and Employer Choice		, ,
	from the list of applicable products because		
	the products are no longer available.		
	Administrative changes made to Purpose,		
	Policy Statement, Delegated Management,		
	and Procedure sections.		
00/01/15		10 /14 /15	00 /16 /1E, MDCTAC
09/01/15	Review for effective date 10/14/15. Added	10/14/15	09/16/15: MPCTAC
	reference to eviCore healthcare in the	Version 13	10/14/15: QIC
	Delegated Management section. Updated list		
	of applicable products, including the removal		
	of Common-wealth Care, Commonwealth		
	Choice, and Employer Choice because the		
	products are no longer available.		
06/01/16	Review for effective date 07/13/16. Updated	07/13/16	06/15/16: MPCTAC
	with administrative changes to the Delegated	Version 14	07/13/16: QIC
	Management, References, and References to		
	Applicable Laws and Regulations sections.		
05/01/17	Review for effective date 06/01/17.	06/01/17	05/17/17: MPCTAC
	Administrative changes made to the policy	Version 15	
	title and the Purpose, Policy Statement,		
	Responsibility and Accountability, Definitions,		
	References, and Reference to Applicable		
	Laws and Regulations sections to clarify the		
	Plan's clinical criteria review process and the		
	Trians chilical criteria review process and the		

	use of these clinical criteria in utilization review activities.		
08/31/17	Updated the definition of Clinical Review Criteria (for Massachusetts products) to include requirements for the medical necessity guidelines applicable for the Accountable Care Organization (ACO). Updated Product Applicability and Reference sections to incorporate ACO.	08/31/17 Version 16	08/31/17: MPCTAC (electronic vote)
06/01/18	Review for effective date 07/01/18. Administrative changes made to the Policy Statement, Procedure, Responsibility and Accountability, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	07/01/18 Version 17	06/20/18: MPCTAC
09/01/18	Review for effective date 12/01/18.  Administrative changes made to the Purpose and Policy Summary sections. Updated criteria in the Procedure section (clarifying the existing process).	12/01/18 Version 18	09/19/18: MPCTAC
11/01/18	Review for effective date 12/01/18.  Administrative changes made to the Policy Statement, Delegated Management, and Procedure sections to clarify the existing process available for practitioners to submit comments related to clinical review criteria.	12/01/18 Version 19	11/21/18: MPCTAC
06/01/19	Review for effective date 07/01/19. Administrative changes made to the Policy Summary (formerly Purpose section), Policy Statement, Delegated Management, Procedure, Definitions, Responsibility and Accountability, References, and Reference to Applicable Laws and Regulations sections to clarify the existing process.	07/01/19 Version 20	06/19/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Administrative changes made to the Delegated Management and Procedure sections.	01/01/20 Version 21	12/18/19: MPCTAC
06/01/20	Review for effective date 07/01/20. Administrative changes made to the Policy Summary, Procedure, References, and Reference to Applicable Laws and Regulations sections.	07/01/20 Version 22	06/17/20: MPCTAC
12/01/20	Review for effective date 01/01/21. Administrative changes made to the Delegated Management, Responsibility and Accountability, and Definitions sections.	01/01/21 Version 23	12/16/20: MPCTAC

12/22/20	Review for effective date 01/01/21 (replacing	01/01/21	12/23/20: MPCTAC
12/22/20	version 23). Updated documentation related to the Plan's Pharmacy Manager, Express Scripts, in the Delegated Management section.	Version 24	(electronic vote)
06/01/21	Review for effective date 07/01/21. Clarified current guidelines with administrative changes made to the Policy Summary, Policy Statement, Delegated Management, and Procedure sections to clarify existing guidelines. Updated References section.	07/01/21 Version 25	06/16/21: MPCTAC
08/01/21	Review for effective date 09/01/21. Administrative changes made to the Policy Summary, Policy Statement, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections to clarify current guidelines.	09/01/21 Version 26	08/13/21: MPCTAC (electronic vote)
11/01/21	Review for effective date 12/01/21. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary and Policy Statement sections. Added the Variations section.	12/01/21 Version 27	11/17/21: MPCTAC
07/01/22	Review for effective date 08/01/22. Administrative changes made to the Policy Summary, Policy Statement, Delegated Management, Procedure, Responsibility and Accountability, Definitions, and Other Applicable Policies sections.	08/0/122 Version 28	07/25/22: MPCTAC (electronic vote)
08/01/22	Review for effective date 11/01/22. Revised the list of the Plan's delegated services and partner clinical vendors in the Delegated Management section. eviCore healthcare served as the Plan's delegated vendor for radiology services from 03/15/20 to 10/31/22. Effective 11/01/22, the Plan will delegate the management of radiology services, musculoskeletal services (i.e., spine surgeries, joint surgeries, and interventional pain management treatments), genetic testing, and outpatient rehabilitation services (i.e., physical therapy, occupational therapy, and speech therapy after the initial evaluation) to AIM Specialty Health.	11/01/22 Version 29	08/26/22: MPCTAC (electronic vote)



### **Medical Policy**

# **Complementary and Alternative Medicine**

**Policy Number**: OCA 3.194

Version Number: 21

**Version Effective Date**: 11/01/22

### **Impacted Products**

	All Products
	NH Medicaid
$\boxtimes$	NH Medicare Advantage
$\boxtimes$	MA MassHealth ACO
$\boxtimes$	MA MassHealth MCO
	MA Qualified Health Plans/Employer Choice Direct
$\boxtimes$	MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers complementary and alternative medicine (CAM) NOT medically necessary unless the service (including indication for treatment) is covered for the member. Prior authorization from AIM Specialty Health is required for outpatient therapeutic services.

#### Clinical Criteria

The member's product-specific benefit documents will determine coverage for CAM services, as specified below in items 1 and 2:

- 1. The Plan considers CAM services NOT medically necessary for Plan members, except as covered in the member's applicable benefit documents.
- 2. There may be separate medical policies that address the treatment of specific conditions or procedures that supersede this policy. See the Plan's *Prior Authorization/Notification Requirements* matrix available at the Plan's website for prior authorization guidelines by service type.

### **Limitations and Exclusions**

The Plan considers CAM to NOT be medically necessary due to insufficient scientific evidence demonstrating the clinical validity and clinical utility of treatment unless the service (including indication for treatment) is covered for the member. CAM include but are not limited to any of the following services:

- 1. Whole medicine systems (e.g., homeopathic and naturopathic medicine, traditional Chinese medicine such as Ayurveda).
- 2. Mind body medicine to improve the mind's ability to affect bodily function and symptoms (e.g., biofeedback except for treatment of urinary incontinence, hypnotherapy/hypnosis, meditation, prayer, mental healing, therapies that use creative outlets such as art, music, or dance).
- 3. Substances found in nature (e.g., herbal products, vitamins, dietary supplements).
- 4. Manipulative and body based practices (e.g., massage, myotherapy, craniosacral therapy, osteopathic manipulation, hippotherapy, yoga, reflexology).
- 5. Energy medicine (e.g., Reiki, therapeutic touch, pulsed fields, magnetic fields, electromagnetic, or alternating-current or direct-current field).

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and NH Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, there was no applicable clinical policies by CMS. Verify CMS guidelines in effect on the date of the prior authorization request for the service and indication for treatment. When there is no guidance from CMS for the requested service, plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding

section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT/HCPCS Codes	Description: Service is considered NOT medically necessary, except as specified in the member's applicable benefit document	
90880	Hypnotherapy  Plan note: Code is NOT payable for the Senior Care Options product.	
M0075	Cellular therapy  Plan note: Code is NOT payable for the Senior Care Options and NH Medicare Advantage HMO products.	

### References

American Chronic Pain Association (ACPA). ACPA Resource Guide to Chronic Pain management, An Integrated Guide to Medical, Interventional, Behavioral Pharmacologic and Rehabilitation Therapies. Feinberg S (ed.) American Chronic Pain Association Inc., Rocklin, California. 2019.

American College of Chest Physicians (ACCP). Deng GE, Rausch SM, Jones LW, Gulati A, Kumar NB, Greenlee H, Pietanza MC, Cassileth BR. Complementary therapies and integrative medicine in lung cancer: diagnosis and management of lung cancer, 3rd ed: ACCP evidence-based clinical practice quidelines. Chest. 2013 May;143(5 Suppl):e420S-36S. doi: 10.1378/chest.12-2364. PMID: 23649450.

American College of Physicians (ACP). Qaseem A, Wilt TJ, McLean RM, Forciea MA; Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute and Chronic Low Back Pain: A Clinical Guideline from the ACP. Ann Intern Med. 2017 Apr 4;166(7):514-30. doi: 10.7326/M16-2367. Epub 2017 Feb 14. PMID: 28192789.

American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA). Rosenquist RW, Benzon HT, Connis RT, De Leon-Casasola OA, Glass D, Korevaar WC, Cynwyd B, Mekhail NA, Merrill DG, NIckinovich DG, Rathnmell JP, Nai-Mei Sang C, Simon DL; ASA Task Force on Chronic Pain Management. Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA. Anesthesiology. 2010 Apr;112(4):810-33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt E. Noninvasive Treatments for Low Back Pain. Comparative Effectiveness Review No. 169. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2012-00014-I.) AHRQ Publication No. 16-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality. 2016 Feb.

Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt ED. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. Ann Intern Med. 2017 Apr 4;166(7):493–505. doi: 10.7326/M16-2459. Epub 2017 Feb 14. PMID: 28192793.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins. Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Greenlee H, Balneaves LG, Carlson LE, Cohen M, Deng G, Hershman D, Mumber M, Perlmutter J, Seely D, Sen A, Zick SM, Tripathy D; Society for Integrative Oncology. Clinical practice guidelines on the use of integrative therapies as supportive care in patients treated for breast cancer. J Natl Cancer Inst Monogr. 2014 Nov;2014(50):346-58. doi: 10.1093/jnci monographs/lgu041. Review. Erratum in: J Natl Cancer Inst Monogr. 2015 May;2015(51):98. PMID: 25749602.

Institute for Clinical Systems Improvement (ICSI). Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management. Eighth Edition. Version 2. 2017 Aug.

Levy SE, Hyman SL. Complementary and alternative medicine treatments for children with autism spectrum disorders. Child Adolesc Psychiatr Clin N Am. 2015 Jan;24(1):117-43. doi: 10.1016/j.chc.2014.09.004. Epub 2014 Oct 3. PMID: 25455579.

National Academies of Sciences, Engineering, and Medicine. 2017. Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use. 2017 Jul 13. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/24781.

National Cancer Institute. National Institutes of Health (NIH). Complementary and Alternative Medicine. 2019 Sep 30.

National Center for Complementary and Integrative Health (NCCIH). National Institutes of Health (NIH). Acupuncture. 2017 Sep 24.

National Center for Complementary and Integrative Health (NCCIH). National Institutes of Health (NIH). Acupuncture: In Depth. 2017 Feb 21.

National Center for Complementary and Integrative Health (NCCIH). National Institutes of Health (NIH). Complementary, Alternative, or Integrative Health: What's In a Name? 2019 Apr 2.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Office of Patient Centered Care and Cultural Transformation (OPCC&CT). Complementary and Integrative Health (CIH) Resource Guide. Version 2. Last Update: 2017 Oct.

U.S. Department of Veterans Affairs (VA), Department of Defense (DoD). VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain. Version 2.0 – 2017.

U.S. Department of Veterans Affairs. Department of Defense (DoD). VA/DoD Clinical Practice Guideline for the Management of Chronic Multisymptom Illness CMI 2014.

U.S. National Library of Medicine. National Institutes of Health. Collection Development Manual. Complementary and Alternative Medicine. 2018 Mar 26.

Yuan QL, Guo TM, Liu L, Sun F, Zhang YG. Traditional Chinese medicine for neck pain and low back pain: a systematic review and meta-analysis. PLoS One. 2015 Feb 24;10(2):e0117146. doi: 10.1371/journal.pone.0117146. eCollection 2015. PMID: 25710765.

### **Next Review Date**

02/01/23

## **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or

investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

## Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	11/01/09 Version 1	Director of Medical Policy as	MPCTAC and QIC
Internal Approval:		Chair of	
07/28/09: Medical Policy, Criteria, and		MPCTAC	
Technology Assessment Committee			
(MPCTAC)			
08/26/09: Quality Improvement			
Committee (QIC)			

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

Policy title was Complementary and Alternative Medicine, Including Acupuncture Treatment until 06/30/19. As of 07/01/19, policy title changed to Complementary and Alternative Medicine, Including Acupuncture. As of 01/01/22, policy title changed to Complementary and Alternative Medicine.

Policy Rev	isions History		
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
07/01/10	Removed osteopathic manipulation from the list of CAM services. Changed the "non-covered" language to "not medically necessary," added massage by a massage therapist and updated references.	Version 2	07/21/10: MPCTAC 08/25/10: QIC
07/01/11	Updated references and added commercial language.	Version 3	07/22/11: MPCTAC 08/24/11: QIC
07/01/12	Updated references, added language to Applicable Code section and added applicable code list. Updated Summary section and Applicable Code section to specify that acupuncture is considered a medically necessary service for Commonwealth Care and MassHealth members when used for substance abuse detoxification, as managed and authorized by Beacon Health Strategies. Included statement that acupuncture is not a covered service for Commercial members and	Version 4	07/18/12: MPCTAC 08/22/12: QIC

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for NH Medicare Advantage HMO Product: 01/01/22

	added a reference to the Medically Necessary policy in the Summary section.		
05/01/13	Review for effective date 09/01/13. Updated Summary section and applicable code list. Referenced Reimbursement Guidelines: Chiropractic Services (Spinal Manipulation), policy number 4.114. Medical Policy Statement section revised without changing criteria. Hippotherapy added to applicable code list, and the reference to the Hippotherapy policy deleted from Medical Policy Statement section (since Hippotherapy policy will be retired effective 09/01/13). Renumbered policy from OCA: 3.193 to OCA: 3.194.	09/01/13 Version 5	05/15/13: MPCTAC 06/20/13: QIC
05/01/14	Review for effective date 07/01/14. Updated Summary section. Added acupuncture services in the Description of Item or Service and Clinical Background Information sections. Revised language in Medical Policy Statement section and Limitations section without changing criteria. Updated references. Revised policy title.	07/01/14 Version 6	05/21/14: MPCTAC 06/11/14: QIC
01/01/15	Review for effective date 03/01/15. Updated Medical Policy Statement section to clarify guidelines without changing criteria. Updated references.	03/01/15 Version 7	01/21/15: MPCTAC 02/11/15: QIC
04/01/15	Review for effective date 06/01/15. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Administrative changes made to the Applicable Coding section, but no changes made to the code list. Updated Summary and References sections.	06/01/15 Version 8	04/15/15: MPCTAC 05/13/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Administrative changes made to the Summary, Medical Policy Statement, and Limitations section without revising criteria. Revised language in the Applicable Coding section.	01/01/16 Version 9	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
04/01/16	Review for effective date 06/01/16. Updated the Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.	06/01/16 Version 10	04/20/16: MPCTAC 05/23/16: QIC

04/01/17	Review for effective date 05/08/17.	05/08/17	04/19/17: MPCTAC
04/01/17		Version 11	04/19/17. MFCTAC
	Administrative changes made to the Medical	version ii	
	Policy Statement and Applicable Coding		
	sections (without changing the code list or		
	criteria). Updated Definitions, Clinical		
	Background Information, References, and		
	Reference to Applicable Laws and Regulations		
	sections.		
02/01/18	Review for effective date 03/01/18. Updated	03/01/18	02/21/18: MPCTAC
	Description of Item or Service and Other	Version 12	
	Applicable Policies sections.		
05/01/18	Review for effective date 06/01/18.	06/01/18	05/16/18: MPCTAC
	Administrative changes made to the Limitations	Version 13	
	sections. Updated Plan notes in the Applicable		
	Coding section without changing the code list.		
	Removed QHP/ConnectorCare/Employer		
	Choice Direct from the list of applicable		
	products for this policy. Updated Policy		
	Summary, Definitions, References, and Other		
	Applicable Policies sections.		
03/01/19	Review for effective date 04/01/19.	04/01/19	03/20/19: MPCTAC
	Administrative changes made to the Description	Version 14	
	of Item or Service, Limitations, Applicable		
	Coding (with Plan notes added), References,		
	and Other Applicable Policies sections.		
04/01/19	Review for effective date 05/01/19.	05/01/19	04/18/19: MPCTAC
	Administrative changes made to the Policy	Version 15	(electronic vote)
	Summary, Description of Item or Service,		
	Medical Policy Statement, and Limitations		
	sections. Revised the policy title. Removed		
	non-payable code listed as not medical		
	necessary (administrative change) and updated		
	Plan notes in the Applicable Coding section.		
12/01/19	Review for effective date 01/01/20.	01/01/20	12/18/19: MPCTAC
, ,	Administrative changes made to Plan notes in	Version 16	
	the Applicable Coding section, References		
	section, and Reference to Applicable Laws and		
	Regulations section.		
04/01/20	Review for effective date 07/01/20.	07/01/20	04/15/20:
	Administrative changes made to the Policy	Version 17	MPCTAC
	Summary, Clinical Background Information,		
	References, and Reference to Applicable Laws		
	and Regulations sections. Revised the Plan		
	notes in the Applicable Coding section. Add a		
	prior authorization requirement for acupuncture		
	P addition Edition Tequilient for acapanetare	l	1

	for Senior Care Options members in the Medical		
	Policy Statement and Limitations sections.		
12/01/20	Review for effective date 01/01/21.	01/01/21	12/16/20: MPCTAC
	Administrative changes made to the Description	Version 18	
	of Item or Service, Medical Policy Statement,		
	Applicable Coding, and References sections.		
11/01/21	Review for effective date 12/01/21. Adopted	01/01/22	11/17/21: MPCTAC
	new medical policy template; removed	Version 19	
	administrative sections, the Medical Policy		
	Statement section renamed the Clinical Criteria		
	section, and the Limitations section renamed		
	the Limitations and Exclusions section. Added		
	NH Medicare Advantage HMO as an applicable		
	product effective 01/01/22. Administrative		
	changes made to the Policy Summary, Clinical		
	Criteria, Limitations and Exclusions, Applicable		
	Coding, and References sections.		
12/01/21	Review for effective date 01/01/22. Removed	01/01/22	12/15/21: MPCTAC
	acupuncture references. Review the Plan's	Version 20	
	Acupuncture medical policy, policy number OCA		
	3.17, rather than this policy for acupuncture		
	services as of 01/01/22.		
08/01/22	Review for effective date 11/01/22.	11/01/22	08/26/22: MPCTAC
	Administrative changes made to the Policy	Version 21	(electronic vote)
	Summary, Clinical Criteria, and Limitations and		
	Exclusions sections. Revised coding in the		
	Applicable Coding section.		



Medical Policy - Policy Retired and AIM Criteria Adopted as of 11/01/22

### **Facet Joint Nerve Injections**

Policy Number: OCA 3.9641

**Version Number**: 23

Policy Retired Date: 11/01/22

### Impacted Products

#### 

- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers diagnostic or therapeutic facet joint nerve injections (including intra-facet injections/facet blocks and facet medial branch blocks) to be medically necessary when AIM clinical appropriateness guidelines are met. Prior authorization from AIM Specialty Health is required.

### Clinical Criteria

No medical policy criteria.

### **Limitations and Exclusions**

None.

### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and NH Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, (LCD) L35936 includes guidelines for facet joint injections, medial branch blocks, and facet joint radiofrequency ablation. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no

guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

### **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for this service, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet
	(zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or
	CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet
	(zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or
	CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet
	(zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or
	CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet
	(zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or
	CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet
	(zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or
	CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet
	(zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or
	CT), lumbar or sacral; third and any additional level(s)
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or
	nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or
	nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or
	nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any
	additional level(s)
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or
	nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or
	nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level

0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or
	nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any
	additional level(s)

#### References

Allegri M, Montella S, Salici F, Valente A, Marchesini M, Compagnone C, Baciarello M, Manferdini ME, Fanelli G. Mechanisms of low back pain: a guide for diagnosis and therapy. Version 2. F1000Res. 2016 Jun 28 [revised 2016 Jan 1];5. pii: F1000 Faculty Rev-1530. eCollection 2016. doi: 10.12688/f1000research.8105.2. PMID: 27408698.

American Association of Neurological Surgeons (AANS). AANS Position Statements.

American Association of Neurological Surgeons (AANS). Cervical Spine.

American College of Occupational and Environmental Medicine (ACOEM). Cervical and Thoracic Spine Disorders Guideline. 2016 May 27.

American College of Occupational and Environmental Medicine (ACOEM). Occupational Medicine Practice Guidelines.

American College of Physicians (ACP), American Pain Society (APS). Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK; Clinical Efficacy Assessment Committee of the ACP; ACP; APS Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the ACP and the APS. Ann Intern Med. 2007 Oct 2;147(7):478-91. Erratum in: Ann Intern Med. 2008 Feb 5;148(3):247-8. PMID: 17909209.

American College of Physicians (ACP). Clinical Guidelines & Recommendations.

American College of Radiology (ACR). ACR Appropriateness Criteria.

American College of Radiology (ACR). ACR Appropriateness Criteria. Cervical Neck Pain or Cervical Radiculopathy. 2018.

American College of Radiology (ACR). ACR Appropriateness Criteria. Chronic Back Pain: Suspected Sarcoilitis/Spondyloarthropasty. 2016.

American College of Radiology (ACR). ACR Appropriateness Criteria. Low Back Pain. 2015.

American Pain Society (APS). Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical Interventional Therapies for Low Back Pain: a Review of the Evidence for an American Pain Society Clinical Practice Guideline. Spine. 2009 May 1;34(10):1078-93. doi: 10.1097/BRS.0b013e3181a103b1. PMID: 19363456.

American Pain Society (APS). Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, Carragee EJ, Grabois M, Murphy DR, Resnick DK, Stanos SP, Shaffer WO, Wall EM; APS Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain:

an evidence-based clinical practice guideline from the APS. Spine (Phila Pa 1976). 2009 May 1;34(10):1066-77. doi: 10.1097/BRS.0b013e3181a1390d. PMID: 19363457.

American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA). Rosenquist RW, Benzon HT, Connis RT, De Leon-Casasola OA, Glass D, Korevaar WC, Cynwyd B, Mekhail NA, Merrill DG, NIckinovich DG, Rathnmell JP, Nai-Mei Sang C, Simon DL; ASA Task Force on Chronic Pain Management. Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA. Anesthesiology. 2010 Apr;112(4):810–33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.

American Society of Interventional Pain Physicians (ASIPP). Boswell MV, Trescot AM, Datta S, Schultz DM, Hansen HC, Abdi S, Sehgal N, Shah RV, Singh V, Benyamin RM, Patel VB, Buenaventura RM, Colson JD, Cordner HJ, Epter RS, Jasper JF, Dunbar EE, Atluri SL, Bowman RC, Deer TR, Swicegood JR, Staats PS, Smith HS, Burton AW, Kloth DS, Giordano J, Manchikanti L; ASIPP. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. Pain Physician. 2007 Jan;10(1):7-111. PMID: 17256025.

American Society of Interventional Pain Physicians (ASIPP). Interventional Pain Management (IPM) Practice Guidelines.

American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks TA, Caraway DL, Calodney AK, Cash KA, Christo PJ, Cohen SP, Colson J, Conn A, Cordner HJ, Coubarous S, Datta S, Deer TR, Diwan SA, Falco FJE, Fellows B, Geffert SC, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm II S, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel V, Racz GB, Sehgal N, Sharma M, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood J, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. Interventional Pain Management (IPM) Practice Guideline. An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part 2: Guidance and Recommendations. Pain Physician. 2013;16:S49-283. PMID: 23615883.

American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, Falco FJE, Singh V, Benyamin RM, Racz GB, Helm II S, Caraway DL, Calodney AK, Snook LT, Smith HS, Gupta S, Ward SP, Grider JS, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: introduction and general considerations. Pain Physician 2013 Apr;16(2 Suppl):S1-48. PMID: 23615882.

American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, Kaye AD, Soin A, Albers SL, Beall D, Latchaw RE, Sanapati MR, Shah S, Atluri S, Abd-Elsayed A, Abdi S, Aydin S, Bakshi S, Boswell M, Buenaventura R, Cabaret J, Calodney AK, Candido KD, Christo PJ, Cintron L, Diwan S, Gharibo C, Grider J, Gupta M, Haney B, Harned ME, Helm II S, Jameson J, Jha S, Kaye AM, Knezevic NN, Kosanovic R, Manchikanti MV, Navani A, Racz G, Pampati V, Pasupuleti R, Philip C, Rajput K, Sehgal N, Sudarshan G, Vanaparthy R, Wargo BW, Hirsch JA. Comprehensive Evidence-Based Guidelines for Facet Joint Interventions in the Management of Chronic Spinal Pain: ASIPP Guidelines. Pain Physician 2020 May-Jun;23:S1-127. PMID: 32503359.

American Society of Regional Anesthesia and Pain Medicine (ASRA). Cohen SP, Bhaskar A, Bhatia A, Buvanendran A, Deer T, Garg S, Hooten WM, Hurley RW, Kennedy DJ, McLean BC, Moon JY, Narouze S, Pangarkar S, Provenzano DA, Rauck R, Sitzman BT, Smuck M, van Zundert J, Vorenkamp K, Wallace MS, Zhao Z. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Reg Anesth Pain Med. 2020;45:424–67. doi:10.1136/rapm-2019-101243. PMID: 32245841.

American Society of Regional Anesthesia and Pain Medicine (ASRA). The specialty of chronic pain management.

Atluri S, Singh V, Datta S, Geffert S, Sehgal N, Falco FJ. Diagnostic accuracy of thoracic facet joint nerve blocks: an update of the assessment of evidence. Pain Physician. 2012 Jul-Aug;15(4):E483-96. PMID:

22828695.

Baber Z, Erdek MA. Failed back surgery syndrome: current perspectives. J Pain Res. 2016 Nov 7;9:979–87. eCollection 2016. doi: 10.2147/JPR.S92776. PMID: 27853391.

Backer RM. Cervical, Thoracic, and Lumbar Facet Joint Injections. Spine-Health. 2013 Mar 22.

Baker RM. Cervical, Thoracic, and Lumbosacral Medial Branch Nerves. Spine-Health. 2013 Oct 4. Baker RM. Medial Branch Nerve Blocks. Spine-Health. 2013 Oct 4.

Bartleson JD, Maus TP. Diagnostic and therapeutic spinal interventions. Neurol Clin Pract. 2014 Aug; 4(4):342–346. doi: 10.1212/CPJ.000000000000044. PMID: 29473559.

Beinart NA, Goodchild CE, Weinman JA, Ayis S, Godfrey EL. Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: a systematic review. Spine J. 2013 Dec;13(12):1940-50. doi: 10.1016/j.spinee.2013.08.027. Epub 2013 Oct 26. PMID: 24169445.

Beresford ZM, Kendall RW, Willick SE. Lumbar facet syndromes. Curr Sports Med Rep. 2010 Jan-Feb;9(1):50-6. doi: 10.1249/JSR.0b013e3181caba05. PMID: 20071922.

Binder DS, Nampiaparampil DE. The provocative lumbar facet joint. Curr Rev Musculoskelet Med. 2009 Mar;2(1):15–24. doi: 10.1007/s12178-008-9039-y. PMID: 19468914.

Bodguk N, Dreyfuss P, Govind J. A narrative review of lumbar medial branch neurotomy for the treatment of back pain. Pain Med. 2009 Sep;10(6):1035-45. doi: 10.1111/j.1526-4637.2009.00692.x. Epub 2009 Aug 18. PMID: 19694977.

Boswell MV, Manchikanti L, Kaye AD, Bakshi S, Gharibo CG, Gupta S, Jha SS, Nampiaparampil DE, Simopoulos TT, Hirsch JA. A Best-Evidence Systematic Appraisal of the Diagnostic Accuracy and Utility of Facet (Zygapophysial) Joint Injections in Chronic Spinal Pain. Pain Physician. 2015 Jul-Aug;18(4):E497-533. PMID: 26218947.

Bykowski JL, Wong WH. Role of facet joints in spine pain and image-guided treatment: a review. AJNR Am J Neuroradiol. 2012 Sep;33(8):1419-26. doi: 10.3174/ajnr.A2696. Epub 2011 Sep 22. PMID: 21940805.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L35936). National Government Services, Inc.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD). Centers for Medicare & Medicaid Services (CMS). Transmittals.

Cimolin V, Vismara L, Galli M, Zaina F, Negrini S, Capodaglio P. Effects of obesity and chronic low back pain on gait. J Neuroeng Rehabil. 2011 Sep 26;8:55. doi: 10.1186/1743-0003-8-55. PMID: 21943156.

Cohen SP, Bhaskar A, Bhatia A, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Reg Anesth Pain Med. 2020 Jun;45(6):424-467. doi: 10.1136/rapm-2019-101243. Epub 2020 Apr 3. PMID: 32245841.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Department of Veterans Affairs (VA), Department of Defense (DoD). The Diagnosis and Treatment of Low Back Pain Work Group. VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain. J Gen Intern Med. 2019 Nov;34(11):2620-2629. doi: 10.1007/s11606-019-05086-4. Epub 2019 Sep 16. PMID: 31529375.

Falco FJ, Datta S, Manchikanti L, Sehgal N, Geffert S, Singh V, Smith HS, Boswell MV. An updated review of the diagnostic utility of cervical facet joint injections. Pain Physician. 2012 Nov-Dec;15(6):E807-38. PMID: 23159977.

Falco FJ, Manchikanti L, Datta S, Sehgal N, Geffert S, Onyewu O, Zhu J, Coubarous S, Hameed M, Ward SP, Sharma M, Hameed H, Singh V, Boswell MV. An update of the effectiveness of therapeutic lumbar facet joint interventions. Pain Physician. 2012 Nov-Dec;15(6):E909-53. PMID: 23159980.

Falco FJ, Manchikanti L, Datta S, Wargo BW, Geffert S, Bryce DA, Atluri S, Singh V, Benyamin RM, Sehgal N, Ward SP, Helm S 2nd, Gupta S, Boswell MV. Systematic review of the therapeutic effectiveness of cervical facet joint interventions: an update. Pain Physician. 2012 Nov-Dec;15(6):E839-68. PMID: 23159978.

Han SH, Park KD, Cho KR, Park Y. Ultrasound versus fluoroscopy-guided medial branch block for the treatment of lower lumbar facet joint pain. A retrospective comparative study. Medicine (Baltimore). 2017 Apr;96(16):e6655. Published online 2017 Apr 21. doi: 10.1097/MD.0000000000006655. PMID: 28422871.

Hayes. Health Technology Assessment. Intra-Articular Facet Joint Injections for the Treatment of Chronic Nonmalignant Spinal Pain of Facet Joint Origin. Dallas, TX: Hayes; 2018 Apr 19. Annual Review 2021 Jun 08.

Hayes. Health Technology Assessment. Medial Branch Nerve Block Injections for the Treatment of Chronic Nonmalignant Spinal Pain of Facet Joint Origin. Dallas, TX: Hayes; 2018 Jan 18. Annual Review 2021 Apr 23.

Institute for Clinical Systems Improvement (ICSI). Pain: Assessment, Non-Opioid Treatment Approaches and Opioid Management. Eighth Edition. 2017 August.

Kennedy DJ, Shokat M, Visco CJ. Sacroiliac joint and lumbar zygapophysial joint corticosteroid injections. Phys Med Rehabil Clin N Am. 2010 Nov;21(4):835-42. doi: 10.1016/j.pmr.2010.06.009. PMID: 20977966.

Lee DG, Ahn SH, Cho YW, Do KH, Kwak SG, Chang MC. Comparison of Intra-articular Thoracic Facet Joint Steroid Injection and Thoracic Medial Branch Block for the Management of Thoracic Facet Joint Pain. Spine (Phila Pa 1976). 2018 Jan 15;43(2):76-80. doi: 10.1097/BRS.0000000000002269. PMID: 28591071.

Manchikanti L, Falco FJ, Benyamin RM, Caraway DL, Kaye AD, Helm S 2nd, Wargo BW, Hansen H, Parr AT, Singh V, Swicegood JR, Smith HS, Schultz DM, Malla Y, Hirsch JA. Assessment of bleeding risk of interventional techniques: a best evidence synthesis of practice patterns and perioperative management of anticoagulant and antithrombotic therapy. Pain Physician. 2013 Apr;16(2 Suppl):SE261-318. PMID: 23615893.

Manchikanti L, Hirsch JA, Falco FJ, Boswell MV. Management of lumbar zygapophysial (facet) joint pain. World J Orthop. 2016 May 18;7(5):315–37. 2016 May 18;7(5):315–37. doi: 10.5312/wjo.v7.i5.315. eCollection 2016 May 18. PMID: 27190760.

Manchikanti L, Hirsch JA, Kaye AD, Boswell MV. Cervical zygapophysial (facet) joint pain: effectiveness of interventional management strategies. Postgrad Med. 2016 Jan;128(1):54-68. doi: 10.1080/00325481.2016.1105092. Epub 2015 Dec 10. PMID: 26653406.

Manchikanti L, Hirsch JA, Pampati V, Boswell MV. Utilization of Facet Joint and Sacroiliac Joint Interventions in Medicare Population from 2000 to 2014: Explosive Growth Continues! Curr Pain Headache Rep. 2016 Oct;20(10):58. doi: 10.1007/s11916-016-0588-2. PMID: 27646014.

Manchikanti L, Manchikanti KN, Cash KA, Singh V, Giordano J. Age-related prevalence of facet-joint involvement in chronic neck and low back pain. Pain Physician. 2008 Jan;11(1):67-75. PMID: 18196171.

Meucci RD, Fassa AG, Faria NM. Prevalence of chronic low back pain: systemic review. Rev Saude Publica. 2015;49:1. 2015;49. pii: S0034-89102015000100408. doi: 10.1590/S0034-8910.2015049005874. Epub 2015 Oct 20. PMID: 26487293.

National Institute for Health and Clinical Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. NICE guideline NG59. 2016 Nov.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

North American Spine Society (NASS). Clinical Guidelines.

North American Spine Society (NASS). Current Coverage Policy Recommendations. Facet Joint Injections.

North American Spine Society (NASS), NASS Coverage Policy Recommendations: Facet Joint Interventions, 2016.

Odonkor CA, Chen Y, Adekoya P, Marascalchi BJ, Chaudhry-Richter H, Tang T, Abruzzese C, Cohen BK, Cohen SP. Inciting Events Associated With Lumbar Facet Joint Pain. Anesth Analg. 2018 Jan;126(1):280-8. doi: 10.1213/ANE.000000000002242. PMID: 28704245.

Official Disability Guidelines (ODG). Treatment Guidelines.

Pampati S, Cash KA, Manchikanti L. Accuracy of diagnostic lumbar facet joint nerve blocks: a 2-year follow-up of 152 patients diagnosed with controlled diagnostic blocks. Pain Physician. 2009 Sep-Oct;12(5):855-66. PMID: 19787011.

Patel DR, Kinsella E. Evaluation and management of lower back pain in young athletes. Transl Pediatr. 2017 Jul;6(3):225–35. doi: 10.21037/tp.2017.06.01. PMID: 28795014.

Patel VB, Wasserman R, Imani F. Interventional Therapies for Chronic Low Back Pain: A Focused Review (Efficacy and Outcomes). Anesth Pain Med. 2015 Aug 22;5(4):e29716. doi: 10.5812/aapm.29716. eCollection 2015 Aug. PMID: 26484298.

Snidvongs S, Taylor RS, Ahmad A, Thomson S, Sharma M, Farr A, Fitzsimmons D, Poulton S, Mehta V, Langford R. Facet-joint injections for non-specific low back pain: a feasibility RCT. Health Technol Assess. 2017 Dec;21(74):1-130. doi: 10.3310/hta21740. PMID: 29231159.

Spine Intervention Society (SIS) Bogduk N, ed. ISIS Practice Guidelines. Practice Guidelines for the Spinal Diagnostic and Treatment Procedures. (Formerly known as International Spine Intervention Society/ISIS.) Second Edition. San Francisco. 2013.

Staal JB, de Bie RA, de Vet HC, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low back pain: an updated Cochrane review. Spine (Phila Pa 1976). 2009 Jan 1;34(1):49–59. doi: 10.1097/BRS.0b013e3181909558. PMID: 19127161.

Tibrewal S, Khan OH, Tibrewal SB. Facet joint injection in lower back pain—is its continued use justified? J R Soc Med. 2007 Jul;100(7):301–2. doi: 10.1258/jrsm.100.7.301. PMID: 17606742.

Vekaria R, Bhatt R, Ellard DR, Henschke N, Underwood M, Sandhu H. Intra-articular facet joint injections for low back pain: a systematic review. Eur Spine J. 2016 Apr;25(4):1266-81. doi: 10.1007/s00586-016-4455-y. Epub 2016 Feb 23. PMID: 26906169.

#### **Next Review Date**

Not applicable

#### **Retired Date**

11/01/22

### **Authorizing Entity**

**MPCTAC** 

### **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or

investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

## **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	11/01/08	Director of Medical	MPCTAC, UMC, and
	Version 1	Policy as Chair of	QIC
Internal Approval:		MPCTAC	
06/10/08: Medical Policy, Criteria,			
and Technology Assessment			
Committee (MPCTAC			
06/24/08: Utilization Management			
Committee (UMC)			
08/13/08: Quality Improvement			
Committee (QIC)			

<sup>\*</sup>Effective Date for the QHP Commercial Product: 01/01/12

Effective 06/01/13, this medical policy replaced the Facet Joint Nerve Injections and Sacroiliac Joint Injections for Chronic Neck Pain and Chronic Back Pain medical policy, policy number OCA 3.964, which was effective from 11/01/08 to 05/31/13. Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
06/23/09	Changed name of the policy, added additional criteria for SIJ injections and replaced the criteria for radiological findings negative for disc herniation and nerve root compression with: negative physical signs of radiculopathy or radicular pain, including negative straight leg raising or root tension signs, normal neurological examination, absence of signs of radiculopathy on any electrodiagnostic examinations. Updated the diagnostic clinical criteria to allow no more than 2 joint levels bilaterally or 3 joint levels unilaterally in a 7 to 14-day period to determine the origin of the patient's pain. For SIJ injections, no more than 2 procedures may be allowed in a 7 to 14-day period to determine the origin of the patient's pain. Updated references and coding sections. Effective date of changes is 10/01/09.	10/01/09 Version 2	06/23/09: MPCTAC 06/23/09: UMC 07/22/09: QIC

<sup>\*</sup>Effective Date for the New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for the Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for the New Hampshire Medicare Advantage HMO Product: 01/01/22

Policy Rev	risions History		
06/01/10	No changes to criteria. Updated references and coding.	Version 3	06/30/10: MPCTAC 07/28/10: QIC
06/01/11	Updated clinical criteria to clarify that the absence of prior spinal fusion must be at the clinically suspect levels, updated references.	Version 4	06/29/11: MPCTAC 07/27/11: QIC
07/01/12	Updated references and revised the introductory paragraph in Applicable Coding section. Code descriptions updated but no change to list of applicable codes. Revised policy title and text to specify the policy relates to chronic neck pain and chronic back pain. Added the following additional contraindication for procedures: 'Patient with a malignancy at the injection site.' Medical criteria updated for facet joint nerve injections and sacroiliac joint injections. Definitions added for radiculopathy and straight leg raise test. For facet joint injections, added symptoms of axial pain and signs of facet disease. For sacroiliac joint injections, added types of tests used for a sacroiliac exam. Added definition of a comprehensive pain management program and referenced the Plan's Medically Necessary policy.	Version 5	06/20/12: MPCTAC 07/18/12: MPCTAC 08/22/12: QIC
08/01/12	Off cycle review for the New Hampshire Medicaid product. No changes.	Version 6	08/13/12: MPCTAC 09/06/12: QIC
12/01/12	Revised sacroiliac joint injection frequency guidelines in Medical Policy Statement section.	Version 7	12/19/12: MPCTAC 12/20/12: QIC
02/01/13	Review for effective date 06/01/13. Separated facet joint nerve injections and sacroiliac joint injections into two separate policies; policy formerly titled Facet Joint Nerve Injections and Sacroiliac Joint Injections for Chronic Neck Pain and Chronic Back Pain (formerly 3.964). Revised title and renumbered policy. Updated language in Summary, Description of Item or Service, Definitions, and Clinical Background Information sections. Changed name of policy category from "Clinical Coverage Guidelines" to "Medical Policy." Revised applicable code list and updated references. Revised and added clinical criteria in the Medical Policy Statement section (formerly named the Clinical Guideline Statement section), and revised limitations.	06/01/13 Version 8	02/20/13: MPCTAC 03/21/13: QIC
08/14/13 and 08/15/13	Off cycle review for the New Hampshire Medicaid product and merged policy format. Incorporate policy revisions dated 12/01/12 and 02/01/13 (as specified above) for the New Hampshire Medicaid product; these policy revisions were approved by	Version 9	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC

Policy Rev	isions History		
	MPCTAC (on 12/19/12 and 02/20/13) and QIC (on 12/20/12 and 03/21/13) for applicable Plan products.		
03/01/14	Review for effective date 07/01/14. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, and References section. Revised policy title from Fact Joint Nerve Injections for Chronic Back Pain and Chronic Neck Pain to Facet Joint Nerve Injections. Revised and reformatted criteria in the Medical Policy Statement section and Limitations section.	07/01/14 Version 10	03/19/14: MPCTAC 04/16/14: QIC
02/01/15	Review for effective date 06/01/15. Updated Definitions and References sections. Revised criteria in the Medical Policy Statement section. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.	06/01/15 Version 11	02/27/15: MPCTAC (electronic vote) 03/11/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.	01/01/16 Version 12	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
02/01/16	Review for effective date 06/01/16. Updated criteria in the Medical Policy Statement and Limitations sections. Updated the Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.	06/01/16 Version 13	02/17/16: MPCTAC 03/09/16: QIC
01/01/17	Review for effective date 05/01/17. Updated Summary, Definitions, Clinical Background Information, and References sections. Administrative changes made to the Limitations section. Revised criteria in the Medical Policy Statement section.	05/01/17 Version 14	01/18/17: MPCTAC 02/08/17: QIC
02/01/18	Review for effective date 05/01/18. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, References, and Other Applicable Policies sections. Revised criteria in the Medical Policy Statement and Limitations sections.	05/01/18 Version 15	02/21/18: MPCTAC
02/01/19	Review for effective date 05/01/19. Administrative changes made to the Policy Summary, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Updated criteria in the Medical Policy Statement and Limitations sections.	05/01/19 Version 16	02/20/19: MPCTAC
02/01/20	Review for effective date 03/01/20. Administrative changes made to the Description of Item or Service,	03/01/20 Version 17	02/19/20: MPCTAC

Policy Rev	visions History		
	Medical Policy Statement, Limitations, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.		
11/01/20	Review for effective date 12/01/20. Administrative changes made to the Medical Policy and Limitations sections to clarify clinical review criteria.	12/01/20 Version 18	11/18/20: MPCTAC
02/01/21	Review for effective date 03/01/21. Administrative changes made to the References section.	03/01/21 Version 19	02/17/21: MPCTAC
03/01/21	Review for effective date 06/01/21. Administrative changes made to the Policy Summary, Limitations, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement section.	06/01/21 Version 20	03/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 21	11/17/21: MPCTAC
02/01/22	Review for effective date 03/01/22. Updated the References section. Administrative changes made to the Applicable Coding section.	03/01/22 Version 22	02/16/22: MPCTAC
08/01/22	Review for policy retired date 11/01/22.  Administrative changes made to the Policy Summary and Applicable Coding sections. Criteria revised in the Clinical Criteria and Limitations and Exclusions sections. AIM medical necessity criteria adopted for this service and AIM prior authorization is required as of 11/01/22, even when applicable codes are not listed in this Plan policy.	11/01/22 Version 23	08/26/22: MPCTAC (electronic vote)



## **Medical Policy**

# **Gender Affirmation Services**

Policy Number: OCA 3.11 Version Number: 21

Version Effective Date: 11/01/22

## **Impacted Products**

**⋈** All Products

- ☑ NH Medicare Advantage
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

Gender affirmation surgeries and permanent hair removal require prior authorization and are considered medically necessary for a member seeking treatment for gender dysphoria when Plan medical criteria are met. Gender affirmation surgeries may include one (1) or more surgical procedures and are part of a complex treatment plan involving medical, surgical, and behavioral health interventions to achieve the desired outcomes for the individual.

Voice therapy is considered medically necessary as a treatment option for gender dysphoria when AIM clinical appropriateness guidelines are met; prior authorization from AIM Specialty Health is required. The Plan and the Plan's delegated clinical vendors conducting utilization management do NOT discriminate, arbitrarily deny, and/or impose stricter requirements by reducing the amount, duration, and/or scope of required and medically necessary services for ANY Plan member based on the member's diagnosis, type of illness, health status or condition, sex, gender identity/gender dysphoria, and/or sexual orientation. The full range of medical and/or surgical treatment options available to individuals diagnosed with gender dysphoria may include, but are not limited to, those listed in professional medical publications such as the current version of WPATH Standards of Care for Health and Transsexual, Transgender and Gender-Nonconforming People.

Breast reconstruction used for the treatment of members with persistent, well-documented gender dysphoria may include the medically necessary surgical removal of breast implants and/or the

replacement of breast implants after implant explantation (including when the implant was initially inserted as a component of a gender affirmation surgery); review the criteria in the *Breast Reconstruction* medical policy, policy number OCA 3.43, rather than the criteria included in this policy. Feminizing/masculinizing hormonal therapy and/or gender affirmation surgeries may limit the member's fertility. Infertility services are covered for some Plan products. Review the Plan's *Infertility Services* medical policy, policy number OCA 3.725.

## **Clinical Criteria**

Applicable criteria must be met for gender affirmation services in item I for gender affirmation surgery and permanent hair removal and/or item II for gender affirmation services that require Plan Medical Director review.

- I. The Plan considers gender affirmation services medically necessary for the treatment of gender dysphoria, and Plan prior authorization is required for the services specified in this section. ALL applicable Plan clinical review criteria must be met in items A through C:
  - A. Referral/Initial Assessment by Qualified Licensed Mental Health Professional:

There is a referral/initial assessment from a licensed qualified mental health professional that contains ALL of the following documentation listed in items 1 through 8:

- Gender identity resulting in a definitive diagnosis of persistent, well-documented gender dysphoria (meeting DSM-5 criteria) for at least 6 months, history and development of gender dysphoric feelings, and impact of stigma attached to gender nonconformity; AND
- 2. If living in an identity-congruent gender role, documentation of member's experience, start date, and if living full-time in identity-congruent gender role; AND
- 3. The member's general identifying characteristics; AND
- Results of psychosocial assessment, including any diagnoses and confirmation that other behavioral health conditions are appropriately managed, reasonably controlled, and not contributing to gender dysphoria); AND
- 5. Duration of mental health professional's relationship with member, including type of evaluation and therapy/counseling to date; AND
- 6. Written clinical rationale supporting member's request for specific treatment(s); AND
- 7. Statement that mental health professional is available for coordination of care and plan of care is in place; AND
- 8. Member's psychological readiness for the requested treatment(s) with no contraindications to treatment documented, including member's capacity to make a fully informed decision

and has the capacity to consent for treatment(s), and includes parental or guardian consent (as applicable) if the member is younger than age 18 on the date of service unless the adolescent member is emancipated at the time the service is rendered; AND

- B. Member age 18 or older on the date of service; AND
- C. Service-Specific Criteria:

Criteria must be met in item 1 for all gender affirmation surgical procedures and procedure specific criteria must be met in item 2:

1. Gender Affirmation Surgical Procedures:

All criteria must be met in items a through e for any gender affirmation surgery:

- a. Requests for prior authorization for each gender affirmation surgery must be submitted by the surgeon (or the surgeon's designee) performing the procedure and accompanied by written clinical documentation; AND
- b. Surgeon has reviewed the documentation by the qualified licensed mental health professional (referenced above in item A), including the DSM-5 diagnosis of gender dysphoria, and documentation from the member's health care provider; AND
- c. Surgeon has discussed risks and complications of proposed surgery and various surgical techniques, surgeon's own complication rates, impact on fertility, procedures for preservation of fertility, and has obtained member's informed consent; AND
- d. If hormone therapy is a required criterion for a gender affirmation surgery (as specified below in the procedure-specific criteria), medical records must document member compliance with the prescribed regimen and clinical response over the course of hormone therapy; AND
- e. Member's treating surgeon has documented that there are no contraindications to the planned surgery, verified significant medical conditions are stable, and agrees with the plan of care; AND
- 2. Procedure-Specific Criteria:

Procedure-specific criteria must be met for ANY procedure listed in items a through h:

- a. Chest Procedures:
  - (1) Bilateral augmentation mammoplasty (with implantation of breast prostheses or lipofilling) when the member has had 12 continuous months of clinician-supervised

- hormone therapy (unless hormone therapy is medically contraindicated for the member), and the hormone therapy has not resulted in sufficient breast development as self-reported by the member to the treating provider; OR
- (2) Bilateral breast reduction, mastectomy, and/or chest reconstruction is requested; OR
- b. Feminizing Genital Surgery:

ALL guidelines must be met in items (1) through (4):

- (1) ANY of the procedures in items (a) through (g) will be performed:
  - (a) Clitoroplasty/neoclitoroplasty;
  - (b) Labiaplasty/neolabiaplasty;
  - (c) Orchiectomy;
  - (d) Penectomy;
  - (e) Urethroplasty and urethra-meatoplasty;
  - (f) Vaginoplasty (also known as neovaginoplasty); e.g., penile inversion vaginoplasty, colovaginoplasty, peritoneal pulldown vaginoplasty;
  - (g) Vulvoplasty/neovulvoplasty; AND
- (2) Member has been assessed by 2 independently licensed health professionals, one of whom must be a licensed qualified behavioral health professional (referenced above in item A) and the other a clinician familiar with the member's health, with each assessment resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. The initial diagnosis (from one professional) must have been present for at least 6 months; AND
- (3) Member has had 12 continuous months of living as the gender that is congruent with the member's identity. Exceptions may be provided on a case-by-case basis should the request for prior authorization document that compliance with this requirement would jeopardize the health, safety, and/or well-being of the member; AND
- (4) The member has had 12 continuous months of clinician-supervised hormone therapy appropriate to the member's gender goals, unless hormone therapy is medically contraindicated; OR

c. Masculinizing Genital Surgery: ALL guidelines must be met in items (1) through (4): ANY of the procedures listed in items (a) through (i) will be performed: (1) (a) Hysterectomy; Metoidioplasty; (b) (c) Oophorectomy; Phalloplasty with implantation of penile prosthesis; (d) (e) Salpingectomy; (f) Scrotoplasty with insertion of testicular implants; (g) Urethroplasty; (h) Vaginectomy; Vulvectomy; AND (i) (2) Member has been assessed by 2 independently licensed health professionals, one of whom must be a licensed qualified behavioral health professional (referenced above in item A) and the other a clinician familiar with the member's health, with each assessment resulting in a diagnosis of gender dysphoria meeting DSM-5 criteria. The initial diagnosis (from 1 professional) must have been present for at least 6 months; AND (3) Member has had 12 continuous months of living as the gender that is congruent with the member's identity. Exceptions may be provided on a case-by-case basis should the request for PA document that compliance with this requirement would jeopardize the health, safety, or well-being of the member; AND (4) Member has had 12 continuous months of clinician-supervised hormone therapy

d. Facial Feminization or Facial Masculinization Surgical Procedures:

contraindicated; OR

ONE (1) or more of the procedures listed in items (1) through (12) will be performed:

appropriate to the member's gender goals, unless hormone therapy is medically

(1)	Blepharoplasty (eyelid surgery) ONLY in conjunction with other medically necessary facial feminization or facial masculinization procedures;
(2)	Brow reconstruction/brow lift;
(3)	Cheek augmentation;
(4)	Forehead contouring (including forehead reshaping or forehead reduction);
(5)	Genioplasty (chin augmentation, chin reconstruction, or chin reduction/narrowing);
(6)	Scalp/hairline advancement;
(7)	Lateral canthopexy;
(8)	Surgical lip lift;
(9)	Lysis intranasal synechiae;
(10)	Mandibuloplasty;
(11)	Osteoplasty;
(12)	Rhinoplasty and septoplasty;
(13)	Rhytidectomy (facelift surgery) of the forehead, cheek, and/or neck (platysmaplasty);
(14)	Suction-assisted lipectomy in conjunction with medically necessary facial procedures; AND/OR
(15)	Tracheoplasty/tracheal shave; OR
Hair	Removal with Laser or Electrolysis:
Elect	crolysis and/or laser treatments for face and neck hair removal is performed by a

Electrolysis and/or laser treatments for face and neck hair removal is performed by a licensed and qualified treating clinician and ALL criteria are met in items (1) through (5):

(1) A licensed qualified health professional recommends hair removal of the face and/or neck as part of the member's medically necessary treatment for gender dysphoria; AND

e.

- (2) A letter from the clinician performing the hair removal is submitted to the Plan and includes attestation of the medical necessity of hair removal and a summary of the member's care as it relates to gender dysphoria treatment; AND
- (3) Documentation submitted to the Plan includes the area size and location(s) for permanent hair removal, the type of hair removal treatment (laser or electrolysis), and the expected timeframe and number of treatments requested. The Plan will authorize medically necessary requests for electrolysis and/or laser ablation treatments for medically necessary permanent hair removal of the face and/or neck for up to 12 calendar months from the date of the authorization request. Additional treatments require a separate Plan authorization; AND
- (4) Clinician performing the hair removal has discussed risks and complications of the proposed procedure, including the clinician's own complication rates, and has obtained informed consent from the member; AND
- (5) Member has had 12 continuous months of clinician-supervised hormone therapy appropriate to the member's gender goals unless hormone therapy is medically; OR
- f. Hair removal for standard pre-operative preparation for genital gender affirmation surgery:

Electrolysis and/or laser treatments for hair removal is performed by a licensed and qualified treating provider and ALL criteria are met in items (1) through (4):

- (1) Permanent hair removal is required as part of the standard pre-operative preparation for genital affirming surgery(ies) and is recommended by the treating surgeon, with documentation verifying that hair removal is medically necessary; AND
- (2) A letter from the clinician performing the hair removal is submitted to the Plan and includes attestation of the medical necessity of hair removal and a summary of the member's care as it relates to gender dysphoria treatment; AND
- (3) Documentation submitted to the Plan includes the area size and location(s) for permanent hair removal, the type of hair removal treatment (laser or electrolysis), expected timeframe and number of treatments requested, and the estimated date of the genital gender affirmation surgical procedure(s). The Plan will authorize medically necessary requests for electrolysis and/or laser ablation treatments for medically necessary pre-operative permanent hair removal as standard preparation for genital gender affirmation surgery for up to 18 calendar months from the date of the authorization request. Additional treatments require a separate Plan authorization; AND

- (4) Clinician performing the hair removal has discussed risks and complications of the proposed procedure, including the clinician's own complication rates, and has obtained informed consent from the member; OR
- g. Gender Affirmation Procedures NOT Requiring Medically Necessary Permanent Hair Removal of Graft Site:
  - The Plan will authorize medically necessary requests for gender affirmation surgery(ies) up to 12 calendar months from the date of the authorization request; OR
- h. Genital Gender Affirmation Procedures Requiring Medically Necessary Permanent Hair Removal of Graft Site:

The Plan will authorize medically necessary requests for genital gender affirmation procedure(s) that require pre-operative permanent hair removal as standard preparation for surgery up to 18 calendar months from the date of the authorization request.

- II. The following requests require Plan Medical Director review:
  - A. Permanent hair removal in preparation for planned genital gender affirmation procedure if the procedure has not yet been authorized by the Plan.
  - B. Hair removal when documentation from the member's surgeon and/or qualified licensed health provider(s) is within 13-18 calendar months of the prior authorization request and permanent hair removal is NOT a medically necessary component of pre-operative preparation for genital gender affirmation procedure(s). Additional documentation must be submitted to the Plan to report the extenuating circumstances that necessitate an extension of the standard 12 calendar month time limit.
  - C. Gender affirmation surgery for a member who does NOT meet DSM-5 definitive diagnosis of persistent gender dysphoria (e.g., non-binary members who do not meet traditional diagnostic criteria for gender dysphoria).
  - D. Gender affirmation services for a member unable to live in the chosen gender role full-time. This includes members who identify as genders other than male or female. Treating provider must submit documentation indicating why it would be clinically inappropriate to require the member to meet this criterion and why this requirement should be waived.
  - E. Gender affirmation surgery and/or permanent hair removal for a member age 17 or younger on the date of service. The Plan Medical Director will review the current version of WPATH Standards of Care and member's clinical situation, including but not limited to the amount of time the adolescent member has been living in the gender congruent role, treatment timeframe with hormone therapy, age of the member, and the requested intervention. Adolescent

members may be eligible for interventions when adolescents and their parents (or guardian) make informed decisions about treatment, and the service is a covered benefit for the Plan member. Informed consent by a parent or guardian for treatment of an adolescent member may not apply if the adolescent member is emancipated at the time the service is rendered (as determined by state requirements).

- F. Surgical revision of a previously performed gender affirmation surgery.
- G. Laparoscopic prostatectomy as a component of gender affirmation surgical procedure(s).
- H. Post-operative lodging is NOT routinely covered by the Plan; Plan Medical Director review is required.

## **Limitations and Exclusions**

- A. External review will be available to the members enrolled in Qualified Health Plans, ConnectorCare, or Employer Choice Direct products when the Plan determines that coverage for treatment of gender dysphoria is NOT medically necessary or the Plan considers the treatment experimental or investigational. The external review for Qualified Health Plans, ConnectorCare, or Employer Choice Direct products will be based upon the Massachusetts definition of medical necessity. (Source: The Commonwealth of Massachusetts, Health Policy Commission, Memo: External Review for Denials of Coverage for Medical and/or Surgical Treatment of Gender Dysphoria, July 2, 2015.)
- B. Hair removal is ONLY covered when criteria are met in the Clinical Criteria section for the method of hair removal (i.e., electrolysis and/or laser hair removal). Any other method of hair removal or indication for treatment is NOT covered.
- C. The Plan considers any services or surgical procedures used to reverse gender affirmation surgery to NOT be medically necessary.
- D. The following procedures/services in items 1 through 17 are NOT covered for the treatment of gender dysphoria:
  - 1. Blepharoplasty (eyelid surgery) NOT in conjunction with other facial feminization or facial masculinization procedures used for the treatment of gender dysphoria; OR
  - Body contouring procedures, including abdominoplasty, liposuction, lipofilling, and/or suction-assisted lipectomy UNLESS the treatment is listed as medically necessary in the Clinical Criteria section (e.g., facial procedures for the treatment of gender dysphoria) and ALL applicable clinical review criteria are met for the gender affirmation surgical procedure; OR
  - 3. Calf augmentation (calf implants); OR

- 4. Collagen injections; OR
- 5. Facial feminization surgery, facial masculinization surgery, facial bone reduction, or facial implants or injections UNLESS the treatment is specified as medically necessary in the Clinical Criteria section and applicable clinical review criteria are met for the facial feminizing or facial masculinizing gender affirmation surgical procedure; OR
- 6. Gluteal augmentation (gluteal implants and/or lipofilling); OR
- 7. Hair transplantation or hair reconstruction (see the Clinical Criteria section for guidelines for hairline advancement surgery); OR
- 8. Laryngoplasty (technique to alter the voice tract and adjust vocal range); OR
- 9. Lip reduction or lip enhancement (see the Clinical Criteria section for guidelines related to lip lift); OR
- Osteoplasty UNLESS clinical review criteria are met for the facial feminization or facial masculinization gender affirmation surgical procedure in the Clinical Criteria section); OR
- 11. Otoplasty (surgical reshaping of the outer ear); OR
- 12. Pectoral augmentation (pectoral implants); OR
- 13. Removal of redundant skin including but NOT limited to panniculectomy and/or abdominoplasty when used for the treatment of gender dysphoria UNLESS the procedure is listed as medically necessary in the Clinical Criteria section and applicable criteria are met; OR

Note: Review the Plan's medical necessity guidelines included in the *Panniculectomy and Related Redundant Skin Surgery* medical policy, policy number OCA 3.722.

- 14. Silicone injections of the breast; OR
- 15. Skin resurfacing treatments including but NOT limited to chemical peels and/or dermabrasion; OR
- 16. Tattooing; OR
- 17. Vocal cord surgery (laryngoplasty, cricothyroid approximation or shortening of the vocal cords).

E. Reimbursement for travel expenses is NOT covered by the Plan unless the Plan's product-specific criteria are met, as specified in the Non-Emergency Transportation Services medical policy applicable for the member's product, policy number OCA 3.191.

## **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 140.9 states CMS has determined that no NCD is appropriate at this time for gender affirmation surgery for Medicare beneficiaries with gender dysphoria. LCA A53793 includes billing, coding, and treatment guidelines for gender affirmation services for gender dysphoria. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

ICD-10 Codes	Description: The following primary diagnosis codes apply to gender dysphoria and require prior authorization when billed with a medically necessary procedure code covered by the Plan for gender affirmation surgeries and/or hair removal.	
	Each gender affirmation surgery requires Plan prior authorization for ALL diagnosis and procedure codes, even if coding is not included in this Applicable Coding section. See the member's applicable benefit document to determine coverage of services. Plan Medical Director review is required for each gender affirmation surgery when the member has a diagnosis of gender incongruence (without a diagnosis of gender dysphoria) for individual consideration.	
F64.0-F64.9	Gender identity disorders	
Z87.890	History of sex reassignment surgery	

CPT Codes	Description: Services considered medically necessary for the treatment of gender dysphoria if Plan clinical review criteria are met (when billed with a primary ICD-10 diagnosis code listed above). Prior authorization is required.
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae,
	genitalia, hands and/or feet; defect 10 sq cm or less
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
	Plan note: Code is NOT payable for the MassHealth and QHP products.
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
	Plan note: Code is NOT payable for the MassHealth and QHP products.
15826	Rhytidectomy; glabellar frown lines
	Plan note: Code is NOT payable for MassHealth and QHP products.
15828	Rhytidectomy; cheek, chin, and neck
	Plan note: Code is NOT payable for MassHealth and QHP products.
15876	Suction assisted lipectomy; head and neck
19301	Mastectomy partial (e.g., lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19303	Mastectomy, simple, complete
19318	Breast reduction
19325	Breast augmentation with implant
	Plan note: Breast reconstruction for male-to-female members with persistent, well-
	documented gender dysphoria may include the medically necessary surgical removal of
	breast implants and/or the replacement of breast implants after implant explantation
	(including when the implant was initially inserted as a component of a gender affirmation
	surgery); review the criteria in the Breast Reconstruction medical policy, policy number
	OCA 3.43, rather than the criteria included in this policy for Plan prior authorization
	guidelines for these surgical procedures.
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)

21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone
	wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining
	autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional
	(includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft
	(includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction (e.g.,
	for Long Face Syndrome), without bone graft
21142	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, without
	bone graft
21143	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction,
	without bone graft
21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction,
	requiring bone grafts (includes obtaining autografts)
21146	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, requiring
	bone grafts (includes obtaining autografts) (e.g., ungrafted unilateral alveolar cleft)
21147	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction,
	requiring bone grafts (includes obtaining autografts) (e.g., ungrafted bilateral alveolar
	cleft or multiple osteotomies)
21150	Reconstruction midface, LeFort II; anterior intrusion (e.g., Treacher-Collins Syndrome)
21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining
0415.4	autografts)
21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes
21155	obtaining autografts); without LeFort I
21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes
21159	obtaining autografts); with LeFort I
21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (e.g., mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I
21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement
21100	(e.g., mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration,
2117 2	with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or
2117 3	alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts
	(includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts
-	(allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft
	(includes obtaining grafts)
21188	Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes
	obtaining autografts)

Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	
Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)	
Osteoplasty, facial bones; reduction	
Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)	
Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft	
Reconstruction of mandible, extraoral, with transosteal bone plate (e.g., mandibular staple bone plate)	
Reconstruction of mandible or maxilla, subperiosteal implant; partial	
Reconstruction of mandible or maxilla, subperiosteal implant; complete	
Reconstruction of mandible or maxilla, endosteal implant (e.g., blade, cylinder); partial	
Reconstruction of mandible or maxilla, endosteal implant (e.g., blade, cylinder); complete	
Malar augmentation, prosthetic material	
Lateral canthopexy	
Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip	
Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar	
cartilages, and/or elevation of nasal tip	
Rhinoplasty, primary; including major septal repair	
Rhinoplasty, secondary; minor revision (small amount of nasal tip work)	
Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)	
Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)	
Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including	
columellar lengthening; tip only	
Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including	
columellar lengthening; tip, septum and osteotomies	
Repair of nasal vestibular stenosis (e.g., spreader grafting, lateral nasal wall	
reconstruction)	
Septoplasty or submucous resection, with or without cartilage scoring, contouring or	
replacement with graft	
Lysis intranasal synechia	
Unlisted procedure, trachea, bronchi	
Tracheoplasty; cervical	
Discourates Code wood for two shore shore in a few wells to few all two within	
Plan note: Code used for trachea shaving for male-to-female transition.	
Unlisted procedure, lips	
Plan note: Code used for lip lift.	
Peritoneal Flap, Unlisted	
Urethroplasty, 1-stage reconstruction of male anterior urethra	
Urethroplasty, transpubic or perineal, 1-stage, for reconstruction or repair of prostatic or	
membranous urethra	
Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first	
stage	
Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra;	
second stage	
Urethroplasty, reconstruction of female urethra	
Urethromeatoplasty, with mucosal advancement	
Amputation of penis; partial	

54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401 54405	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component inflatable penile prosthesis, including placement of pump,
T 4F2O	cylinders, and reservoir
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal
F 4660	or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
	Plan note: Series of staged procedures to remove penis and create vagina.
55980	Intersex surgery; female to male
	Plan note: Series of staged procedures to remove or close vagina and for penis and
FCC20	testicles.
56620	Vulvectomy simple; partial
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
56810	Perineoplasty, repair of perineum, non-obstetrical (separate procedure)
57106	Vaginectomy, partial removal of vaginal wall
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical
	vaginectomy)
57110	Vaginectomy, complete removal of vaginal wall
57111	Vaginectomy, complete removal of vaginal wall; with removal of paravaginal tissue (radical
	vaginectomy)
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s),
	with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy) with or without removal
	of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250g or less
58262	Vaginal hysterectomy, for uterus 250g or less; with removal of tube(s), and/or ovary(s)
58275	Vaginal hysterectomy, with total or partial vaginectomy
58290	Vaginal hysterectomy, for uterus greater than 250g
58291	Vaginal hysterectomy, for uterus greater than 250g; with removal of tube(s) and/or
	ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250g or less; with removal of
	tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250g

58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 grams or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical with vaginal hysterectomy, for uterus greater than 250g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 grams; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of
	tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with
	removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with lysis of adhesions (salpingolysis, ovariolysis) (separate
	procedure); with removal of adnexal structures (partial or total oophorectomy and/or
	salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

HCPCS Code	Description: Service is considered medically necessary for the treatment of gender dysphoria if Plan criteria are met and is billed with a primary ICD-10 diagnosis code listed above. Prior authorization is required.
L8600	Implantable breast prosthesis, silicone or equal

CPT Codes	Description: The following services require Plan Medical Director review and approval when used for the treatment of gender dysphoria (and billed with a primary ICD-10 diagnosis code listed above). Prior authorization is required.
19316	Mastopexy
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement
	and/or re-inset of flaps in autologous reconstruction or significant capsular revision
	combined with soft tissue excision in implant-based reconstruction)
31587	Laryngoplasty, cricoid split, without graft placement
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes
	robotic assistance, when performed
57295	Revision (including removal) of prosthetic vaginal graft; vaginal approach
57296	Revision (including removal) of prosthetic vaginal graft; open abdominal approach
57426	Revision (including removal) of prosthetic vaginal graft, laparoscopic approach

CPT Codes	Description: Coverage guidelines based on the indication for treatment and type of service provided (when billed with a primary ICD-10 diagnosis code listed above for gender dysphoria). Prior authorization is required.
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue

Plan note: Code used when billing for laser ablation for hair removal on a skin graft donor
site for a genital gender affirmation surgery.

CPT Codes	Description: Services NOT considered medically necessary for the treatment of gender dysphoria (and billed with a primary ICD-10 diagnosis code listed above). Prior authorization is required.
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10 cc or less
11954	Subcutaneous injection of filling material (e.g., collagen); over 10 cc
15775	Punch graft for hair transplant; 1-15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15786	Abrasion; single lesion (e.g., keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary
	procedure)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15830	Excision, excessive skin and subcutaneous tissue (including lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (including lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (including lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (including lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (including lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (including lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (including lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (including lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (including lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g.,
	abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity

# References

American Academy of Child & Adolescent Psychiatry (AACAP). Adelson SL; AACAP Committee on Quality Issues (CQI): Walter HJ, Bukstein OG, Bellonci C, Beson RS, Chisman A, Farchione TR, Hamilton J, Keable H, Kinlan J, Quiterio N, Schoettle U, Siegel M, Stock S; Medicus J. Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents. J Am Acad Child Adolesc Psychiatry. 2012 Sep;51(9):957-74. doi: 10.1016/j.jaac.2012.07.004. PMID: 22917211.

American Academy of Child & Adolescent Psychiatry (AACAP). AACAP Sexual Orientation and Gender Identity Issues Committee. Conversion Therapy Policy (Lack of Evidence). 2018 Feb.

American Academy of Pediatrics (AAP). Levine DA, the Committee on Adolescence. Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth. Pediatrics. 2013 Jul;132(1):e297-313. doi:10.1542/peds.2013-1283. PMID: 23796737.

American Academy of Pediatrics (AAP). Rafferty J; Committee on Psychosocial Aspects of Child and Family Health; Committee on Adolescence; Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness. Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents. Pediatrics. 2018 Oct;142(4). pii: e20182162. doi: 10.1542/peds.2018-2162. Epub 2018 Sep 17. PMID: 30224363.

American College of Obstetricians and Gynecologists (ACOG). Committee Opinion Number 512. Healthcare for Transgender Individuals. 2011 Dec. Obstet Gynecol. 2011 Dec;118(6):1454-1458. doi: 10.1097/AOG.0b013e31823ed1c1. PMID: 22105293.

American College of Obstetricians and Gynecologists (ACOG). Committee Opinion Number 685. Care for Transgender Adolescents. Obstet Gynecol. 2017 Jan;129(1):e11-16. doi: 10.1097/AOG.0000000001861. PMID: 28002311.

American College of Pediatricians (ACPeds). Position Statement. Gender Dysphoria in Children. 2018 Nov.

American Medical Association (AMA). Policies on Lesbian, Gay, Bisexual, Transgender & Queer (LGBTQ) issues.

American Psychiatric Association (APA). Byne W, Bradley S, Coleman E, Eyler AE, Green R, Menvielle EJ, Meyer-Bahlburg HFL, Pleak RR, Tompkins DA; APA Task Force on Treatment of Gender Identity Disorder. Report of the APA Task Force on Treatment of Gender Identity Disorder. Arch Sex Behav. 2012 Aug;41(4):759-96. doi:10.1007/s10508-012-9975-x. PMID: 22736225.

American Psychiatric Association (APA). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. APA. Arlington, VA. 2013:451-9.

American Psychiatric Association (APA). Parekh R. Help with Gender Dysphoria. 2016 Feb.

American Psychiatric Association (APA). Parekh R. What is Gender Dysphoria? 2016 Feb.

American Psychological Association (APA). APA Task Force on Guidelines for Psychological Practice with Transgender and Gender Nonconforming People; Dickey LM, Singh AA, Bockting WO, Chang S, Ducheny K, Edwards-Leeper L, Ehrbar RD, Fuhrmann MF, Hendricks ML, Magalhaes E. Guidelines for

Psychological Practice with Transgender and Gender Nonconfirming People. American Psychologist. 2015 Dec;70(9):832-64. doi: 10.1037/a0039906. PMID: 26653312.

American Psychological Association (APA). Bockting W. The Psychology of Transgender. 2015 Nov 19.

American Psychological Association (APA). APA Task Force; Schneider MS, Bockting WO, Ehrbar RD, Lawrence AA, Rachlin K, Zucker KJ. Report of the APA Task Force on Gender Identity and Gender Variance. 2009.

American Psychological Association (APA). Transgender, Gender Identity, & Gender Expression Non-Discrimination Resolution. 2008 Aug.

American Psychological Association (APA). Transgender People, Gender Identity and Gender Expression. What does transgender mean? 2014.

Beek TF, Cohen-Kettenis PT, Bouman WP, de Vries ALC, Steensma TD, Witcomb GL, Arcelus J, Richards C, De Cuypere G, Kreukels BP. Gender Incongruence of Childhood: Clinical Utility and Stakeholder Agreement with the World Health Organization's Proposed ICD-11 Criteria. PLoS One. 2017 Jan 12;12(1):e0168522. doi: 10.1371/journal.pone.0168522. eCollection 2017. PMID: 28081569.

Beek TF, Cohen-Kettenis PT, Kreukels BP. Gender incongruence/gender dysphoria and its classification history. Int Rev Psychiatry. 2016;28(1):5-12. doi: 10.3109/09540261.2015.1091293. Epub 2015 Nov 19. PMID: 26782319.

Bekeny JC, Zolper EG, Fan KL, Del Corral G. Breast augmentation for transfeminine patients: methods, complications, and outcomes. Gland Surg. 2020 Jun;9(3):788-796. doi: 10.21037/gs.2020.03.18. PMID: 32775269.

Bradford NJ, Rider GN, Spencer KG. Hair removal and psychological well-being in transfeminine adults: associations with gender dysphoria and gender euphoria. J Dermatolog Treat. 2021 Sep;32(6):635-642.

doi: 10.1080/09546634.2019.1687823. Epub 2019 Nov 22. PMID: 31668100.

Bradley SJ, Zucker KJ. Gender identity disorder: a review of the past 10 years. J Am Acad Child Adolesc Psychiatry. J Am Acad Child Adolesc Psychiatry. 1997 Jul;36(7):872-80. doi: 10.1097/00004583-199707000-00008. PMID: 9204664.

Centers for Disease Control and Prevention (CDC). Lesbian, Gay, Bisexual, and Transgender Health. Resources.

Center of Excellence for Transgender Health. Deutsch MB. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People. 2016 Jun 17.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA) A53793. Billing and Coding: Gender Reassignment Services for Gender Dysphoria. 2015 Oct 1. Revision Effective Date 2021 Jan 1.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) 140.9. Gender Dysphoria and Gender Reassignment Surgery. 2017 Apr 4.

Chung KC. Operative Techniques in Plastic Surgery. First Edition. 2018. Lippincott Williams & Wilkins. ISBN: 978-1-49-633950-8.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Guidelines for Medical Necessity Determination for Gender Affirming Surgery. MNG-GAS-0921. 2021 Sep 1.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Guidelines for Medical Necessity Determination for Hair Removal. MNG-HR-0921. 2021 Sep 1.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Provider Bulletins.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Provider Manuals.

Commonwealth of Massachusetts. Executive Office of Health and Human Services (EOHHS). MassHealth Transmittal Letters.

Commonwealth of Massachusetts. Massachusetts Law about Emancipation of Minors.

Dittrich R, Binder H, Cupisti S, Hoffmann I, Beckmann MW, Mueller A. Endocrine Treatment of Male-to-Female Transsexuals Using Gonadotropin-Releasing Hormone Agonist. Exp Clin Endocrinol Diabetes. 2005 Dec;113(10):586-92. doi: 10.1055/s-2005-865900. PMID: 16320157.

Dubov A, Fraenkel L. Facial Feminization Surgery: The Ethics of Gatekeeping in Transgender Health. Amer J Bioethics. 2018 Dec:18(12):3-9. doi: 10.1080/15265161.2018.1531159.

Endocrine Society. Corrigendum for "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline." J Clin Endocrinol Metab. 2018 Feb 1;103(2):699. doi.org/10.1210/jc.2017-02548. PMID: 29244095.

Endocrine Society. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Nov 1;102(11):3869–3903. doi: 10.1210/jc.2017-01658. Erratum in: J Clin Endocrinol Metab. 2018 Feb 1;103(2):699. J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-59. PMID: 28945902.

Feldman J, Deutsch MB. Primary care of transgender individuals. UpToDate. Updated 2019 Oct 18.

Fernandez JD, Tannock LR. Metabolic Effects of Hormone Therapy in Transgender Patients. Endocr Pract. 2016 Apr;22(4):383-8. doi: 10.4158/EP15950.OR. Epub 2015 Nov 17. PMID: 26574790.

Ferrando CU, Zhao LC, Nikolavsky D. Transgender surgery: Female to male. UptoDate. Updated 2022 Apr.

GLBTQ Legal Advocates and Defenders. GLAD Answers for the LGBTQ Community. Health insurance Coverage for Transgender People in Massachusetts.

Hadj-Moussa M, Agarwal S, Ohl DA, Kuzon WM Jr. Masculinizing Genital Gender Confirmation Surgery. Sex Med Rev. 2019 Jan;7(1):141-155. doi: 10.1016/j.sxmr.2018.06.004. Epub 2018 Aug 16. PMID: 30122339.

Hancock AB, Krissinger J, Owen K. Voice perceptions and quality of life of transgender people. J Voice. 2011 Sep;25(5):553-8. doi: 10.1016/j.jvoice.2010.07.013. Epub 2010 Nov 4. J Voice. 2011. PMID: 21051199. Hayes. Health Technology Assessment. Sex Reassignment Surgery for the Treatment of Gender Dysphoria. Dallas, TX: Hayes; 2017 Aug 1. Annual Review 2021 Jul 27. Healthcare Bill of Rights/HealthLink. What is the Healthcare Bill of Rights?

Horbach SE, Bouman MB, Smit JM, Özer M, Buncamper ME, Mullender MG. Outcome of Vaginoplasty in Male-to-Female Transgenders: A Systematic Review of Surgical Techniques. J Sex Med. 2015 Jun;12(6):1499-512. doi: 10.1111/jsm.12868. Epub 2015 Mar 26. PMID: 25817066.

The Joint Commission. Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (LGBT) Community. A Field Guide. 2014 Apr 3.

Kailas M, Lu HMS, Rothman EF, Safer JD. Prevalence and Types of Gender-Affirming Surgery Among a Sample of Transgender Endocrinology Patients Prior to State Expansion of Insurance Coverage. Endocr Pract. 2017 Jul;23(7):780-786. doi: 10.4158/EP161727.OR. Epub 2017 Apr 27. PMID: 28448757.

Lee J, Lee S. Facial Contouring Surgery-Mandibuloplasty: Genioplasty and Mandible Angle Correction. Plast Reconstr Surg Glob Open. 2017 Oct;5(10):e1296. doi:10.1097/GOX.000000000001296. PMID: 29184722.

Mañero I, Labanca T, Triviño JM. Aesthetic Refinements after Radial Free Flap Phalloplasty: Optimizing the Donor Site and the Phallus. Plast Reconstr Surg Glob Open. 2017 Dec 28;5(12):e1611. doi: 10.1097/GOX.000000000001611. eCollection 2017 Dec. PMID: 29632786.

Marks DH, Hagigeorges D, Manatis-Lornell AJ, Dommasch E, Senna MM. J Cosmet Dermatol. Excess hair, hair removal methods, and barriers to care in gender minority patients: A survey study. J Cosmet Dermatol. 2020 Jun;19(6):1494-1498. doi: 10.1111/jocd.13164. Epub 2019 Sep 25. 2020. PMID: 31553137.

Massachusetts Transgender Political Coalition.

Morrison SD, Capitán-Cañadas F, Sánchez-García A, Ludwig DC, Massie JP, Nolan IT, Swanson M, Rodríguez-Conesa M, Friedrich JB, Cederna PS, Bellinga RJ, Simon D, Capitán L, Satterwhite T. Prospective Quality-of-Life Outcomes after Facial Feminization Surgery: An International Multicenter Study. Plastic and Reconstructive Surgery: 2020 June;145(6):1499-1509. doi: 10.1097/PRS.0000000000006837. PMID: 32459779.

National Center for Transgender Equality. Transgender Rights Toolkit: A Legal Guide for Trans People and Their Allies (Transgender Parents), Lambda. 2015 Jan 14.

National LGBT Health Education Center. A Program of the Fenway Institute.

National LGBT Health Education Center. A Program of the Fenway Institute. Collecting Sexual Orientation and Gender Identity Data.

National LGBT Health Education Center. A Program of the Fenway Institute. Sexual Orientation and Gender Identity Questions: Information for Patients.

National LGBT Health Education Center. A Program of the Fenway Institute. Understanding the Health Needs of LGBT People.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

New Hampshire Legal Aid. Legal Information, Referrals, and Pro Se Assistance. Emancipation.

Nuttbrock L, Hwahng S, Bockting W, Rosenblum A, Mason M, Macri M, Becker J. Psychiatric impact of gender-related abuse across the life course of male-to-female transgender persons. J Sex Res. 2010 Jan;47(1):12-23. doi: 10.1080/00224490903062258. PMID: 19568976.

Olson-Kennedy J, Forcier M. Management of transgender and gender-diverse children and adolescents. UpToDate. 2022 Apr.

Reed GM, Drescher J, Krueger RB, Atalla E, Cochran SD, First MB, Cohen-Kettenis PT, Arango-de Montis I, Parish SJ, Cottler S, Briken P, Saxena S. Disorders related to sexuality and gender identity in

the ICD-11: revising the ICD-10 classification based on current scientific evidence, best clinical practices, and human rights considerations. World Psychiatry. 2016 Oct;15(3):205-221. doi: 10.1002/wps.20354. Erratum in: World Psychiatry. 2017 Jun;16(2):220. PMID: 27717275.

Salgado CJ, AlQattan H, Nugent A, Gerth D, Kassira W, McGee CS, Wo L. Feminizing the Face: Combination of Frontal Bone Reduction and Reduction Rhinoplasty. Case Rep Surg. 2018 Jul 2;2018:1947807. doi: 10.1155/2018/1947807. eCollection 2018. PMID: 30057846.

Salgado CJ, Nugent AG, Satterwaite T, Carruthers KH, Joumblat NR. Gender Reassignment: Feminization and Masculinization of the Neck. Clin Plast Surg. 2018 Oct;45(4):635-645. doi: 10.1016/j.cps.2018.06.006. Epub 2018 Aug 10. PMID: 30268248.

Schwarz K, Fontanari AMV, Schneider MA, Borba Soll BM, da Silva DC, Spritzer PM, Kazumi Yamaguti Dorfman ME, Kuhl G, Costa AB, Cielo CA, Villas Bôas AP, Lobato MIR. Laryngeal surgical treatment in transgender women: A systematic review and meta-analysis. Laryngoscope 2017 Nov;127(11):2596-2603. Epub 2017 Jul 3 doi: 10.1002/lary.26692. PMID: 28671273.

Seal LJ, Franklin S, Richards C, Shishkareva A, Sinclaire C, Barrett J. Predictive Markers for Mammoplasty and a Comparison of Side Effect Profiles in Transwomen Taking Various Hormonal Regimens. J Clin Endocrinol Metab. 2012 Dec;97(12):4422-8. doi: 10.1210/jc.2012-2030. Epub 2012 Oct 9. PMID: 23055547.

Society for Adolescent Health and Medicine (SAHM). Reitman DS, Austin B, Belkind U, Chaffee T, Hoffman ND, Moore E, Morris R, Olson J, Ryan C. Recommendations for promoting the health and well-being of lesbian, gay, bisexual, and transgender adolescents: a position paper of the SAHM. J Adolesc Health. 2013 Apr;52(4):506-10. doi: 10.1016/j.jadohealth.2013.01.015. PMID: 23521897.

Soll BM, Robles-García R, Brandelli-Costa A, Mori D, Mueller A, Vaitses-Fontanari AM, Cardoso-da-Silva D, Schwarz K, Abel-Schneider M, Saadeh A, Lobato MI. Gender incongruence: a comparative study using ICD-10 and DSM-5 diagnostic criteria. Braz J Psychiatry. 2017 Oct 2;40(2):174-180. doi: 10.1590/1516-4446-2016-2224. Print Apr-June 2018. PMID: 28977069.

Spack NP, Edwards-Leeper L, Feldman HA, Leibowitz S, Mandel F, Diamond DA, Vance SR. Children and adolescents with gender identity disorder referred to a pediatric medical center. Pediatrics. 2012 Mar;129(3):418-25. doi: 10.1542/peds.201. 1-0907. Epub 2012 Feb 20. PMID: 22351896.

Tangpricha V, den Heijer M. Oestrogen and anti-androgen therapy for transgender women. Lancet Diabetes Endocrinol. 2017 Apr;5(4):291-300. doi: 10.1016/S2213-8587(16)30319-9. Epub 2016 Dec 2. PMID: 27916515.

Tangpricha V, Safer JD. Transgender men: Evaluation and management. UpToDate. 2022 Apr.

Tangpricha V, Safer JD. Transgender women: Evaluation and management. UpToDate. 2022 Apr.

Thomas JP, Macmillan C. Feminization laryngoplasty: assessment of surgical pitch elevation. Eur Arch Otorhinolaryngol. 2013 Sep;270(10):2695-700. doi: 10.1007/s00405-013-2511-3. Epub 2013 Apr 30. PMID: 23632870.

Unger CA. Hormone therapy for transgender patients. Transl Androl Urol. 2016 Dec;5(6):877–884. doi: 10.21037/tau.2016.09.04. PMID: 28078219.

Vance SR, Ehrensaft D, Rosenthal SM. Psychological and Medical Care of Gender Nonconforming Youth. Pediatrics. 2014 Dec;134(6):1184-92. doi: 10.1542/peds.2014-0772. Epub 2014 Nov 17. PMID: 25404716.

Wierckx K, Gooren L, T'sjoen G. Clinical Review: Breast Development in Trans Women Receiving Cross-Sex Hormones. J Sex Med. 2014 May;11(5):1240-7. doi: 10.1111/jsm.12487. Epub 2014 Mar 12. PMID: 24618412.

The World Professional Association for Transgender Health (WPATH). Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A. 2016 Dec 21.

The World Professional Association for Transgender Health (WPATH). Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People. 7th Version.

Zhang WR, Garrett GL, Arron ST, Garcia MM. Laser hair removal for genital gender affirming surgery. Transl Androl Urol. 2016 Jun;5(3):381–7. doi: 10.21037/tau.2016.03.27. PMID: 27298787.

Zucker KJ. The DSM diagnostic criteria for gender identity disorder in children. Arch Sex Behav. 2010 Apr;39(2):477-98. doi: 10.1007/s10508-009-9540-4. PMID: 19842027.

## **Next Review Date**

04/01/23

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	07/01/15	Medical Policy	MPCTAC and QIC
	Version 1	Manager as Chair	
Internal Approval:		of MPCTAC	
03/18/15: Medical Policy, Criteria, and			
Technology Assessment Committee			
(MPCTAC)			
04/08/15: Quality Improvement Committee			
(QIC)			

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

Policy title Gender Reassignment Surgery from 01/01/16 to 05/31/18. Policy title changed to Gender Affirmation Surgeries from 06/01/18 to 12/31/21. Policy title changed to Gender Affirmation Services as 01/01/22.

Policy Revis	ions History		
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
09/01/15	Review for effective date 01/01/16. Updated criteria in the Medical Policy Statement and Limitations sections. Removed requirement for 18 months of treatment for gender dysphoria. Added guidelines on external review for services denied by the Plan when members are enrolled in Qualified Health Plans, ConnectorCare, and/or Employer Choice Direct products. Update the Summary, Clinical Background Information, Definitions, and References sections and the list of applicable products.	01/01/16 Version 2	09/16/15: MPCTAC 10/14/15: QIC
11/25/15	Review for effective date 01/01/16. Updated language in the Applicable Coding section.	01/01/16 Version 3	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
04/01/16	Review for effective date 08/01/16. Revised the Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Removed ICD9 codes, added CPT code 17380 as applicable code, and added a Plan not in the Applicable Coding section.	08/01/16 Version 4	04/20/16: MPCTAC 05/23/16: QIC

<sup>\*</sup>Effective Date for NH Medicaid Product: 07/01/17

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for NH Medicare Advantage HMO Product: 01/01/22

Policy Revi	sions History		
	Revised criteria in the Medical Policy Statement		
	and Limitations sections.		
07/05/16	Review for effective date 10/01/16. Revised	10/01/16	07/05/16: MPCTAC
	criteria in the Medical Policy Statement and	Version 5	(electronic vote)
	Limitations section. Revised the applicable code		07/13/16: QIC
	list and added Plan notes to codes. Updated		
	Summary and References sections.		
09/01/16	Review for effective date 10/01/16. Added	10/01/16	Not applicable
	reference to the CMS Decision Memo for Gender	Version 6	because industry-
	Dysphoria and Gender Reassignment Surgery		wide update of CMS
	(CAG-00446N) effective 08/30/16 in the Clinical		guidelines with no
	Background Information and References sections.		change to criteria
	CMS industry-wide update with no change to		and/or the applicable
	criteria and/or the applicable code list for Plan		code list
	members (including members enrolled in a SCO		
	product).		
09/28/16	Review for effective date 11/01/16. Administrative	11/01/16	09/30/16: MPCTAC
	changes made to clarify language related to	Version 7	(electronic vote)
	gender. Revised Definitions section.		10/12/16: QIC
06/01/17	Review for effective date 07/01/17. Added the NH	07/01/17	06/21/17: MPCTAC
	Medicaid product as applicable new product for	Version 8	
	this policy as of 07/01/17 with the necessary		
	administrative changes made to the Medical Policy		
	Statement, Summary, Definitions, Clinical		
	Background Information, References, and		
	Reference to Applicable Laws and Regulations		
	sections. NH Medicaid criteria added in product-		
	specific Medical Policy Statement section and		
	product-specific Limitations section.		
05/01/17	Review for effective date 08/01/17. Criteria for	08/01/17	05/17/17: MPCTAC
	MA products were revised in the Medical Policy	Version 9	
	Statement section in 05/17 (with adequate		
	provider notification); new criteria are effective		
	08/01/17 for MA products. Administrative		
	changes made to the Summary, Definitions, and		
	References sections.		
06/01/17	Review for effective date 08/01/17. Administrative	08/01/17	06/21/17: MPCTAC
	change made to combine criteria in the Medical	Version 10	
	Policy Statement sections and in the Limitations		
	sections for all MA products and NH Medicaid		
	product (since all criteria are consistent among		
	Plan products as of 08/01/17). Administrative		
	change made to the Limitations section to be		
	consistent with the Applicable Coding section.		20.00.00
03/01/18	Review for effective date 06/01/18. Revised policy	06/01/18	03/21/18: MPCTAC
	title. Administrative changes made to the Policy	Version 11	

Policy Revis	ions History		
	Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections. Coding updated and Plan notes revised in the Applicable Coding section.		
05/01/19	Review for effective date 08/01/19. Administrative changes made to the Policy Summary, Description of Item or Service, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Criteria updated in the Medical Policy Statement and Limitations sections. Coding updated in the Applicable Coding section.	08/01/19 Version 12	05/15/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide update to coding (as a code deletion) included in the Applicable Coding section.	01/01/20 Version 13	Not applicable because industry- wide code changes
04/01/20	Review for effective date 08/01/20.  Administrative changes made to the Definitions, References, and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement and Limitations sections. Coding updated in the Applicable Coding section.	08/01/20 Version 14	04/15/20: MPCTAC
12/01/20	Review for effective date 01/01/21. Industry-wide updates to coding in the Applicable Coding section. Administrative changes made to the Limitations and Other Applicable Policies sections.	01/01/21 Version 15	Not applicable because industry- wide code changes; 12/16/20: MPCTAC review
01/01/21	Review for effective date 02/01/21. Revised criteria in the Medical Policy Statement section.	02/01/21 Version 16	01/22/21: MPCTAC (electronic vote)
04/01/21	Review for effective date 07/01/21. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Updated the applicable code list.	07/01/21 Version 17	04/21/21: MPCTAC
10/01/21	Review for effective date 01/01/22.  Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Administrative changes made	01/01/22 Version 18 Version 18 replaced with version 19 as of	10/20/21: MPCTAC

Policy Revi	sions History		
	to the Policy Summary and References sections. Criteria revised in the Clinical Criteria and Limitations and Exclusions sections. Coding revised in the Applicable Coding section.	01/01/22 and version 18 not implemented	
11/01/21	Review for effective date 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations, and Applicable Coding sections. Criteria and coding for voice therapy used for the treatment of gender dysphoria moved from the Plan's speech therapy medical policies to this policy with Plan notification (rather than prior authorization) required when applicable coding guidelines followed. Revised policy title.	01/01/22 Version 19 Version 19 replaced version 18 as of 01/01/22 and all revisions in version 18 adopted	11/30/21: MPCTAC (electronic vote)
05/01/22	Review for effective date 08/01/22.  Administrative changes made to the Policy Summary, Clinical Criteria, Limitations, References and Applicable Coding sections. Added CPT codes 49329 and 53450. Non-material changes made to Clinical Criteria and Limitations and Exclusions sections.	08/01/22 Version 20	05/11/22: MPCTAC (electronic vote)
08/01/22	Review for effective date 11/01/22. Administrative changes made to Policy Summary, Clinical Criteria, and Applicable Coding sections. Removed coding and criteria for voice therapy when used for the treatment of gender dysphoria; prior authorization requests for voice therapy must be submitted to AIM Specialty Health as of 11/01/22.	11/01/22 Version 21	MPCTAC: 08/26/22 (electronic vote)



Medical Policy - Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 11/01/22

# **Genetic/Genomic Testing and Pharmacogenetics**

**Policy Number**: OCA 3.727

Version Number: 44

Policy Retired Date: 11/01/22

## **Impacted Products**

#### 

- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers genetic and genomic testing to be medically necessary for the diagnosis of genetic disease in children and adults, for the determination of future risk of a suspected disease, for the prediction of drug responses, and/or for the detection of risks of specific diseases to future children when AIM clinical appropriateness guidelines are met. Prior authorization from AIM Specialty Health is required for genetic testing.

## Clinical Criteria

No medical policy criteria.

### **Limitations and Exclusions**

None.

### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review,

there are CMS guidelines for some types of genetic testing (e.g., NCD 90.1 for pharmacogenomics testing for warfarin response, NCD 23.18, NCD 90.2 for next generation sequencing, NCD 190.3 for cytogenetic studies, NCD 210.3 for stool DNA test, and LCD L35000 for molecular pathology procedures). Verify if applicable CMS criteria are in effect (through an NCD, LCD, or other CMS guidelines) for the specified genetic test, product name, site-specific gene analysis, and the indication for testing on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for genetic testing, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions
0001U	Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported
0004M	Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPs), using saliva, prognostic algorithm reported as a risk score
0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score
0006M	Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier
0007M	Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index
0011M	Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk
0012M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma
0012U	Germline disorders, gene rearrangement detection by whole genome next-generation sequencing, DNA, whole blood, report of specific gene rearrangement(s)
0013M	Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma

0013U	Opening (colid organ populacia), gone rearrangement detection by whole general rest
00130	Oncology (solid organ neoplasia), gene rearrangement detection by whole genome next- generation sequencing, DNA, fresh or frozen tissue or cells, report of specific gene
	rearrangement(s)
0014U	Hematology (hematolymphoid neoplasia), gene rearrangement detection by whole genome
00110	next-generation sequencing, DNA, whole blood or bone marrow, report of specific gene
	rearrangement(s)
0016M	Oncology (bladder) mRNA, microarray gene expression profiling of 209 genes, utilizing
	formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal,
	luminal infiltrated, basal, basal claudin-low, neiroendocrine-like)
0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion
	transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not
	detected or detected with quantitation
0017M	Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by
	fluorescent probe hybridization of 20 genes, formalin-fixed paraffin-embedded tissue,
	algorithm reported as cell of origin (Do not report 0017M in conjunction with 0120U)
0017U	Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-
	14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or
	detected
0018U	Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine-
	needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of
	malignancy
0019U	Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin
	embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for
0.00011	therapeutic agents
0022U	Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA
	analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as
002211	presence/absence of variants and associated therapy(ies) to consider
0023U	Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.1836, using mononuclear cells, reported as detection or non-detection of FLT3
	mutation and indication for or against the use of midostaurin
0026U	Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle
00200	aspirate of thyroid nodule, algorithmic analysis reported as a categorical result
0027U	JAK2 (Janus kinase 2) (e.g.
002, 0	, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15
0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis
00230	(i.e., CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1
	and rs12777823)
0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (i.e., CYP2C9,
	CYP4F2, VKORC1, rs12777823)
0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(e.g., drug metabolism) gene
	analysis, common variants (i.e., *1F, *1K, *6, *7)
0032U	COMT (catechol-O-methyltransferase)(drug metabolism) gene analysis, c.472G>A (rs4680)
	variant
0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (e.g.,
	citalopram metabolism) gene analysis, common variants (i.e., HTR2A rs7997012 [c.614-
	2211T>C], HTR2C rs3813929 [c 759C>T] and rs1414334 [c.551-3008C>G])

0034U	TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(e.g., thiopurine metabolism), gene analysis, common variants (i.e., TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5)
0036U	Exome (i.e., somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses
0037U	Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden
0040U	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative
0045U	Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by realtime RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
0046U	FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative
0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)
0049U	NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, quantitative
0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma
0056U	Hematology (acute myelogenous leukemia), DNA, whole genome nextgeneration sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood
0069U	Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score
0070U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, common and select rare variants (i.e., *2, *3, *4, *4N, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14A, *14B, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *xN)
0071U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, full gene sequence (List separately in addition to code for primary procedure) (Use 0071U in conjunction with 0070U)
0072U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (i.e., CYP2D6-2D7 hybrid gene) (List separately in addition to code for primary procedure) (Use 0072U in conjunction with 0070U)
0073U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism) gene analysis, targeted sequence analysis (i.e., CYP2D7-2D6 hybrid gene) (List separately in addition to code for primary procedure) (Use 0073U in conjunction with 0070U)

0074U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism)
	gene analysis, targeted sequence analysis (i.e., non-duplicated gene when
	duplication/multiplication is trans) (List separately in addition to code for primary procedure)
	(Use 0074U in conjunction with 0070U)
0075U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism)
	gene analysis, targeted sequence analysis (i.e., 5' gene duplication/multiplication) (List
	separately in addition to code for primary procedure) (Use 0075U in conjunction with 0070U)
0076U	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism)
	gene analysis, targeted sequence analysis (i.e., 3' gene duplication/ multiplication) (List
	separately in addition to code for primary procedure) (Use 0076U in conjunction with 0070U)
0078U	Pain management (opioid-use disorder) genotyping panel, 16 common variants (i.e., ABCB1,
	COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR,
	OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive
	or negative risk of opioid-use disorder
0079U	Comparative DNA analysis using multiple selected single-nucleotide polymorphisms (SNPs),
	urine and buccal DNA, for specimen identity verification
0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes,
	transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score
0088U	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of
	1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for
	rejection
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, <i>PRAME</i> and
	<i>LINC00518</i> , superficial collection using adhesive patch(es)
0090U	Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes
	(14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm
	reported as a categorical result (i.e., benign, indeterminate, malignant)
0094U	Genome (e.g., unexplained constitutional or heritable disorder or syndrome), rapid sequence
	analysis
0101U	Hereditary colon cancer disorders (e.g., Lynch syndrome, <i>PTEN</i> hamartoma syndrome,
01010	Cowden syndrome, familial adenomatosis polyposis), genomic sequence analysis panel
	utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve
	variants of unknown significance when indicated (15 genes [sequencing and
	deletion/duplication], <i>EPCAM</i> and <i>GREMI</i> [deletion/duplication only])
0102U	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian
01020	cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a
	combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants
	of unknown significance when indicated (17 genes [sequencing and deletion/duplication])
0103U	Hereditary ovarian cancer (e.g., hereditary ovarian cancer, hereditary endometrial cancer),
01030	genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array
	CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24
<b>○111</b> I	genes [sequencing and deletion/duplication], <i>EPCAM</i> [deletion/duplication only])
0111U	Oncology (colon cancer), targeted KRAS (codons 12, 13, and 61) and NRAS (codons 12, 13, and
01101.1	61) gene analysis utilizing formalin-fixed paraffin-embedded tissue
0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum
	following prostatic massage, by RNA amplification and fluorescence-based detection,
	algorithm reported as risk score

0114U	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA
0120U	Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter
0129U	Hereditary breast cancer–related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)
0130U	Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53) (List separately in addition to code for primary procedure) u(Use 0130U in conjunction with 81435, 0101U)t
0131U	Hereditary breast cancer–related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure) u(Use 0131U in conjunction with 81162, 81432, 0102U)t
0132U	Hereditary ovarian cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes) (List separately in addition to code for primary procedure)u(Use 0132U in conjunction with 81162, 81432, 0103U)t
0133U	Hereditary prostate cancer–related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure) (Use 0133U in conjunction with 81162)
0134U	Hereditary pan cancer (e.g., hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure) (Use 0134U in conjunction with 81162, 81432, 81435)
0135U	Hereditary gynecological cancer (e.g., hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes) (List separately in addition to code for primary procedure) (Use 0135U in conjunction with 81162)
0136U	ATM (ataxia telangiectasia mutated) (e.g., ataxia telangiectasia) mRNA sequence analysis (List separately in addition to code for primary procedure) (Use 0136U in conjunction with 81408)
0137U	PALB2 (partner and localizer of BRCA2) (e.g., breast and pancreatic cancer) mRNA sequence analysis (List separately in addition to code for primary procedure) u(Use 0137U in conjunction with 81406)t
0138U	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) mRNA sequence analysis (List separately in addition to code for primary procedure) u(Use 0138U in conjunction with 81162)t

0153U	Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101
	genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple
	negative breast cancer clinical subtype(s) with information on immune cell involvement
0154U	FGFR3 (fibroblast growth factor receptor 3) gene analysis (i.e., p.R248C [c.742C>T], p.S249C
	[c.746C>G], p.G370C [c.1108G>T], p.Y373C [c.1118A>G], FGFR3-TACC3v1, and FGFR3-
	TACC3v3)
0155U	PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) (e.g., breast
	cancer) gene analysis (i.e., p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G,
	p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y)
0156U	Copy number (e.g., intellectual disability, dysmorphology), sequence analysis
0157U	APC (APC regulator of WNT signaling pathway) (e.g., familial adenomatosis polyposis [FAP])
	mRNA sequence analysis (List separately in addition to code for primary procedure)(Use
	0157U in conjunction with 81201)
0158U	MLH1 (mutL homolog 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome)
	mRNA sequence analysis (List separately in addition to code for primary procedure)(Use
	0158U in conjunction with 81292)
0159U	MSH2 (mutS homolog 2) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence
	analysis (List separately in addition to code for primary procedure) (Use 0159U in conjunction
	with 81295)
0160U	MSH6 (mutS homolog 6) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence
	analysis (List separately in addition to code for primary procedure) (Use 0160U in conjunction
	with 81298)
0161U	PMS2 (PMS1 homolog 2, mismatch repair system component) (e.g., hereditary nonpolyposis
	colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to
	code for primary procedure)(Use 0161U in conjunction with 81317)
0162U	Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1,
	MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure)
0168U	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using
	maternal plasma without fetal fraction cutoff, algorithm reported as a risk score for each
	trisomy
0169U	NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (e.g., drug
	metabolism) gene analysis, common variants
0170U	Neurology (autism spectrum disorder [ASD]), RNA, next-generation sequencing, saliva,
	algorithmic analysis, and results reported as predictive probability of ASD diagnosis
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic
	syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for
	sequence variants, rearrangements and minimal residual disease, reported as
	presence/absence
0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1,
	DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous
	recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm
	quantifying tumor genomic instability score
0173U	Psychiatry (i.e., depression, anxiety), genomic analysis panel, includes variant analysis of 14
	genes
0175U	Psychiatry (e.g., depression, anxiety), genomic analysis panel, variant analysis of 15 genes
	-,, \ 3, \ 2, \ 1 1, \ 1 1, \ 1 1, \ 1 1

O1771 I	Opening (Assert concer) DNA DIVOCA (phosphotidalise steel 4.5 bisebosebox 2.13
0177U	Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status
0179U	Oncology (non-small cell lung cancer), cell-free DNA, targeted sequence analysis of 23 genes (single nucleotide variations, insertions and deletions, fusions without prior knowledge of partner/breakpoint, copy number variations), with report of significant mutation(s)
0203U	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness
0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected
0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements
0208U	Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma
0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities
0211U	Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association
0212U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
0213U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (e.g., parent, sibling)
0214U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband
0215U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (e.g., parent, sibling)
0216U	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
0217U	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants

	in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants
0218U	Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants
0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer
0229U	BCAT1 (Branched chain amino acid transaminase 1) or IKZF1 (IKAROS family zinc finger 1) (e.g., colorectal cancer) promoter methylation analysis
0230U	AR (androgen receptor) (e.g., spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
0231U	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (e.g., spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions
0232U	CSTB (cystatin B) (e.g., progressive myoclonic epilepsy type 1A, Unverricht-Lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
0233U	FXN (frataxin) (e.g., Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions
0234U	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
0235U	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
0236U	SMN1 (survival of motor neuron 1, telomeric) and SMN2 (survival of motor neuron 2, centromeric) (e.g., spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions
0237U	Cardiac ion channelopathies (e.g., Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
0238U	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
0239U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations

0242U	Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA
02420	
	analysis of 55-74 genes, interrogation for sequence variants, gene copy number
024411	amplifications, and gene rearrangements
0244U	Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for
	single-nucleotide variants, insertions/deletions, copy number alterations, gene
	rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-
	fixed paraffin-embedded tumor tissue
0245U	Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4
	mRNA markers using next-generation sequencing, fine needle aspirate, report includes
	associated risk of malignancy expressed as a percentage
0250U	Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes,
	interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and
	deletions, one amplification, and four translocations), microsatellite instability and tumor-
	mutation burden
0252U	Fetal aneuploidy short tandem–repeat comparative analysis, fetal DNA from products of
	conception, reported as normal (euploidy), monosomy, trisomy, or partial
	deletion/duplications, mosaicism, and segmental aneuploidy
0253U	Reproductive medicine (endometrial receptivity analysis), RNA gene expression profile, 238
	genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as
	endometrial window of implantation (e.g., pre-receptive, receptive, post-receptive)
0254U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes
	using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA
	score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial
	deletion/duplications, mosaicism, and segmental aneuploidy, per embryo tested
0258U	Autoimmune (psoriasis), mRNA, next[1]generation sequencing, gene expression profiling of
02300	50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood
	of response to psoriasis biologics
0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations,
02000	inversions, insertions, translocations, and other structural variants by optical genome mapping
	(For additional PLA code with identical clinical descriptor, see 0264U. See Appendix O or the
	most current listing on the AMA CPT website to determine appropriate code assignment.)
026211	
0262U	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways
	(ER, AR, PI3K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin[1]embedded (FFPE),
00041	algorithm reported as gene pathway activity score
0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations,
	inversions, insertions, translocations, and other structural variants by optical genome mapping
	(For additional PLA code with identical clinical descriptor, see 0260U. See Appendix O or the
	most current listing on the AMA CPT website to determine appropriate code assignment.)
0265U	Rare constitutional and other heritable disorders, whole genome and mitochondrial DNA
	sequence analysis, blood, frozen and formalin-fixed paraffin[1]embedded (FFPE) tissue, saliva,
	buccal swabs or cell lines, identification of single nucleotide and copy number variants
0266U	Unexplained constitutional or other heritable disorders or syndromes, tissue[1]specific gene
	expression by whole[1]transcriptome and next-generation sequencing, blood, formalin-fixed
	paraffin[1]embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of
	splicing or expression changes
	, · · ·

0267U	Rare constitutional and other heritable disorders, identification of copy number variations,
020/0	inversions, insertions, translocations, and other structural variants by optical genome mapping
	and whole genome sequencing
0268U	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15
02000	genes, blood, buccal swab, or amniotic fluid
0269U	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis
	of 14 genes, blood, buccal swab, or amniotic fluid
0270U	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes,
	blood, buccal swab, or amniotic fluid
0271U	Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal
	swab, or amniotic fluid
0272U	Hematology (genetic bleeding disorders), genomic sequence analysis of 51 genes, blood,
	buccal swab, or amniotic fluid, comprehensive
0273U	Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8
	genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, PLAU), blood, buccal
	swab, or amniotic fluid
0274U	Hematology (genetic platelet disorders), genomic sequence analysis of 43 genes, blood,
	buccal swab, or amniotic fluid
0276U	Hematology (inherited thrombocytopenia), genomic sequence analysis of 23 genes, blood,
007711	buccal swab, or amniotic fluid
0277U	Hematology (genetic platelet function disorder), genomic sequence analysis of 31 genes,
0278U	blood, buccal swab, or amniotic fluid
02/60	Hematology (genetic thrombosis), genomic sequence analysis of 12 genes, blood, buccal swab, or amniotic fluid
0285U	Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA
02030	amplification, plasma, reported as a radiation toxicity score
0286U	CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-
0200	methyltransferase) (e.g., drug metabolism) gene analysis, common variants
0287U	Oncology (thyroid), DNA and mRNA, nextgeneration sequencing analysis of 112 genes, fine
	needle aspirate or formalinfixed paraffin-embedded (FFPE) tissue, algorithmic prediction of
	cancer recurrence, reported as a categorical risk result (low, intermediate, high)
0288U	Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6,
	CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD,
	TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic
	interpretation reported as a recurrence risk score
0289U	Neurology (Alzheimer disease), mRNA, gene expression profiling by RNA sequencing of 24
	genes, whole blood, algorithm reported as predictive risk score
0290U	Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole
	blood, algorithm reported as predictive risk score
0291U	Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144
20001	genes, whole blood, algorithm reported as predictive risk score
0292U	Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72
020211	genes, whole blood, algorithm reported as predictive risk score
0293U	Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54
020 41 1	genes, whole blood, algorithm reported as predictive risk score
0294U	Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes,
	whole blood, algorithm reported as predictive risk score - MindX Blood Test™ - Longevity

0296U	Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing
32300	at least 20 molecular features (e.g., human and/or microbial mRNA), saliva, algorithm reported
	as positive or negative for signature associated with malignancy
0297U	Oncology (pan tumor), whole genome sequencing of paired malignant and normal DNA
	specimens, fresh or formalinfixed paraffin-embedded (FFPE) tissue, blood or bone marrow,
	comparative sequence analyses and variant identification
0298U	Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA
	specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow,
	comparative sequence analyses and expression level and chimeric transcript identification
0299U	Oncology (pan tumor), whole genome optical genome mapping of paired malignant and
	normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural
	variant identification
0300U	Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired
	malignant and normal DNA specimens, fresh tissue, blood, or bone marrow, comparative
	sequence analyses and variant identification
81120	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (e.g., glioma), common variants (e.g.,
	R132H, R132C)
81121	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (e.g., glioma), common variants
	(e.g., R140W, R172M)
81161	DMD (dystrophin) (e.g., Duchenne/Becker muscular dystrophy) deletion analysis, and
	duplication analysis, if performed
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g.,
	hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full
	duplication/deletion analysis (i.e., detection of large gene rearrangements)
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g.,
	hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g.,
	hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e.,
	detection of large gene rearrangements)
81165	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene
044.6.6	analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene
044.67	analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene
01160	analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81168	CCND1/IGH (t(11;14)) (e.g., mantle cell lymphoma) translocation analysis, major breakpoint,
04470	qualitative and quantitative, if performed
81170	ABLI (ABL proto-oncogene 1, non-receptor tyrosine kinase) (e.g., acquired imatinib tyrosine
04474	kinase inhibitor resistance), gene analysis, variants in the kinase domain
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (e.g., fragile X mental retardation 2 [FRAXE])
01170	gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (e.g., fragile X mental retardation 2 [FRAXE])
04475	gene analysis; characterization of alleles (e.g., expanded size and methylation status)
81173	AR (androgen receptor) (e.g., spinal and bulbar muscular atrophy, Kennedy disease, X
	chromosome inactivation) gene analysis; full gene sequence
81174	AR (androgen receptor) (e.g., spinal and bulbar muscular atrophy, Kennedy disease, X
	chromosome inactivation) gene analysis; full gene sequence

81175	ASXL1 (additional sex combs like 1, transcriptional regulator) (e.g., myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence
81176	ASXL1 (additional sex combs like 1, transcriptional regulator) (e.g., myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis (e.g., exon 12)
81177	ATN1 (atrophin 1) (e.g., dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81178	ATXN1 (ataxin 1) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81179	ATXN2 (ataxin 2) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81180	ATXN3 (ataxin 3) (e.g., spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81181	ATXN7 (ataxin 7) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81183	ATXN10 (ataxin 10) (e.g., spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (e.g., spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (e.g., spinocerebellar ataxia) gene analysis; full gene sequence
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (e.g., spinocerebellar ataxia) gene analysis; known familial variant
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (e.g., myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81188	CSTB (cystatin B) (e.g., Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
81189	CSTB (cystatin B) (e.g., Unverricht-Lundborg disease) gene analysis; full gene sequence
81190	CSTB (cystatin B) (e.g., Unverricht-Lundborg disease) gene analysis; known familial variant(s)
81191	NTRK1 (neurotrophic receptor tyrosine kinase 1) (e.g., solid tumors) translocation analysis
81192	NTRK2 (neurotrophic receptor tyrosine kinase 2) (e.g., solid tumors) translocation analysis
81193	NTRK3 (neurotrophic receptor tyrosine kinase 3) (e.g., solid tumors) translocation analysis
81194	NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (e.g., solid tumors) translocation analysis
81200	ASPA (aspartoacylase) (e.g., Canavan disease) gene analysis, common variants (e.g., E285A, Y231X)
81201	APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence
81202	APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants
81203	APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants

81204	AR (androgen receptor) (e.g., spinal and bulbar muscular atrophy, Kennedy disease, X
	chromosome inactivation) gene analysis; characterization of alleles (e.g., expanded size or
01005	methylation status)
81205	BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (e.g., Maple syrup
	urine disease) gene analysis, common variants (e.g., R183P, G278S, E422X)
81206	BCR/ABL1 (t[9;22]) (e.g., chronic myelogenous leukemia) translocation analysis; major
	breakpoint, qualitative or quantitative
81207	BCR/ABL1 (t[9;22]) (e.g., chronic myelogenous leukemia) translocation analysis; minor
	breakpoint, qualitative or quantitative
81208	BCR/ABL1 (t[9;22]) (e.g., chronic myelogenous leukemia) translocation analysis; other
	breakpoint, qualitative or quantitative
81209	BLM (Bloom syndrome, RecQ helicase-like) (e.g., Bloom syndrome) gene analysis,
	2281del6lns7 variant
81210	BRAF (B-Raf proto-oncogene, serine/threonine kinase) (e.g., colon cancer, melanoma), gene
	analysis, V600 variant(s)
81212	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g.,
	hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene
	analysis; known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene
	analysis; full sequence analysis
81217	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene
	analysis; known familial variant
81218	CEBPA (CCAAT/enhancer binding protein[C/EBP], alpha) (e.g., acute myeloid leukemia),
	gene analysis, full gene sequence
81219	CALR (calreticulin) (e.g., myeloproliferative disorders), gene analysis, common variants in
	exon 9
81220	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene
	analysis; common variants (e.g., ACMG/ACOG guidelines)
81221	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene
	analysis; known familial variants
81222	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene
	analysis; duplication/deletion variants
81223	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene
	analysis; full gene sequence
81224	CFTR (cystic fibrosis transmembrane conductance regulator) (e.g., cystic fibrosis) gene
	analysis; intron 8 poly-T analysis (e.g., male infertility)
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (e.g., drug metabolism),
	gene analysis, common variants (e.g., *2, *3, *4, *8, *17)
81226	CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (e.g., drug metabolism),
	gene analysis, common variants (e.g., *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN,
	*2XN, *4XN)
81227	CYP2C9 (Cytochrome P450, family 2, subfamily C, polypeptide 9) (e.g., drug metabolism),
	gene analysis, common variants (e.g., *2, *3, *5, *6)

81228	Cytogenetic (genome-wide) analysis for constitutional chromosomal abnormalities;
	interrogation of genomic regions for copy number variants (comparative genomic
	hybridization [CGH] microarray analysis)
81229	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities;
	interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP)
	variants for comparative genomic hybridization (CGH) microarray analysis
81230	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (e.g., drug metabolism), gene
	analysis, common variant(s) (e.g., *2, *22)
81231	CYP3A5 (cytochrome P450 family 3 subfamily A member 5) (e.g., drug metabolism), gene
01231	analysis, common variants (e.g., *2, *3, *4, *5, *6, *7)
81232	DPYD (dihydropyrimidine dehydrogenase) (e.g., 5-fluorouracil/5-FU and capecitabine drug
01232	metabolism), gene analysis, common variant(s) (e.g., *2A, *4, *5, *6)
01222	
81233	BTK (Bruton's tyrosine kinase) (e.g., chronic lymphocytic leukemia) gene analysis, common
0100.1	variants (e.g., C481S, C481F)
81234	DMPK (DM1 protein kinase) (e.g., myotonic dystrophy type 1) gene analysis; evaluation to
	detect abnormal (expanded) alleles
81235	EGFR (epidermal growth factor receptor) (e.g., non-small cell lung cancer) gene analysis,
	common variants (e.g., exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)
81236	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (e.g., myelodysplastic
	syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence
81237	EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (e.g., diffuse large B-cell
	lymphoma) gene analysis, common variant(s) (e.g., codon 646)
81238	F9 (coagulation factor IX) (e.g., hemophilia B), full gene sequence
81239	DMPK (DM1 protein kinase) (e.g., myotonic dystrophy type 1) gene analysis; characterization
01233	of alleles (e.g., expanded size)
010.10	
81240	F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis,
	20210G>A variant
81241	F5 (coagulation Factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant
81242	FANCC (Fanconi anemia, complementation group C) (e.g., Fanconi anemia, type C) gene
	analysis, common variant (e.g., IVS4+4A>T)
81243	FMR1 (fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis;
	evaluation to detect abnormal (e.g., expanded) alleles
81244	FMR1 (fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis;
0.2 1 1	characterization of alleles (e.g., expanded size and promoter methylation status)
81245	FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia), gene analysis, internal
01243	tandem duplication (ITD) variants (i.e., exons 14, 15)
91246	
81246	FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia), gene analysis; tyrosine
010.47	kinase domain (TKD) variants (e.g., D835, I836)
81247	G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice), gene
010.46	analysis; common variant(s) (e.g., A, A-)
81248	G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice), gene
	analysis; known familial variant(s)
81249	G6PD (glucose-6-phosphate dehydrogenase) (e.g., hemolytic anemia, jaundice), gene
	analysis; full gene sequence
81250	G6PC (glucose-6-phosphatase, catalytic subunit) (e.g., Glycogen storage disease, Type 1a,
	von Gierke disease) gene analysis, common variants (e.g., R83C, Q347X)

04054	
81251	GBA (glucosidase, beta, acid) (e.g., Gaucher disease) gene analysis, common variants (e.g.,
	N370S, 84GG, L444P, IVS2+1G>A)
81252	GJB2 (gap junction protein, beta 2, 26kDa; connexin 26) (e.g., nonsyndromic hearing loss)
	gene analysis; full gene sequence
81253	GJB2 (gap junction protein, beta 2, 26kDa; connexin 26) (e.g., nonsyndromic hearing loss)
	gene analysis; known familial variants
81254	GJB6 (gas junction protein, beta 6, 30kDa, connexin 30) (e.g., nonsyndromic hearing loss)
	gene analysis, common variants (e.g., 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-
	D13S1854)])
81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g., Tay-Sachs disease) gene analysis,
	common variants (e.g., 1278insTATC, 1421+1G>C, G269S)
81256	HFE (hemochromatosis) (e.g., hereditary hemochromatosis) gene analysis, common variants
	(e.g., C282Y, H63D)
81257	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops
	fetalis syndrome, HbH disease), gene analysis; common deletions or variant (e.g., Southeast
	Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, Constant Spring)
81258	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops
	fetalis syndrome, HbH disease), gene analysis; known familial variant
81259	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops
	fetalis syndrome, HbH disease), gene analysis; full gene sequence
81260	IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-
	associated protein) (e.g., familial dysautonomia) gene analysis, common variants (e.g.,
	2507+6T>C, R696P)
81261	IGH@ (Immunoglobulin heavy chain locus) (e.g., leukemias and lymphomas, B-cell), gene
	rearrangement analysis to detect abnormal clonal population(s); amplified methodology (e.g.,
	polymerase chain reaction)
81262	IGH@ (Immunoglobulin heavy chain locus) (e.g., leukemias and lymphomas, B-cell), gene
	rearrangement analysis to detect abnormal clonal population(s); direct probe methodology
	(e.g., Southern blot)
81263	IGH@ (Immunoglobulin heavy chain locus) (e.g., leukemia and lymphoma, B-cell), variable
	region somatic mutation analysis
81264	IGK@ (Immunoglobulin kappa light chain locus) (e.g., leukemia and lymphoma, B-cell), gene
	rearrangement analysis, evaluation to detect abnormal clonal population(s)
81265	Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative
	specimen (e.g., pre-transplant recipient and donor germline testing, post-transplant non-
	hematopoietic recipient germline [e.g., buccal swab or other germline tissue sample]
81266	Comparative analysis using Short Tandem Repeat (STR) markers; each additional specimen
	(e.g., additional cord blood donor, additional fetal samples from different cultures, or
	additional zygosity in multiple birth pregnancies) (List separately in addition t
81269	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops
	fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants
81270	JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder) gene analysis, p.Val617Phe (V617F)
	variant
81271	HTT (huntingtin) (e.g., Huntington disease) gene analysis; evaluation to detect abnormal (e.g.,
	expanded) alleles

81272	KIT (v-kit-Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (e.g., gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence
	analysis (e.g., exons 8,11,13,17,18)
81273	KIT(v-kit-Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (e.g., mastocytosis), gene analysis, D816 variant(s)
81274	HTT (huntingtin) (e.g., Huntington disease) gene analysis; characterization of alleles (e.g., expanded size)
01075	·
81275	KRAS (Kirsten rat sarcoma viral oncogene homolog) (e.g., carcinoma) gene analysis, variants in exon 2 (e.g., codons 12 And 13)
81276	KRAS (V-Ki-ras2 Kirsten rat sarcoma viral oncogene) (e.g., carcinoma) gene analysis, variants in codons 12 And 13; additional variants(s) (e.g., codon 61, codon 146)
81277	Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions
	for copy number and loss-of-heterozygosity variants for chromosomal abnormalities
81278	IGH@/BCL2 (t(14;18)) (e.g., follicular lymphoma) translocation analysis, major breakpoint
	region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative
81279	JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder) targeted sequence analysis (e.g., exons 12 and 13)
81283	IFNL3 (interferon, lambda 3) (e.g., drug response), gene analysis, rs12979860 variant
81284	HTT (huntingtin) (e.g., Huntington disease) gene analysis; characterization of alleles (e.g.,
	expanded size)
81285	FXN (frataxin) (e.g., Friedreich ataxia) gene analysis; characterization of alleles (e.g.,
	expanded size)
81286	FXN (frataxin) (e.g., Friedreich ataxia) gene analysis; full gene sequence
81287	MGMT (O-6-methylguanine-DNA methyltransferase) (e.g., glioblastoma multiforme ),
	promoter methylation analysis
81288	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis
81289	FXN (frataxin) (e.g., Friedreich ataxia) gene analysis; full gene sequence
81290	MCOLN1 (mucolipin 1) (e.g., Mucolipidosis, type IV) gene analysis, common variants (e.g.,
	IVS3-2A>G, del6.4kb)
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (e.g., hereditary hypercoagulability)
	gene analysis, common variants (e.g., 677T, 1298C)
81292	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81293	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81294	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81295	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81296	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81297	MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis
-	colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81298	MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch
	syndrome) gene analysis; full sequence analysis

	<del>_</del>
81299	MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81300	
81300	MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81301	Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch
	syndrome) of markers for mismatch repair deficiency (e.g., BAT25, BAT26), includes
	comparison of neoplastic and normal tissue, if performed
81302	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; full sequence
	analysis
81303	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; known familial
	variant
81304	MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis;
	duplication/deletion variants
81305	MYD88 (myeloid differentiation primary response 88) (e.g., Waldenstrom's
	macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant
81306	NUDT15 (nudix hydrolase 15) (e.g., drug metabolism) gene analysis, common variant(s) (e.g.,
	*2, *3, *4, *5, *6)
81307	PALB2 (partner and localizer of BRCA2) (e.g., breast and pancreatic cancer) gene analysis; full
	gene sequence
81308	PALB2 (partner and localizer of BRCA2) (e.g., breast and pancreatic cancer) gene analysis;
	known familial variant
81309	PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (e.g.,
	colorectal and breast cancer) gene analysis, targeted sequence analysis (e.g., exons 7, 9, 20)
81310	NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, exon 12 variants
81311	NRAS (Neuroblastoma RAS viral[v-ras] oncogene homolog) (e.g., colorectal carcinoma), gene
	analysis, variants in exon 2 (e.g., codons 12 and 13) and exon 3 (e.g., codon 61)
81312	PABPN1 (poly[A] binding protein nuclear 1) (e.g., oculopharyngeal muscular dystrophy) gene
	analysis, evaluation to detect abnormal (e.g., expanded) alleles
81313	PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3
	[prostate specific antigen]) ratio (e.g., prostate cancer)
81314	PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (e.g., gastrointestinal
	stromal tumor[GIST]), gene analysis, targeted sequence analysis (e.g., exons 12,18)
81315	PML/RARalpha, (t[15;17]), (promyelocytic leukemia/retinoic acid receptor alpha) (e.g.,
	promyelocytic leukemia) translocation analysis; common breakpoints (e.g., intron 3 and intron
	6), qualitative or quantitative
81316	PML/RARalpha, (t[15;17]), (promyelocytic leukemia/retinoic acid receptor alpha) (e.g.,
	promyelocytic leukemia) translocation analysis; single breakpoint (e.g., intron 3, intron 6 or
	exon 6), qualitative or quantitative
81317	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81318	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; known familial variants
81319	PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis
	colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants
81320	PLCG2 (phospholipase C gamma 2) (e.g., chronic lymphocytic leukemia) gene analysis,
	common variants (e.g., R665W, S707F, L845F)

01001	DTENTAL LA LA LA LA LA CALLA DEPARTA DE LA CALLA DEL CALLA DEL CALLA DE LA CAL
81321	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor
	syndrome) gene analysis; full sequence analysis
81322	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor
	syndrome) gene analysis; known familial variant
81323	PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor
	syndrome) gene analysis; duplication/deletion variant
81324	PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth, hereditary neuropathy with
	liability to pressure palsies) gene analysis; duplication/deletion analysis
81325	PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth, hereditary neuropathy with
	liability to pressure palsies) gene analysis; full sequence analysis
81326	PMP22 (peripheral myelin protein 22) (e.g., Charcot-Marie-Tooth, hereditary neuropathy with
01320	liability to pressure palsies) gene analysis; known familial variant
01227	
81327	SEPT9 (Septin9) (e.g., colorectal cancer) promoter methylation analysis
81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (e.g., adverse drug
01220	reaction), gene analysis, common variant(s) (e.g., *5)
81329	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis;
	dosage/deletion analysis (e.g., carrier testing), includes SMN2 (survival of motor neuron 2,
01000	centromeric) analysis, if performed
81330	SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal) (e.g., Niemann-Pick disease, Type
	A) gene analysis, common variants (e.g., R496L, L302P, FsP330)
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase
	E3A) (e.g., Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
81332	SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1)
	(e.g., alpha-1-antitrypsin deficiency), gene analysis, common variants (e.g., *S and *Z)
81333	TGFBI (transforming growth factor beta-induced) (e.g., corneal dystrophy) gene analysis,
	common variants (e.g., R124H, R124C, R124L, R555W, R555Q)
81334	RUNX1 (runt related transcription factor 1) (e.g., acute myeloid leukemia, familial platelet
	disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (e.g.,
	exons 3-8)
81335	TPMT (thiopurine S-methyltransferase) (e.g., drug metabolism), gene analysis, common
	variants (e.g., *2, *3)
81336	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis; full
	gene sequence
81337	SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy) gene analysis;
	known familial sequence variant(s)
81338	MPL (MPL proto-oncogene, thrombopoietin receptor) (e.g., myeloproliferative disorder)
	gene analysis; common variants (e.g., W515A, W515K, W515L, W515R)
81339	MPL (MPL proto-oncogene, thrombopoietin receptor) (e.g., myeloproliferative disorder)
	gene analysis; sequence analysis, exon 10
81340	TRB@ (T cell antigen receptor, beta) (e.g., leukemia and lymphoma), gene rearrangement
	analysis to detect abnormal clonal population(s); using amplification methodology (e.g.,
	polymerase chain reaction)
81341	TRB@ (T cell antigen receptor, beta) (e.g., leukemia and lymphoma), gene rearrangement
J. 11	analysis to detect abnormal clonal population(s); using direct probe methodology (e.g.,
	Southern blot)
	oddinom bloch

010.40	TDC o /T cell cellings are center are seen as less than the seed to be the seed t
81342	TRG@ (T cell antigen receptor, gamma) (e.g., leukemia and lymphoma), gene rearrangement
010.40	analysis, evaluation to detect abnormal clonal population(s)
81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (e.g., spinocerebellar ataxia)
010.4.4	gene analysis, evaluation to detect abnormal (e.g., expanded) alleles
81344	TBP (TATA box binding protein) (e.g., spinocerebellar ataxia) gene analysis, evaluation to
010.45	detect abnormal (e.g., expanded) alleles
81345	TERT (telomerase reverse transcriptase) (e.g., thyroid carcinoma, glioblastoma multiforme)
010.16	gene analysis, targeted sequence analysis (e.g., promoter region)
81346	TYMS (thymidylate synthetase) (e.g., 5-fluorouracil/5-FU drug metabolism), gene analysis,
	common variant(s) (e.g., tandem repeat variant)
81347	SF3B1 (splicing factor [3b] subunit B1) (e.g., myelodysplastic syndrome/acute myeloid
	leukemia) gene analysis, common variants (e.g., A672T, E622D, L833F, R625C, R625L)
81348	SRSF2 (serine and arginine-rich splicing factor 2) (e.g., myelodysplastic syndrome, acute
	myeloid leukemia) gene analysis, common variants (e.g., P95H, P95L)
81349	Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities;
	interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-
01050	pass sequencing analysis
81350	UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1) (e.g., irinotecan metabolism),
04054	gene analysis, common variants (e.g., *28, *36, *37)
81351	TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome) gene analysis; full gene sequence
81352	TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome) gene analysis; targeted sequence
	analysis (e.g., 4 oncology)
81353	TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome) gene analysis; known familial variant
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (e.g., warfarin metabolism), gene
	analysis, common variants (e.g., -1639G>A, c.173+1000C>T)
81357	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (e.g., myelodysplastic syndrome, acute myeloid
040.50	leukemia) gene analysis, common variants (e.g., S34F, S34Y, Q157R, Q157P)
81360	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (e.g.,
	myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (e.g.,
010.61	E65fs, E122fs, R448fs)
81361	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia,
010.60	hemoglobinopathy); common variant(s) (e.g., HbS, HbC, HbE)
81362	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia,
010.60	hemoglobinopathy); known familial variant(s)
81363	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia,
010.6.4	hemoglobinopathy); duplication/deletion variant(s)
81364	HBB (hemoglobin, subunit beta) (e.g., sickle cell anemia, beta thalassemia,
01400	hemoglobinopathy); full gene sequence
81400	Molecular pathology procedure, Level 1 (e.g., identification of single germline variant [e.g.,
01401	SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
81401	Molecular pathology procedure, Level 2 (e.g., 2-10 SNPs, 1 methylated variant, or 1 somatic
	variant [typically using non-sequencing target variant analysis], or detection of a dynamic
01.100	mutation disorder/triplet repeat)
81402	Molecular pathology procedure, Level 3 (e.g., >10 SNPs, 2-10 methylated variants, or 2-10
	somatic variants [typically using non-sequencing target variant analysis], immunoglobulin and
	T-cell receptor gene rearrangements, duplication/deletion variants 1 exon, loss of
	heterozygosity [LOH], uniparental disomy [UPD])

81403	Molecular pathology procedure, Level 4 (e.g., analysis of single exon by DNA sequence
	analysis, analysis of >10 amplicons using multiplex PCR in 2 or more independent reactions,
	mutation scanning or duplication/deletion variants of 2-5 exons)
81404	Molecular pathology procedure, Level 5 (e.g., analysis of 2-5 exons by DNA sequence analysis,
	mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a
	dynamic mutation disorder/triplet repeat by Southern blot analysis)
81405	Molecular pathology procedure, Level 6 (e.g., analysis of 6-10 exons by DNA sequence
	analysis, mutation scanning or duplication/deletion variants of 11-25 exons), regionally
	targeted cytogenomic array analysis
81406	Molecular pathology procedure, Level 7 (e.g., analysis of 11-25 exons By DNA sequence
01100	analysis, mutation scanning or duplication/deletion variants of 26-50 exons, cytogenomic
	array analysis for neoplasia)
81407	Molecular pathology procedure, Level 8 (e.g., analysis Of 26-50 exons By DNA sequence
01407	analysis, mutation scanning or duplication/deletion variants Of >50 exons, sequence analysis
91409	of multiple genes on one platform)  Malagular pathology procedure Level 9 (e.g. analysis Of NEO evens in a single gene By DNA
81408	Molecular pathology procedure, Level 9 (e.g., analysis Of >50 exons in a single gene By DNA
01.410	sequence analysis)
81410	Aortic dysfunction or dilation (e.g., Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos
	syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must
	include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11,
	ACTA2, SLC2A10, SMAD3, and MYLK
81411	Aortic dysfunction or dilation (e.g., Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos
	syndrome type IV, arterial tortuosity syndrome); duplication/deletion analysis panel, must
	include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1
81412	Ashkenazi Jewish associated disorders (e.g., Bloom syndrome, Canavan disease, cystic
	fibrosis, familial dysautonomia, Franconi anemia group C, Gaucher disease, Tay-Sachs
	disease), genomic sequence analysis panel, must include sequencing of at least 9 genes,
	including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1
81413	Cardiac ion channelopathies (e.g., Brugada syndrome, long QT syndrome, short QT syndrome,
01110	catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel,
	must include sequencing of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2,
	KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A
81414	Cardiac ion channelopathies (e.g., Brugada syndrome, long QT syndrome, short QT syndrome,
01414	catecholaminergic polymorphic ventricular tachycardia); duplication/deletion gene analysis
	panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1
01.41E	
81415	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81416	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis,
	each comparator exome (e.g., parents, siblings) (List separately in addition to code for
	primary procedure)
81417	Exome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of
	previously obtained exome sequence (e.g., updated knowledge or unrelated
	condition/syndrome)
81419	Epilepsy genomic sequence analysis panel, must include analyses for ALDH7A1, CACNA1A,
	CDKL5, CHD2, GABRG2, GRIN2A, KCNQ2, MECP2, PCDH19, POLG, PRRT2, SCN1A, SCN1B,
	SCN2A, SCN8A, SLC2A1, SLC9A6, STXBP1, SYNGAP1, TCF4, TPP1, TSC1, TSC2, and ZEB2

04.40.0	
81420	Fetal chromosomal aneuploidy (e.g., trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (e.g., DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
81425	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure)
81427	Genome (e.g., unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (e.g., updated knowledge or unrelated condition/syndrome)
81430	Hearing loss (e.g., nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A, and WFS1
81431	Hearing loss (e.g., nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes
81432	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53
81433	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
81434	Hereditary retinal disorders (e.g., retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A
81435	Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11
81436	Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11
81437	Hereditary neuroendocrine tumor disorders (e.g., medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paragaglioma), genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX,SDHB,SDHC,SDHD,TMEM127 and VHL
81438	Hereditary neuroendocrine tumor disorders (e.g., medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paragaglioma), genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX,SDHB,SDHC,SDHD,TMEM127 and VHL; duplication/deletion analysis panel, must include analyses for SDHB, SDHC,SDHD and VHL

01/120	Inharitad cardiamyonathy (a.g. hypartranhia aardiamyonathy, dilatad arrhythma a ari- ri-lat
81439	Inherited cardiomyopathy (e.g., hypertrophic cardiomyopathy, dilated arrhythmogenic right ventricular cardiomyopathy), genomic sequence analysis panel, must include sequencing of at least 5 cardiomyopathy-related genes (e.g. DSG2, MYBPC3, MYH7, PKP2, and TTN)
81440	Nuclear encoded mitochondrial genes (e.g., neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP
81442	Noonan spectrum disorders (e.g., Noonan Syndrome, cardio-facio-cutaneous syndrome, Costello Syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF,CBL,HRAS,KRAS,MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2 and SOS1
81443	Genetic testing for severe inherited conditions (e.g., cystic fibrosis, Ashkenazi Jewish-associated disorders [e.g., Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (e.g., ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, 5-50 genes (e.g., ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81448	Hereditary peripheral neuropathies (e.g., Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (e.g., BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, SPTLC1)
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (e.g., BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed
81455	Targeted genomic sequence analysis panel, solid organ neoplasm or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (e.g., ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, NRAS, MLL,NPM1, NRAS, MET,NOTCH1, PDGFRA, PDGFRB, PGR,PIK3CA, PTEN, RET), interrogation for sequence variants, and copy number variants or rearrangements, if performed
81460	Whole mitochondrial genome (e.g., Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection
81465	Whole mitochondrial genome large deletion analysis panel (e.g., Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed
81470	X-linked intellectual disability (XLID) (e.g., syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2

81471	X-linked intellectual disability (XLID) (e.g., syndromic and non-syndromic XLID);
	duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX,
	ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL,
	RPS6KA3, and SLC16A2
81479	Unlisted molecular pathology procedure
81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes,
	utilizing whole peripheral blood, algorithm reported as a risk score
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing
	formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using
	maternal plasma, algorithm reported as a risk score of each trisomy
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7
	content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms
	reported as percentage risk for metastatic recurrence and likelihood of benefit from extended
	endocrine therapy
	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes,
81519	utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score
	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50
	content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm
81520	reported as a recurrence risk score
	Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465
	housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue,
81521	algorithm reported as index related to risk of distant metastasis
81522	Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4
	housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as
	recurrence risk score
81523	Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70
	content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue,
01505	algorithm reported as index related to risk to distant metastasis
81525	Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7
	content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm
01520	reported as a recurrence score
81529	Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31
	genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue,
01E 4.0	algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis
81540	Oncology (tumor of unknown origin). mRNA, gene expression profiling by real-time RT-PCR
	of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and
	subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability
015.//1	of a predicted main cancer type and subtype  Oncology (prestate), mPNA gone expression prefiling by real, time PT, PCP of 46 gones (21)
81541	Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm
015.40	reported as a disease-specific mortality risk score
81542	Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes,
01E 1 6	utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score
81546	Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle
	aspirate, algorithm reported as a categorical result (e.g., benign or suspicious)

81551	Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy
81552	Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (e.g., positive or negative for high probability of usual interstitial pneumonia [UIP])
81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing sub fraction of peripheral blood, algorithm reported as a rejection risk score

<b>HCPCS Codes</b>	Code Descriptions	
G9143	Warfarin responsiveness testing by genetic technique using any method, any number of	
	specimen(s)	
G9840	KRAS gene mutation testing performed before initiation of anti-EGFR MoAb	
G9841	KRAS gene mutation testing not performed before initiation of anti-EGFR MoAb	
S3800	Genetic testing for amyotrophic lateral sclerosis (ALS)	
S3840	DNA analysis for germline mutations of the RET proto-oncogene for susceptibility to multiple	
	endocrine neoplasia type 2	
S3841	Genetic testing for retinoblastoma	
S3842	Genetic testing for Von Hippel-Lindau disease	
S3844	DNA analysis of the connexin 26 gene (GJB2) for susceptibility to congenital, profound	
	deafness	
S3845	Genetic testing for alpha-thalassemia	
S3846	Genetic testing for hemoglobin E beta-thalassemia	
S3849	Genetic testing for Niemann-Pick disease	
S3850	Genetic testing for sickle cell anemia	
S3852	DNA analysis for APOE epsilon 4 allele for susceptibility to Alzheimer's disease	
S3853	Genetic testing for myotonic muscular dystrophy	
S3854	Gene expression profiling panel for use in the management of breast cancer treatment	
S3861	Genetic testing, sodium channel, voltage-gated, type V, alpha subunit (SCN5A) and variants	
	for suspected Brugada Syndrome	
S3865	Comprehensive gene sequence analysis for hypertrophic cardiomyopathy	
S3866	Genetic analysis for a specific gene mutation for hypertrophic cardiomyopathy (HCM) in an	
	individual with a known HCM mutation in the family	
S3870	Comparative genomic hybridization (CGD) microarray testing for developmental delay,	
	autism spectrum disorder and/or intellectual disability	

# References

Agency for Healthcare Research and Quality (AHRQ). U. S. Department of Health & Human Services. ECRI Evidence-Based Practice Center. Sun F, Bruening W, Uhl S, Ballard R, Tipton K, Schuelles K. Quality, Regulation and Clinical Utility of Laboratory-Developed Molecular Tests. Technology Assessment Report LABC0707. Original Date 2010 May 19. Correction Date 2010 Oct 6.

Agency for Healthcare Research and Quality (AHRQ). U. S. Department of Health & Human Services. Raman G, Avendano EE, Chen M. Technology Assessment Report. Update on Emerging Genetic Tests Currently Available for Clinical Use in Common Cancers. 2013 Jul 19.

Alexander EK, Schorr M, Klopper J, Kim C, Sipos J, Nabhan F, Parker C, Steward DL, Mandel SJ, Haugen BR. Multicenter clinical experience with the Afirma gene expression classifier. J Clin Endocrinol Metab. 2014 Jan;99(1):119-25. doi: 10.1210/jc.2013-2482. Epub 2013 Dec 20. PMID: 24152684.

Allegue C, Coll M, Mates J, Campuzano O, Iglesias A, Sobrino B, Brion M, Amigo J, Carracedo A, Brugada P, Brugada J, Brugada R. Genetic Analysis of Arrhythmogenic Diseases in the Era of NGS: The Complexity of Clinical Decision–Making in Brugada Syndrome. PLoS One. 2015 Jul 31;10(7):e0133037. doi: 10.1371/journal.pone.0133037. eCollection 2015. PMID: 26230511.

Allyse M, Minear MA, Berson E, Sridhar S, Rote M, Hung A, Chandrasekharan S. Non-invasive prenatal testing: a review of international implementation and challenges. Int J Womens Health. 2015 Jan 16;7: 113–26. doi: 10.2147/IJWH.S67124. eCollection 2015. PMID: 25653560.

American Academy of Pediatrics (AAP). Guideline Summaries.

American Association of Clinical Endocrinology (AACE), American College of Endocrinology (ACE), and Associazione Medici Endocrinologyi (AME). Gharib H, Papini E, Garber JR, Duick DS, Harrell RM, Hegedüs L, Paschke R, Valcavi R, Vitti P; AACE/ACE/AME Task Force on Thyroid Nodules. AACE, ACE, and AME Medical Guidelines for Clinical Practice for the Diagnosis and Management of Thyroid Nodules – 2016 Update. Endocr Pract. 2016 May;22(5):622–39. doi: 10.4158/EP161208.GL. PMID: 27167915.

American Cancer Society. Global Cancer Facts & Figures.

American College of Cardiology (ACC). Guidelines and Clinical Documents.

American College of Gastroenterology (ACG). Clinical Guidelines.

American College of Medical Genetics and Genomics (ACMG). ACMG Board of Directors. Direct-to-consumer genetic testing: a revised position statement of the ACMGC. Genet Med. 2016 Feb;18(2):207-8. doi: 10.1038/gim.2015.190. Epub 2015 Dec 17. PMID: 26681314.

American College of Medical Genetics and Genomics (ACMG). Alford RL, Arnos KS, Fox M, Lin JW, Palmer CG, Pandya A, Rehm HL, Robin NH, Scott DA, Yoshinaga-Itano C. ACMG guideline for the clinical evaluation and etiologic diagnosis of hearing loss. Genet Med. 2014 Apr;16(4):347-55. doi: 10.1038/gim.2014.2. Epub 2014 Mar 20. PMID: 24651602.

American College of Medical Genetics and Genomics (ACMG). ACMG Standards and Guidelines, ACMG Statement, ACMG Policy Statement, ACMG Practice Guidelines, ACMG Practice Resource and ACMG Technical Standards.

American College of Medical Genetics and Genomics (ACMG). Practice Guidelines.

American College of Medical Genetics and Genomics (ACMG). Rehm HL, Bale SJ, Bayrak-Toydemir P, Berg JS, Brown KK, Deignan JL, Friez MJ, Funke BH, Hegde MR, Lyon E; Working Group of ACMG Laboratory Quality Assurance Committee. ACMG clinical laboratory standards for next-generation sequencing. Genet Med. 2013 Sep;15(9):733-47. doi: 10.1038/gim.2013.92. Epub 2013 Jul 25. PMID: 23887774.

The American College of Obstetricians and Gynecologists (ACOG). ACOG's Clinical Guidelines. The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Carrier Screening in the Age of Genomic Medicine. Number 690. 2017 Mar. Reaffirmed 2020.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Carrier Screening for Genetic Conditions. Number 691. 2017 Mar. Reaffirmed 2020.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Counseling About Genetic Testing and Communication of Genetic Test Results. Number 693. 2017 April. Reaffirmed 2020.

The American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal-Fetal Medicine. ACOG Committee on Genetics and Society for Maternal-Fetal Medicine's Publication Committee. Cell-free DNA screening for fetal aneuploidy. Number 640. 2015 Sep.

The American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal–Fetal Medicine. ACOG Committee on Genetics and Society for Maternal–Fetal Medicine's Publication Committee. Microarrays and Next–Generation Sequencing Technology: The Use of Advanced Genetic Diagnostic Tools in Obstetrics and Gynecology. ACOG Committee Opinion. Number 682. 2016 Dec. Reaffirmed 2020.

American Heart Association (AHA). Guidelines and Statements.

American Medical Association (AMA). Genetic Testing.

American Society of Clinical Oncology (ASCO). Guidelines, Tools, & Resources.

American Society of Colon and Rectal Surgeons (ASCRS). Clinical Practice Guidelines.

American Society for Reproductive Medicine (ASRM). Practice Committee Documents.

American Thyroid Association (ATA). ATA Guidelines and Surgical Statements.

American Thyroid Association (ATA). ATA Guidelines and Surgical Statements. Statement on Surgical Application of Molecular Profiling for Thyroid Nodules: Current Impact on Perioperative Decision Making. 2015.

American Thyroid Association (ATA). Haugen BR, Alexander EK, Bible KC, Doherty GM, Mandel SJ, Nikiforov YE, Pacini F, Randolph GW, Sawka AM, Schlumberger M, Schuff KG, Sherman SI, Sosa JA, Steward DL, Tuffle RM, Wartofsky L.2015 ATA Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The ATA Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2016;26(1):1-133. doi:10.1089/thy.2015.0020. PMID: 26462967.

Bianchi DW, Parker RL, Wentworth J, Madankumar R, Saffer C. Das AF, Craig JA, Chudova DI, Devers PL, Jones KW, Oliver K, Rava RP, Sehnert AJ; CARE Study Group. DNA sequencing versus standard prenatal aneuploidy screening. N Engl J Med. 2014 Feb 27;370(9):799–808. doi: 10.1056/NEJMoa1311037. PMID: 24571752.

Bonanno L, Pavan A, Ferro A, Calvetti L, Frega S, Pasello G, Aprile G, Guarneri V, Conte P; Rete Oncologica Veneta (ROV). Clinical Impact of Plasma and Tissue Next-Generation Sequencing in Advanced Non-Small Cell Lung Cancer: A Real-World Experience. Oncologist. 2020 Dec;25(12):e1996-e2005. doi: 10.1634/theoncologist.2020-0148. Epub 2020 Jul 7. PMID: 32557976.

Bose S, Sacks W, Walts AE. Update on Molecular Testing for Cytologically Indeterminate Thyroid Nodules. Adv Anat Pathol. 2019 Mar;26(2):114-123. doi: 10.1097/PAP.00000000000011. PMID: 30664001.

Bousman CA, Bengesser SA, Aitchison KJ, Amare AT, Aschauer H, Baune BT, Asi BB, Bishop JR, Burmeister M, Chaumette B, Chen L, Cordner ZA, Deckert J, Degenhardt F, DeLisi LE, Folkersen L, Kennedy JL, Klein TE, McClay JL, McMahon FJ, Musil R, Saccone NL, Sangkuhl K, Stowe RM, Tan E, Tiwari AK, Zai CC, Zai G, Zhang J, Gaedigk A, Muller DJ. Review and Consensus on Pharmacogenomic Testing in Psychiatry. Pharmacopsychiatry. 2021 Jan;54(1):5-17. doi: 10.1055/a-1288-1061. Epub 2020 Nov 4. PMID: 33147643.

Business Wire. Veracyte Announces New Data Showing Potential of Afirma Genomic Test to Guide Targeted Treatment for Medullary Thyroid Cancer Concurrent with Diagnosis. New Findings Presented at 2019 ASCO Annual Meeting. 2019 Jun 1.

Cavaliere A, Ermito S, Dinatale A, Pedata R. Management of molar pregnancy. J Prenat Med. 2009 Jan-Mar;3(1):15-7. PMID: 22439034.

Centers for Disease Control and Prevention (CDC). Chen B, Gagnon M, Shahangian S, Anderson NL, Howerton DA, Boone JD; CDC. Good laboratory practices for molecular genetic testing for heritable diseases and conditions. MMWR Recomm Rep. 2009 Jun 12;58(RR-6):1-37;quiz CE-1-4. PMID: 19521335.

Centers for Disease Control and Prevention (CDC). Evaluating Genomic Tests.

Centers for Medicare & Medicaid Services (CMS). Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). 2018 Mar 16.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) for Molecular Pathology Procedures L35000. National Government Services, Inc. Effective Date 2015 Oct 1. Revised 2020 Jul 1.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Colorectal Cancer Screening Tests 210.3. Effective Date 2021 Jan 19.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Cytogenetic Studies 190.3. Effective Date 1998 Jul 16.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Next Generation Sequencing 90.2. Effective Date 2020 Jan 27.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Pharmacogenomic Testing for Warfarin Response 90.1. Effective Date 2009 Aug 3.

Centers for Medicare & Medicaid Services (CMS). Technology Assessment. Update on Genetic Tests for Non-Cancer Diseases/Conditions: A Horizon Scan. Agency for Healthcare Research and Quality (AHRQ). 2010 Mar 18.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Change Healthcare. InterQual® Overview.

Chen JM, Férec C, Cooper DN. Revealing the human mutome. Clin Genet. 2010 Oct;78(4):310-20. doi: 10.1111/j.1399-0004.2010.01474.x. PMID: 20569258.

Chiu RW, Akolekar R, Zheng YW, Leung TY, Sun H, Chan KC, Lun FM, Go AT, Lau ET, To WW, Leung WC, Tang RY, Au-Yeung SK, Lam H, Kung YY, Zhang X, van Vugt JM, Minekawa R, Tang MH, Wang J, Oudejans CB, Lau TK, Nicolaides KH, Lo YM. Non-invasive prenatal assessment of trisomy 21 by

multiplexed maternal plasma DNA sequencing: large scale validity study. BMJ. 2011 Jan;342:c7401. doi: 10.1136/bmj.c7401. PMID: 21224326.

Chiu RW, Cantor CR, Dennis Lo YM. Non-invasive prenatal diagnosis by single molecule counting technologies. Trends Genet. 2009 Jul;25(7):324-31. doi: 10.1016/j.tig.2009.05.004. Epub 2009 Jun 18. PMID: 19540612.

Chiu RW, Dennis Lo YM. Non-invasive prenatal diagnosis empowered by high-throughput sequencing. Prenat Diagn. 2012 Apr;32(4):401-6. doi: 10.1002/pd.3822. PMID: 22467171.

Chiu RW, Dennis Lo YM. Non-invasive prenatal diagnosis by fetal nucleic acid analysis in maternal plasma: the coming of age. Semin Fetal Neonatal Med. 2011 Apr;16(2):88-93. doi: 10.1016/j.siny.2010.10.003. Epub 2010 Nov 12. PMID: 21075065.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Counsyl. Counsyl Prelude™ Prenatal Screen.

Dar P, Curnow KJ, Gross SJ, Hall MP, Stosic M, Demko Z, Zimmermann B, Hill M, Sigurjonsson S, Ryan A, Banjevic M, Kolacki PL, Koch SW, Strom CM, Rabinowitz M, Benn P. Clinical experience and follow-up with large scale single-nucleotide polymorphism-based noninvasive prenatal aneuploidy testing. Am J Obstet Gynecol. 2014 Nov;211(5):527.e1-527.e17. doi: 10.1016/j.ajog.2014.08.006. Epub 2014 Aug 8. PMID: 25111587.

de Mello RA, Madureira P, Carvalho LS, Araújo A, O'Brien M, Popat S. EGFR and KRAS mutations, and ALK fusions: current developments and personalized therapies for patients with advanced non-small-cell lung cancer. Pharmacogenomics. 2013 Nov;14(14):1765-77. doi: 10.2217/pgs.13.177. PMID: 24192124.

Demetri GD, Reichardt P, Kang YK, Blay JY, Rutkowski P, Gelderblom H, Hohenberger P, Leahy M, von Mehren M, Joensuu H, Badalamenti G, Blackstein M, Le Cesne A, Schöffski P, Maki RG, Bauer S, Nguyen BB, Xu J, Nishida T, Chung J, Kappeler C, Kuss I, Laurent D, Casali PG; GRID study investigators. Efficacy and safety of regorafenib for advanced gastrointestinal stromal tumors after failure of imatinib and sunitinib (GRID): an international, multicentre, randomized, placebo-controlled, phase 3 trial. Lancet. 2013 Jan 26;381(9863):295-302. doi: 10.1016/S0140-6736(12)61857-1. Epub 2012 Nov 22. PMID: 23177515.

Dey M, Sharma S, Aggarwal S. Prenatal screening methods for aneuploidies. N Am J Med Sci. 2013 Mar;5(3):182-90. doi: 10.4103/1947-2714.109180. PMID: 23626953.

Donley G, Hull SC, Berkman BE. Prenatal whole genome sequencing: just because we can, should we? Hastings Cent Rep. 2012 Jul-Aug;42(4):28-40. doi: 10.1002/hast.50. Epub 2012 Jun 20. PMID: 22777977.

Evaluation of Genomic Applications in Practice and Prevention (EGAPP). EGAPP Working Group Recommendation. Can testing of tumor tissue for mutations in EGFR pathway downstream effector genes in patients with metastatic colorectal cancer improve health outcomes by guiding decisions regarding anti-EGFR therapy? Genet Med. 2013 Jul;15(7):517-27. doi: 10.1038/gim.2012.184. Epub 2013 Feb 21. PMID: 23429431.

Farwell KD, Shahmirzadi L, El-Khechen D, Powis Z, Chao EC, Tippin Davis B, Baxter RM, Zeng W, Mroske C, Parra MC, Gandomi SK, Lu I, Li X, Lu H, Lu HM, Salvador D, Ruble D, Lao M, Fischbach S, Wen J, Lee S, Elliott A, Dunlop CL, Tang S. Enhanced utility of family-centered diagnostic exome sequencing with inheritance model-based analysis: results from 500 unselected families with undiagnosed genetic conditions. Genet Med. 2015 Jul;17(7):578-86. doi: 10.1038/gim.2014.154. Epub 2014 Nov 13. PMID: 25356970.

Ferrusi I, Marshall DA, Kulin NA, Leighl NB, Phillips KA. Looking back at 10 years of trastuzumab therapy: what is the role of HER2 testing? A systematic review of health economic analyses. Per Med. 2009 March;6(2):193–215. doi: 10.2217/17410541.6.2.193. PMID: 20668661.

Han van Krieken J, Kafatos G, Bennett J, Mineur L, Tomášek J, Rouleau E, Fabian P, De Maglio G, García-Alfonso P, Aprile G, Parkar P, Downey G, Demonty G, Trojan J. Panitumumab use in metastatic colorectal cancer and patterns of RAS testing: results from a Europe-wide physician survey and medical records review. BMC Cancer. 2017 Nov 28;17(1):798. doi: 10.1186/s12885-017-3740-4. PMID: 29183279.

Hayes. Clinical Utility Evaluation. Cell-Free DNA (CfDNA) [Formerly NIPS, NIPT] Screening For Fetal Rare Autosomal Trisomies. Dallas, TX: Hayes; 2020 Oct 21. Annual Review 2020 Oct 21.

Hayes. Clinical Utility Evaluation. Clinical Utility of Prenatal Genetic Testing for Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Sep 28. Annual Review 2021 Aug 20.

Hayes. Clinical Utility Evaluation. Liquid Biopsy Tests for Colorectal Cancer Screening. Dallas, TX: Hayes; 2020 Mar 26. Annual Review 2021 Jan 27.

Hayes. Clinical Utility Evaluation. Prenatal and Preimplantation Genetic Testing for Risk of Hearing Loss. Dallas, TX: Hayes; 2019 Dec 11. Annual Review 2020 Nov 18.

Hayes. Clinical Utility Evaluation. Prenatal Whole Genome Sequencing and Prenatal Whole Exome Sequencing. Dallas, TX: Hayes; 2020 Jun 15 Annual Review 2021 May 03.

Hayes. Clinical Utility Evaluation. Whole Exome Sequencing For Neurological Conditions In Pediatric Populations. Dallas, TX: Hayes; 2016 Jul 28. Annual Review 2019 Jun 17.

Hayes. Clinical Utility Evaluation. Whole Genome Sequencing (WGS) and Whole Exome Sequencing (WES) in Patients with Intellectual Disability (ID). Dallas, TX: Hayes; 2021 Jan 21.

Hayes. Medical Code Briefs. 0323U - PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 20.

Hayes. Medical Code Briefs. 0324U - PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 19.

Hayes. Medical Code Briefs. 0325U – PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 19.

Hayes. Medical Code Briefs. 0326U - PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 19.

Hayes. Medical Code Briefs. 0327U - PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 20.

Hayes. Medical Code Briefs. 0329U - PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 19.

Hayes. Medical Code Briefs. 0330U - PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 19.

Hayes. Medical Code Briefs. 0331U - PLA (U Codes). Dallas, TX: Hayes; 2022 Apr 19.

Hayes. Molecular Test Assessment. ColonSentry (Stage Zero Life Sciences). Dallas, TX: Hayes; 2020 May 27. Annual Review 2021 Jun 10.

Hayes. Molecular Test Assessment. Epi proColon (Epigenomics Inc.). Dallas, TX: Hayes; 2020 Sep 30.

Hayes. Molecular Test Assessment. Guardant360 (Guardant Health Inc.). Dallas, TX: Hayes; 2018 Dec 11. Annual Review 2021 Nov 19.

Hayes. Molecular Test Assessment. ThyGeNEXT and ThyraMIR (Interpace Diagnostics Group Inc.). Dallas, TX: Hayes; 2019 Jul 10. Annual Review 2020 Jul 19.

Hayes. Molecular Test Assessment. ThyroSeq v3 (University of Pittsburgh Medical Center, CBLPath Inc.). Dallas, TX: Hayes; 2019 May 9. Annual Review 2021 Oct 10.

Hayes. Precision Medicine Insights. Expanded Carrier Screening. Dallas, TX: Hayes; 2020 Aug 17.

Hayes. Precision Medicine Research Brief. Oncotype MAP Pan-Cancer Tissue Test (Genomic Health Inc.). Dallas, TX: Hayes; 2021 Feb 9.

Hays T, Wapner RJ. Genetic Testing for Unexplained Perinatal Disorders. Curr Opin Pediatr. 2021 Apr 1;33(2):195-202. doi: 10.1097/MOP.000000000000999. PMID: 336025625.

Hong AR, Lim JA, Kim TH, Choi HS, Yoo WS, Min HS, Won JK, Lee KE, Jung KC, Park DJ, Park YJ. The Frequency and Clinical Implications of the BRAF(V600E) Mutation in Papillary Thyroid Cancer Patients in Korea over the Past Two Decades. Endocrinol Metab (Seoul). 2014 Dec 29;29(4):505-13. doi: 10.3803/EnM.2014.29.4.505. Epub 2014 Jul 2. PMID: 25325273.

Iglesias A, Anyane-Yeboa K, Wynn J, Wilson A, Truitt Cho M, Guzman E, Sisson R, Egan C, Chung WK. The usefulness of whole-exome sequencing in routine clinical practice. Genet Med. 2014 Dec;16(12):922-31. doi: 10.1038/gim.2014.58. Epub 2014 Jun 5. PMID: 24901346.

Johansen Taber KA, Dickinson BD, Wilson M. The promise and challenges of next-generation genome sequencing for clinical care. JAMA Intern Med. 2014 Feb 1;174(2):275-80. doi: 10.1001/jamainternmed.2013.12048. PMID: 24217348.

Kagan KO, Sonek J, Wagner P, Hoopmann M. Principles of first trimester screening in the age of non-invasive prenatal diagnosis: screening for chromosomal abnormalities. Arch Gynecol Obstet. 2017 Oct;296(4):645–51. doi: 10.1007/s00404-017-4459-9. Epub 2017 Jul 12. PMID: 28702698.

Kagan KO, Sroka F, Sonek J, Abele H, Lüthgens K, Schmid M, Wagner P, Brucker S, Wallwiener D, Hoopmann M. First-trimester risk assessment based on ultrasound and cell-free DNA vs combined screening: a randomized controlled trial. Ultrasound Obstet Gynecol. 2018 Apr;51(4):437-44. doi: 10.1002/uog.18905. Epub 2018 Mar 4.PMID: 28925570.

Kargi AY, Bustamante MP, Gulec S. Genomic Profiling of Thyroid Nodules: Current Role for ThyroSeq Next-Generation Sequencing on Clinical Decision-Making. Mol Imaging Radionucl Ther. 2017 Feb 9;26(Suppl 1):24-35. doi: 10.4274/2017.26.suppl.04. PMID: 28117287.

Kato S, Schwaederlé MC, Fanta PT, Okamura R, Leichman L, Lippman SM, Lanman RB, Raymond VM, Talasaz AA, Kurzrock R. Genomic Assessment of Blood-Derived Circulating Tumor DNA in Patients With Colorectal Cancers: Correlation With Tissue Sequencing, Therapeutic Response, and Survival. JCO Precis Oncol. 2019; 3: PO.18.00158. doi: 10.1200/PO.18.00158. PMID: 31032472.

Kirsh KL, Christo PJ, Heit H, Steffel K, Passik SD. Specimen validity testing in urine drug monitoring of medications and illicit drugs: clinical implications. J Opioid Manag. 2015 Jan-Feb;11(1):53-9. doi: 10.5055/jom.2015.0252. PMID: 25750165.

Krane JF, Cibas ES, Alexander EK, Paschke R, Eszlinger M. Molecular analysis of residual ThinPrep material from thyroid FNAs increases diagnostic sensitivity. Cancer Cytopathol. 2015 Jun;123(6):356-61. doi: 10.1002/cncy.21546. Epub 2015 Apr 29. PMID: 25926393.

Krstic N, Obican SG. Current Landscape of Prenatal Genetic Screening and Testing. Birth Defects Res. 2020 Mar 1;112(4):321-31. doi: 10.1002/bdr2.1598. Epub 2019 Oct 21. PMID: 31633301.

Lacey S, Chung JY, Lin H. A comparison of whole genome sequencing with exome sequencing for family-based association studies. BMC Proc. 2014 Jun 17;8(Suppl 1 Genetic Analysis Workshop 18Vanessa Olmo):S38. doi: 10.1186/1753-6561-8-S1-S38. eCollection 2014. PMID: 25519383.

Maortua H, Martínez-Bouzas C, García-Ribes A, Martínez MJ, Guillen E, Domingo MR, Calvo MT, Guitart M, Gabau E, Botella MP, Gener B, Rubio I, López-Aríztegui MA, Tejada MI. MECP2 gene study in a large cohort: testing of 240 female patients and 861 healthy controls (519 females and 342 males). J Mol Diagn. 2013 Sep;15(5):723-9. doi: 10.1016/j.jmoldx.2013.05.002. Epub 2013 Jun 26. PMID: 23810759.

Marberger M, McConnell JD, Fowler I, Andriole GL, Bostwick DG, Somerville MC, Rittmaster RS. Biopsy misidentification identified by DNA profiling in a large multicenter trial. J Clin Oncol. 2011 May 1;29(13):1744-9. doi: 10.1200/JCO.2010.32.1646. Epub 2011 Mar 28. PMID: 21444877.

Marcus FI, Edson S, Towbin JA. Genetics of arrhythmogenic right ventricular cardiomyopathy: a practical guide for physicians. J Am Coll Cardiol. 2013 May 14;61(19):1945–8. doi: 10.1016/j.jacc.2013.01.073. Epub 2013 Mar 14. PMID: 23500315.

Marzulla T, Roberts JS, DeVries R, Koeller DR, Green RC, Uhlmann WR. Genetic Councseling Following Direct-to Consumer Genetic Testing: Consumer Perspectives. J Genet Couns. 2021 Feb;30(1):329-34. doi: 10.1002/jgc4.1309. Epub 2020 Jul 9. PMID: 32648332.

Massachusetts Health Quality Partners. Adult Preventive Care Guidelines. 2021.

Matos LL, Trufelli DC, de Matos MG, da Silva Pinhal MA. Immunohistochemistry as an important tool in biomarkers detection and clinical practice. Biomark Insights. 2010 Feb 9;5:9-20. PMID: 20212918.

McCullough RM, Almasri EA, Guan X, Geis JA, Hicks SC, Mazloom AR, Deciu C, Oeth P, Bombard AT, Paxton B, Dharajiya N, Saldivar JS. Non-invasive prenatal chromosomal aneuploidy testing--clinical experience: 100,000 clinical samples. PloS One. 2014 Oct 7;9(10):e109173. doi: 10.1371/journal.pone.0109173. eCollection 2014. PMID: 25289665.

McGregor M, Price TJ. Panitumumab in the treatment of metastatic colorectal cancer, including wild-type RAS, KRAS and NRAS mCRC. Future Oncol. 2018 Oct;14(24):2437-59. doi: 10.2217/fon-2017-0711. Epub 2018 May 8. PMID: 29737864.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).

National Human Genome Research Institute. National Institutes of Health. Genomic Education Websites.

National Human Genome Research Institute. National Institutes of Health. Health Professional Genetics Resources Online.

National Human Genome Research Institute. National Institutes of Health. Online Genetics Education Resources.

National Institute for Health and Care Excellence (NICE). NICE Guidance.

National Society of Genetic Counselors (NSGC). NSGC Practice Guidelines.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Nicholson KJ, Yip L. An update on the status of molecular testing for the indeterminate thyroid nodule and risk stratification of differentiated thyroid cancer. Curr Opin Oncol. 2018 Jan;30(1):8-15. doi: 10.1097/CCO.0000000000000414. PMID: 29028645.

Nikiforova MN, Mercurio S, Wald AI, Barbi de Moura M, Callenberg K, Santana-Santos L, Gooding WE, Yip L, Ferris RL, Nikiforov YE. Analytical performance of the ThyroSeq v3 genomic classifier for cancer diagnosis in thyroid nodules. Cancer. 2018 Apr 15;124(8):1682-90. doi: 10.1002/cncr.31245. Epub 2018 Jan 18. PMID: 29345728.

Nikiforov YE. Role of Molecular Markers in Thyroid Nodule Management: Then and Now. Endocr Pract. 2017 Aug;23(8):979-88. doi: 10.4158/EP171805.RA. Epub 2017 May 23. Review. Erratum in: Endocr Pract. 2017 Nov;23 (11):1362. PMID: 28534687.

Nishino M, Nikiforova M. Update on Molecular Testing for Cytologically Indeterminate Thyroid Nodules. Arch Pathol Lab Med. 2018 Apr;142(4):446-57. doi: 10.5858/arpa.2017-0174-RA. Epub 2018 Jan 16. PMID: 29336606.

Norton ME, Brar H, Weiss J, Karimi A, Laurent LC, Caughey AB, Rodriguez MH, Williams J 3rd, Mitchell ME, Adair CD, Lee H, Jacobsson B, Tomlinson MW, Oepkes D, Hollemon D, Sparks AB, Oliphant A, Song K. Non-Invasive Chromosomal Evaluation (NICE) Study: results of a multicenter prospective cohort study for detection of fetal trisomy 21 and trisomy 18. Am J Obstet Gynecol. 2012;207(2):137.e1-8. doi: 10.1016/j.ajog.2012.05.021. Epub 2012 Jun 1. PMID: 22742782.

Ohori NP, Landau MS, Carty SE, Yip L, LeBeau SO, Manroa P, Seethala RR, Schoedel KE, Nikiforova MN, Nikiforov YE. Benign call rate and molecular test result distribution of ThyroSeq v3. Cancer Cytopathol. 2018 Dec 18. doi: 10.1002/cncy.22088. PMID: 30561907.

Onenerk AM, Pusztaszeri MP, Canberk S, Faquin WC. Triage of the indeterminate thyroid aspirate: What are the options for the practicing cytopathologist? Cancer Cytopathol. 2017 Jun;125(S6):477-85. doi: 10.1002/cncy.21828. PMID: 28609009.

Pagan M, Kloos RT, Lin CF, Travers KJ, Matsuzaki H, Tom EY, Kim SY, Wong MG, Stewart AC, Huang J, Walsh PS, Monroe RJ, Kennedy GC. The diagnostic application of RNA sequencing in patients with

thyroid cancer: an analysis of 851 variants and 133 fusions in 524 genes. BMC Bioinformatics. 2016 Jan 11;17 Suppl 1:6. doi: 10.1186/s12859-015-0849-9. PMID: 26818556.

Partyka KL, Randolph ML, Lawrence KA, Cramer H, Wu HH. Utilization of direct smears of thyroid fine-needle aspirates for ancillary molecular testing: A comparison of two proprietary testing platforms. Diagn Cytopathol. 2018 Apr;46(4):320-5. doi: 10.1002/dc.23902. Epub 2018 Feb 15. PMID: 29446257.

Paschou SA, Vryonidou A, Goulis DG. Thyroid nodules: A guide to assessment, treatment and follow-up. Maturitas. 2017 Feb;96:1-9. doi: 10.1016/j.maturitas.2016.11.002. Epub 2016 Nov 9. PMID: 28041586.

Patel HH, Goyal N, Goldenberg D. Imaging, genetic testing, and biomarker assessment of follicular cell-derived thyroid cancer. Ann Med. 2014;46(6):409-16. doi: 10.3109/07853890.2014.923739. Epub 2014 Jul 2. PMID 24987865.

Pearlstein S, Lahouti AH, Opher E, Nikiforov YE, Kuriloff DB. Thyroseq V3 Molecular Profiling for Tailoring the Surgical Management of Hürthle Cell Neoplasms. Case Rep Endocrinol. 2018 Jul 16;2018:9329035. doi: 10.1155/2018/9329035. eCollection 2018. PMID: 30105107.

Peterson JA, Farland JG, Curtis BR, Aster RH. Neonatal alloimmune thrombocytopenia: pathogenesis, diagnosis and management. Br J Haematol. 2013 Apr;161(1):3–14. doi: 10.1111/bjh.12235. Epub 2013 Feb 6. PMID: 23384054.

Pfeifer JD, Liu J. Rate of occult specimen provenance complications in routine clinical practice. Am J Clin Pathol. 2013 Jan;139(1):93-100. doi: 10.1309/AJCP50WEZHWIFCIV. PMID: 23270904.

Prahallad A, Sun C, Huang S, Di Nicolantonio F, Salazar R, Zecchin D, Beijersbergen RL, Bardelli A, Bernards R. Unresponsiveness of colon cancer to BRAF(V600E) inhibition through feedback activation of EGFR. Nature. 2012 Jan 26;483(7387):100–3. doi: 10.1038/nature10868. PMID: 22281684.

Rehm HL, Bale SJ, Bayrak-Toydemir P, Berg JS, Brown KK, Deignan JL, Friez MJ, Funke BH, Hegde MR, Lyon E; Working Group of the American College of Medical Genetics and Genomics (ACMG) Laboratory Quality Assurance Committee. ACMG clinical laboratory standards for next-generation sequencing. Genet Med. 2013 Sep;15(9):733-47. doi: 10.1038/gim.2013.92. Epub 2013 Jul 25. PMID: 23887774.

Ross DS. Evaluation and management of thyroid nodules with indeterminate cytology. UpToDate. 2020 May 28.

Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. Genet Med. 2013 May;15(5):399-407. doi: 10.1038/gim.2013.32. Epub 2013 Mar 21. Erratum in: Genet Med. 2013 Aug;15(8):669. PMID: 23519317.

Schwaederle M, Husain H, Fanta PT, Piccioni DE, Kesari S, Schwab RB, Banks KC, Lanman RB, Talasaz A, Parker BA, Kurzrock R. Detection rate of actionable mutations in diverse cancers using a biopsy-free (blood) circulating tumor cell DNA assay. Oncotarget. 2016 Mar 1;7(9):9707-17. doi: 10.18632/oncotarget.7110. PMID: 26848768.

Sosman JA, Kim KB, Schuchter L, Gonzalez R, Pavlick AC, Weber JS, McArthur GA, Hutson TE, Moschos SJ, Flaherty KT, Hersey P, Kefford R, Lawrence D, Puzanov I, Lewis KD, Amaravadi RK, Chmielowski B, Lawrence HJ, Shyr Y, Ye F, Li J, Nolop KB, Lee RJ, Joe AK, Ribas A. Survival in BRAF V600-mutant advanced melanoma treated with Vemurafenib. N Engl J Med. 2012 Feb 23;366(8):707-14. doi: 10.1056/NEJMoa1112302. PMID: 22356324.

Steward DL, Carty SE, Sippel RS, Yang SP, Sosa JA, Sipos JA, Figge JJ, Mandel S, Haugen BR, Burman KD, Baloch ZW, Lloyd RV, Seethala RR, Gooding WE, Chiosea SI, Gomes-Lima C, Ferris RL, Folek JM, Khawaja RA, Kundra P, Loh KS, Marshall CB, Mayson S, McCoy KL, Nga ME, Ngiam KY, Nikiforova MN, Poehls JL, Ringel MD, Yang H, Yip L, Nikiforov YE. Performance of a Multigene Genomic Classifier in Thyroid Nodules With Indeterminate Cytology: A Prospective Blinded Multicenter Study. JAMA Oncol. 2019 Feb 1;5(2):204-12. doi: 10.1001/jamaoncol.2018.4616. PMID: 30419129.

Takahama T, Sakai K, Takeda M, Azuma K, Hida T, Hirabayashi M, Oguri T, Tanaka H, Ebi N, Sawa T, Bessho A, Tachihara M, Akamatsu H, Bandoh S, Himeji D, Ohira T, Shimokawa M, Nakanishi Y, Nakagawa K, Nishio K. Detection of the T790M mutation of EGFR in plasma of advanced non-small cell lung cancer patients with acquired resistance to tyrosine kinase inhibitors (west japan oncology group 8014LTR study). Oncotarget. 2016 Sep 6;7(36):58492-9. doi: 10.18632/oncotarget.11303. PMID: 27542267.

ThyroSeq Thyroid Genomic Classifier. ThyroSeq Test Description.

The University of Michigan Department of Pathology. Clinical Test Catalog. Cytogenetics, Cancer Cytogenomic Array, Tumor.

Wang Z, Andrews P, Kendall J, Ma B, Hakker I, Rodgers L, Ronemus M, Wigler M, Levy D. SMASH, a fragmentation and sequencing method for genomic copy number analysis. Genome Res. 2016 Jun;26(6):844-51. doi: 10.1101/gr.201491.115. Epub 2016 Apr 14. PMID: 27197213.

Winand R, Hens K, Dondorp W, de Wert G, Moreau Y, Vermeesch JR, Liebaers I, Aerts J. In vitro screening of embryos by whole-genome sequencing: now, in the future or never? Hum Reprod. 2014 Apr;29(4):842-51. doi: 10.1093/humrep/deu005. Epub 2014 Feb 2. PMID: 24491297.

Yang Y, Luo X, Yang N, Feng R, Xian L. The prognostic value of excision repair cross-complementation group 1 (ERCC1) in patients with small cell lung cancer (SCLC) receiving platinum-based chemotherapy: evidence from meta-analysis. PLoS One. 2014 Nov 6;9(11):e111651. doi: 10.1371/journal.pone. 0111651. eCollection 2014. PMID: 25375151.

Yang Y, Muzny DM, Reid JG, Bainbridge MN, Willis A, Ward PA, Braxton A, Beuten J, Xia F, Niu Z, Hardison M, Person R, Bekheirnia MR, Leduc MS, Kirby A, Pham P, Scull J, Wang M, Ding Y, Plon SE, Lupski JR, Beaudet AL, Gibbs RA, Eng CM. Clinical whole-exome sequencing for the diagnosis of mendelian disorders. N Engl J Med. 2013 Oct 17;369(16):1502-11. doi: 10.1056/NEJMoa1306555. Epub 2013 Oct 2. PMID: 24088041.

Zhang M, Lin O. Molecular Testing of Thyroid Nodules: A Review of Current Available Tests for Fine-Needle Aspiration Specimens. Arch Pathol Lab Med. 2016 Dec;140(12):1338-44. doi: 10.5858/arpa.2016-0100-RA. Epub 2016 Aug 24. PMID: 27557410.

## **Next Review Date**

Not applicable

### **Retired Date**

11/01/22

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

**Appendix: Policy History** 

Original Original Effective
Approval Date Date\* and Version Policy Owner Approved by

Regulatory Approval: N/A	12/01/11	Director of Medical	MPCTAC and QIC
	Version 1	Policy as Chair of	
Internal Approval:		MPCTAC	
08/17/11: Medical Policy, Criteria, and			
Technology Assessment Committee			
(MPCTAC)			
09/28/11: Quality Improvement			
Committee (QIC)			

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

Note: Policy title was *Genetic Testing Guidelines and Pharmacogenetics* until 09/30/18; effective 10/01/18 the policy title has been changed to *Genetic/Genomic Testing and Pharmacogenetics*. Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
07/29/12	Off cycle review for Well Sense Health Plan, reformatted Medical Policy Statement, added Applicable Coding language and code list, deleted references to other products and associated limitations.	Version 2	08/03/12: MPCTAC 09/13/12: QIC
09/01/12	Review for effective date 01/01/13. Added applicable code list, revised language in Applicable Coding section, added newborn screening as a type of genetic testing to Description of Item or Service section (from Clinical Background Information section). Added reference to Experimental and Investigational Treatment policy and Medically Necessary policy. Removed duplicate text from Clinical Background Information section.	01/01/13 Version 3	09/19/12: MPCTAC 10/24/12: QIC
10/01/13 and 11/01/13	Review for effective date 03/01/14. Revised Summary, Medical Policy Statement, Limitations, Clinical Background Information, and References sections. Updated list of applicable codes. Summarized CPT code descriptions for CPT codes 81400-81408 and added Plan note.	03/01/14 Version 4	10/16/13: MPCTAC 11/20/13: MPCTAC 12/19/13: QIC
01/30/14	Review for effective date 04/01/14. Added ICD10 diagnosis code equivalents of existing ICD9 diagnosis codes.	04/01/14 Version 5	01/27/14: MPCTAC 01/30/14: QIC

<sup>\*</sup>Effective Date for New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

07/01/14	Review for effective 10/01/14. Updated Summary	10/01/14	07/21/14: MPCTAC
07/01/14	section. Added CPT code 81507 and HCPCS code	Version 6	(electronic vote)
	S3870 to the applicable code list.	Version o	07/24/14: QIC
	33870 to the applicable code list.		(electronic vote)
11/01/14	Review for effective date 03/01/15. Revised	03/01/15	11/19/14: MPCTAC
and		Version 7	, ,
	Summary, Description of Item or Service, Definitions, and References sections. Revised criteria in the	Version /	12/02/14: MPCTAC
12/01/14			(electronic vote)
	Medical Policy Statement and Limitations section.		12/10/14: QIC
11 / 25 / 15	Updated applicable code list.	01/01/16	11 /10 /1E - NADCTA C
11/25/15	Review for effective date 01/01/16. Updated	01/01/16	11/18/15: MPCTAC
	template with list of applicable products and notes.	Version 8	11/25/15: MPCTAC
	Revised language related to applicable products in		(electronic vote)
	the Limitations section without changing criteria.		12/09/15: QIC
01/01/16	Revised language in the Applicable Coding section.	05 /04 /46	01/00/16 NADOTA O
01/01/16	Review for effective date 05/01/16. Revised	05/01/16	01/20/16: MPCTAC
	language and list of waived pregnancy diagnosis	Version 9	02/10/16: QIC
	codes and corresponding procedure codes in the		
	Applicable Coding section. Revised list of procedure		
	codes according to industry-standard 2016 code		
	changes. Updated Summary, Description of Item or		
	Service, Definitions, Clinical Background Information,		
	and References sections. Revised criteria in the		
	Medical Policy Statement and Limitations sections.		
09/01/16	Review for effective date 11/01/16. Administrative	11/01/16	09/21/16: MPCTAC
and	changes made to the Summary, Description of Item	Version 10	09/30/16: MPCTAC
09/28/16	or Service, Medical Policy Statement, and Applicable		(electronic vote)
	Coding sections to clarify the types of genetic		10/12/16: QIC
	testing that require Plan prior authorization. No		
	changes made to the criteria and/or the applicable		
	code list. Administrative changes made to clarify		
	language related to gender. Added definitions.		
12/05/16	Industry-wide code change with the addition of 2017	01/01/17	Not applicable
	applicable codes effective 01/01/17.	Version 11	because industry-
			wide code revisions
01/01/17	Review for effective date 05/01/17. Revised ICD-10	05/01/17	01/18/17: MPCTAC
	pregnancy diagnosis codes and updated CPT codes	Version 12	02/08/17: QIC
	in the Applicable Coding section. Updated criteria in		
	the Medical Policy Statement and Limitations		
	sections. Revised Summary, Definitions, Clinical		
	Background Information, References, and Reference		
	to Applicable Laws and Regulations sections. Added		
	Plan notes to Applicable Coding section.		
06/01/17	Review for effective date 07/01/17. Industry-wide	07/01/17	06/21/17: MPCTAC.
	code changes made to the Applicable Coding	Version 13	
	section. Administrative changes made to the		
	Summary, Applicable Coding, and References		
	sections. Updated Limitations section to be		
	consistent with industry-wide code addition.		

08/09/17 and	Revision effective 10/01/17. Industry-wide updates to the ICD-10 diagnosis and HCPCS codes included	10/01/17 Version 14	Not applicable because CMS
09/08/17	in the Applicable Coding section.	VCISIONITY	industry wide changes to HCPCS and ICD10 diagnosis codes
09/20/17	Review for effective date 12/01/17. Revised criteria in the Limitations section. Updated Policy Summary, Description of Item or Service, References, and Other Applicable Policies sections. Revised the applicable code list and administrative changes made to the Applicable Coding section.	12/01/17 Version 15	09/20/17: MPCTAC
12/01/17	Review for effective 01/01/18. Industry-wide updates to codes included in the Applicable Coding section.	01/01/18 Version 16	Not applicable because industry- wide code changes
01/01/18	Review for effective date 04/01/18. Revised Summary, Definitions, Clinical Background Information, and References sections. Updated Medical Policy Statement, Limitations, and Applicable Coding sections.	04/01/18 Version 17	01/17/18: MPCTAC
06/01/18	Review for effective date 09/01/18. Criteria updated in the Limitations section. Administrative change made to the References and Other Applicable Policies sections.	09/01/18 Version 18	06/20/18: MPCTAC
06/25/18	Review for effective date 09/01/18. Revised criteria in the Medical Policy Statement section. Updated References section.	09/01/18 Version 19	06/25/18: MPCTAC (electronic vote)
09/01/18	Review for effective date 10/01/18. Revised the policy title. Administrative changes made to the Policy Summary, Description of Item or Service, Medical Policy Statement, References, and Other Applicable Policies sections. Industry-wide code changes and Plan notes added to Applicable Coding section.	10/01/18 Version 20	Not applicable because industry- wide code changes
09/19/18	Review for effective date 12/01/18. Revised criteria in the Limitations section.	12/01/18 Version 21	09/19/18: MPCTAC
01/01/19	Review for effective date 04/01/19. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to the Policy Summary, Definitions, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Industry-wide code updates and Plan notes revised in the Applicable Coding section.	04/01/19 Version 22	01/16/19: MPCTAC
02/01/19	Review for effective date 05/01/19. Administrative changes made to the Policy Summary, Definitions, References, and Other Applicable Policies sections.	05/01/19 Version 23	02/20/19: MPCTAC

	Criteria revised in the Medical Policy Statement and Limitations sections.		
03/01/19	Review for effective date 05/01/19. Administrative changes made to the Applicable Coding section to be consistent with the criteria revisions approved in version 23.	05/01/19 Version 24	03/20/19: MPCTAC
02/01/19	Review for effective date 06/01/19. Updated the code list in the Applicable Coding section.	06/01/19 Version 25 (formerly Version 24)	02/20/19: MPCTAC
03/01/19	Review for effective date 06/01/19. Administrative changes made to the Applicable Coding section to make consistent with the criteria revisions approved in version 23.	06/01/19 Version 26	03/20/19: MPCTAC
06/01/19	Review for effective date 07/01/19. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections. Industry-wide code additions and Plan notes included in the Applicable Coding section. Revised language in the Policy Summary, Medical Policy Statement, and Applicable Coding section to clarify that the prior authorization waiver for the specified primary pregnancy diagnosis codes only applies to genetic tests ordered, administered, and processed by participating providers and participating laboratories.	07/01/19 Version 27	06/19/19: MPCTAC
07/01/19	Review for effective date 10/01/19. Adopted InterQual® criteria for genetic testing unless specified otherwise in a Plan medical policy. Revised criteria in the Medical Policy Statement and Limitations sections by including medical necessity criteria for genetic testing for indeterminate thyroid nodules and papillary thyroid carcinoma, criteria for targeted genetic testing when indication not specified as medically necessary in Plan-adopted InterQual® criteria or a Plan medical policy, and criteria for multigene panel testing (rather than targeted genetic testing) when Plan-adopted InterQual® criteria are not met or not available. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, and Other Applicable Policies sections. Maintained diagnosis code list for prior authorization pregnancy waiver and updated applicable procedure code list.	10/01/19 Version 28	07/17/19: MPCTAC
09/01/19	Review for effective 12/01/19. Updated the list of procedure codes and added high-risk diagnosis code in the Applicable coding section.	12/01/19 Version 29	09/18/19: MPCTAC

12/01/19	Review for effective date 01/01/20. Industry-wide	01/01/20	12/18/19: MPCTAC
, ,	code updates made in the Applicable Coding	Version 30	, ,
	section. Administrative changes made to the Policy		
	Summary, Medical Policy Statement, Applicable		
01/01/00	Coding, Definitions, and References sections.	0.4.01.00	01/15/00 NADOTA O
01/01/20	Review for effective date 04/01/20. Administrative changes made to the Policy Summary, References,	04/01/20 Version 31	01/15/20: MPCTAC
	and Reference to Applicable Laws and Regulations	version 31	
	sections. Plan notes revised in the Applicable		
	Coding section. Criteria revised in the Medical		
	Policy Statement and Limitations sections.		
04/01/20	Review for effective date 05/01/20. Industry-wide	05/01/20	04/15/20: MPCTAC
	code additions and Plan notes included in the	Version 32	
	Applicable Coding section.		
06/01/20	Review for effective date 07/01/20. Industry-wide	07/01/20	Not applicable
	coding and pertinent Plan notes added to the Applicable Coding section.	Version 33	because industry- wide code changes;
	Applicable Couling Section.		06/17/20: MPCTAC
			review
09/01/20	Review for effective date 12/01/20. Industry-wide	12/01/20	09/16/20: MPCTAC
	coding and pertinent Plan notes added to the	Version 34	
	Applicable Coding section. Plan notes added to the		
	Applicable Coding section. Administrative changes		
	made to the Policy Summary, Description of Item or		
	Service, Clinical Background Information, and References sections. Criteria revised in the Medical		
	Policy Statement and Limitations sections.		
12/01/20	Review for effective date 01/01/21. Industry-wide	01/01/21	Not applicable
, ,	updates to coding in the Applicable Coding section.	Version 35	because industry-
			wide code changes;
			12/16/20: MPCTAC
02 (01 (21	D. 1. (((),),()	0.0 (01/21	review
02/01/21	Review for effective date 06/01/21. Administrative changes made to the Policy Summary, Medical	06/01/21 Version 36	02/17/21: MPCTAC
	Policy Statement, Limitations, Clinical Background	VEISION 30	
	Information, References, and Other Applicable	Not	
	Policies sections. Code-specific prior authorization	implemented -	
	requirements revised in the Applicable Coding	replaced with	
	section.	Version 37	
03/22/21	Review for effective 06/01/21. Industry-wide	06/01/21	Not applicable
	updates to coding in the Applicable Coding section	Version 37	because industry-
04/01/21	and revisions approved in version 36 implemented.	07/01/21	wide code changes
04/01/21	Review for effective date 07/01/21. Criteria revised in the Limitation section. Plan note added in the	07/01/21 Version 38	04/21/21: MPCTAC
	Applicable Coding section and updated References	v C131011 30	
	section.	Not	
		implemented -	

		replaced with	
		Version 39	
06/01/21	Review for an effective date 07/01/21. Industry-	07/01/21	Not applicable
0 0, 0 ., = .	wide code updates made in the Applicable Coding	Version 39	because industry-
	section. Revisions approved in version 38		wide code changes;
	implemented. Updated References section.		06/16/21: MPCTAC
	F		review
10/01/21	Review for effective date 01/01/22. Adopted new	01/01/22	10/20/21: MPCTAC
, ,	medical policy template; removed administrative	Version 40	, ,
	sections, Medical Policy Statement section renamed		
	Clinical Criteria section, and the Limitations section		
	renamed Limitations and Exclusions section. Added		
	New Hampshire Medicare Advantage HMO as an		
	applicable product effective 01/01/22.		
	Administrative changes made to the Policy		
	Summary, Clinical Criteria, and References sections.		
	Industry-wide code updates and other code		
	additions made to the Applicable Coding section.		
	Revised criteria in the Limitations and Exclusions		
01/01/00	section.	0.4/04/00	04.40.400 140.074.0
01/01/22	Review for effective date 04/01/22. Policy	04/01/22	01/19/22: MPCTAC
	Summary and References sections updated.	Version 41	
	Industry-wide code updates and other code		
	additions made to the Applicable Coding section.		
	ICD-10 diagnosis code added for carrier screening		
	for female members (one per lifetime) for CF and SMA. Added male and female carrier screening		
	criteria to the Clinical Criteria section.		
04/01/22	Review for effective date 05/01/22. Administrative	05/01/22	04/20/22: MPCTAC
04/01/22	changes made to the Limitations and Exclusions and	Version 42	04/20/22. WII CTAC
	Applicable Coding sections. Industry-wide code	V C131011 +2	
	updates made to the Applicable Coding section.		
07/01/22	Review for effective date 08/01/22. Industry-wide	08/01/22	07/25/22: MPCTAC
07/01/22	code updates made to the Applicable Coding	Version 43	(electronic vote)
	section. Administrative changes made to the Policy		(
	Summary, Limitations and Exclusions, and		
	References sections.		
08/01/22	Review for policy retired date 11/01/22. Revised the	11/01/22	08/26/22: MPCTAC
	Policy Summary, Clinical Criteria, Limitations and	Version 44	(electronic vote)
	Exclusions, and Applicable Coding sections.		
	InterQual medical necessity criteria and medical		
	policy retired on 11/01/22. Plan prior authorization		
	waivers removed after 10/31/22. AIM medical		
	necessity criteria adopted for genetic testing on		
	11/01/22. Plan prior authorization waivers removed		
	after 10/31/22. AIM prior authorization is required		
	for genetic testing as of 11/01/22, even when		
	applicable codes are not listed in this Plan policy.		



Medical Policy - Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 11/01/22

# **Genetic Testing for Fragile X-Associated Disorders**

**Policy Number**: OCA 3.571

**Version Number**: 26

Policy Retired Date: 11/01/22

## Impacted Products

#### 

- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

Genetic testing for a fragile X-associated disorder is considered medically necessary for the diagnosis of an adult or pediatric member with unexplained intellectual disability, developmental delay, and/or symptoms or findings consistent with an autism spectrum disorder when AIM clinical appropriateness quidelines are met. Prior authorization from AIM Specialty Health is required for genetic testing.

#### Clinical Criteria

No medical policy criteria.

#### **Limitations and Exclusions**

None.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 190.3 includes guidelines for the use of cytogenetic studies. Verify CMS guidelines in effect on

the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for genetic testing, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions
81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (e.g., fragile X mental retardation 2
	[FRAXE]) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles
81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (e.g., fragile X mental retardation 2
	[FRAXE]) gene analysis; characterization of alleles (e.g., expanded size and methylation status)
81243	FMR1 (Fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis;
	evaluation to detect abnormal (e.g., expanded) alleles
81244	FMR1 (Fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis; characterization of alleles (e.g., expanded size and promoter methylation status)
81401	Molecular pathology procedure, Level 2 (e.g., 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using non-sequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (e.g., fragile X mental retardation 2 {FRAXE]), evaluation to detect abnormal (e.g., expanded) alleles
81404	Molecular pathology procedure, Level 5 (e.g., analysis of 2-5 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 6-10 exons, or characterization of a dynamic mutation disorder/triplet repeat by Southern blot analysis)
	NLGN4X (neuroligin 4, X-linked) (e.g., autism spectrum disorders), duplication/deletion analysis
81405	Molecular pathology procedure, Level 6 (e.g., analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons), regionally targeted cytogenomic array analysis

NLGN4X (neuroligin 4, X-linked) (e.g., autism spectrum disorders), full gene
sequence

#### References

American Academy of Neurology (AAN) and Child Neurology Society (CNS). AAN and CNS Guideline Summary for Clinicians. Screening and Diagnosis for Autism.

American Academy of Neurology (AAN) and Child Neurology Society (CNS). Shevell M, Ashwal S, Donley D, Flint J, Gingold M, Hirtz D, Majnemer A, Noetzel M, Sheth RD; Quality Standards Subcommittee of the AAN; Practice Committee of the CNS. Practice parameter: evaluation of the child with global developmental delay: report of the Quality Standards Subcommittee of the American Academy of Neurology and The Practice Committee of the Child Neurology Society. Neurology. 2003 Feb 11; 60(3):367-80.

American Academy of Neurology (AAN). Policy & Guidelines.

American Academy of Pediatrics (AAP). Guideline Summaries.

American Academy of Pediatrics (AAP). Hersh JH, Saul RA. Committee on Genetics. Health Supervision for Children with Fragile X Syndrome. Pediatrics. 2011 May; 127(5):994-1006. doi: 10.1542/peds.2010-3500. Epub 2011 Apr 25. PMID: 21518720.

American Academy of Pediatrics (AAP). Hyman SL, Levy SE, Myers SM, Council on Children with Disabilities, Section on Development and Behavioral Pediatrics. Pediatrics. 2020 Jan;145(1):e20193447. doi: https://doi.org/10.1542/peds.2019-3447.

American Academy of Pediatrics (AAP). Moeschler JB, Shevell M, and Committee on Genetics. Clinical Report: Comprehensive Evaluation of the Child with Intellectual Disability or Global Developmental Delays. Pediatrics. 2014 Sep; 134(3):e903-18. doi: 10.1542/peds.2014-1839. PMID: 25157020.

American College of Medical Genetics and Genomics (ACMG). ACMG Board of Directors. Direct-to-consumer genetic testing: a revised position statement of the ACMGC. Genet Med. 2016 Feb; 18(2):207-8. doi: 10.1038/gim.2015.190. Epub 2015 Dec 17. PMID: 26681314.

American College of Medical Genetics and Genomics (ACMG). Manning M, Hudgins L; Professional Practice and Guidelines Committee ACMG. Array based technology and recommendations for utilization in medical genetics practice for detection of chromosomal abnormalities. Genet Med. 2010 Nov; 12(11):742-5. doi: 10.1097/GIM.0b013e3181f8baad. PMID: 20962661.

American College of Medical Genetics and Genomics (ACMG). Monaghan KG, Lyon E, Spector EB; ACMG. ACMG Standards and Guidelines for fragile X testing: a revision to the disease-specific supplements to the Standards and Guidelines for Clinical Genetics Laboratories of the American

College of Medical Genetics and Genomics. Genet Med. 2013 Jul; 15(7):575-86. doi: 10.1038/gim.2013.61. Epub 2013 Jun 13. PMID: 23765048.

American College of Medical Genetics and Genomics (ACMG). Practice Guidelines.

American College of Medical Genetics and Genomics (ACMG). Schaefer GB, Mendelsohn NJ; Professional Practice and Guidelines Committee. Clinical genetics evaluation in identifying the etiology of autism spectrum disorders: 2013 guideline revisions. Genet Med. 2013 May; 15(5):399-407. doi: 10.1038/gim.2013.32. Epub 2013 Mar 21. Erratum in: Genet Med. 2013. Aug; 15(8):669. PMID: 23519317.

The American College of Obstetricians and Gynecologists (ACOG). ACOG's Clinical Guidelines.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Carrier Screening in the Age of Genomic Medicine. Number 690. 2017 Mar.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Carrier Screening for Genetic Conditions. Number 691. 2017 Mar. Reaffirmed 2020.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Counseling About Genetic Testing and Communication of Genetic Test Results. Number 693. 2017 April. Reaffirmed 2020.

The American College of Obstetricians and Gynecologists (ACOG). Committee Opinion. Primary Ovarian Insufficiency in Adolescents and Young Women. Number 605. Reaffirmed 2022.

The American College of Obstetricians and Gynecologists (ACOG) and Society for Maternal–Fetal Medicine. ACOG Committee on Genetics and Society for Maternal–Fetal Medicine's Publication Committee. Microarrays and Next–Generation Sequencing Technology: The Use of Advanced Genetic Diagnostic Tools in Obstetrics and Gynecology. ACOG Committee Opinion. Number 682. 2016 Dec. Reaffirmed 2020.

Anderson JA, Hayeems RZ, Shuman C, Szego MJ, Monfared N, Bowdin S, Zlotnik Shaul R, Meyn MS. Predictive genetic testing for adult-onset disorders in minors: a critical analysis of the arguments for and against the 2013 ACMG guidelines. Clin Genet. 2015 Apr; 87(4):301-10. doi: 10.1111/cge.12460. Epub 2014 Oct 7. PMID: 25046648.

Basehore MJ, Friez MJ. Molecular analysis of fragile X syndrome. Curr Protoc Hum Genet. 2014 Jan 21;80:Unit 9.5. doi: 10.1002/0471142905.hg0905s63. PMID: 19806593.

Budworth H, McMurray CT. A Brief History of Triplet Repeat Disorders. Methods Mol Biol. 2013:1010:3-17. doi: 10.1007/978-1-62703-411-1\_1. PMID: 23754215.

Centers for Disease Control and Prevention (CDC). Autism Spectrum Disorder (ASD).

Centers for Medicare & Medicaid Services (CMS). Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N). 2018 Mar 16.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Centers for Medicare & Medicaid Services (CMS). Update on Mapping the Landscape of Genetic Tests for Non-Cancer Diseases/Conditions. Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. Final Report. 2012 May 22.

Child Neurology Society (CNS). Practice Parameters.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. Mandatory Benefits Guide. Consumer Affairs and Business Regulation.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts, MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

European Molecular Genetics Quality Network (EMQN). Biancalana V, Glaeser D, McQuaid S, Steinbach P. EMQN best practice guidelines for the molecular genetic testing and reporting of fragile X syndrome and other fragile X-associated disorders. Eur J Hum Genet. 2015 Apr;23(4):417-25. doi: 10.1038/ejhg.2014.185. Epub 2014 Sep 17. PMID: 25227148.

Haga SB, Burke W, Agans R. Primary-care physicians' access to genetic specialists: an impediment to the routine use of genomic medicine? Genet Med. 2013 Jul;15(7):513-4. doi: 10.1038/gim.2012.168. Epub 2013 Jan 10. PMID: 23306802.

Hagerman RJ, Berry-Kravis E, Hazlett HC, Bailey DB Jr, Moine H, Kooy RF, Tassone F, Gantois I, Sonenberg N, Mandel JL, Hagerman PJ. Fragile X Syndrome. Nat Rev Dis Primers. 2017 Sep 29;3:17065. doi: 10.1038/nrdp.2017.65. PMID: 28960184.

Hayes. Clinical Utility Evaluation. Clinical Utility of Genetic Testing to Aid in the Evaluation of Idiopathic Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Aug 22. Annual Review 2021 Aug 09.

Hayes. Clinical Utility Evaluation. Clinical Utility of Genetic Testing to Aid in the Evaluation of Syndromic or Complex Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Aug 22. Annual Review 2021 Aug 09.

Hayes. Clinical Utility Evaluation. Clinical Utility of Genetic Testing for Primary Diagnosis of Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Jun 29. Annual Review 2021 Aug 09.

Hayes. Clinical Utility Evaluation. Clinical Utility of Prenatal Genetic Testing for Autism Spectrum Disorder. Dallas, TX: Hayes; 2018 Sep 28. Annual Review 2021 Aug 20.

Hayes. Clinical Utility Evaluation. Genetic Testing For Fragile X-Associated Primary Ovarian Insufficiency (FXPOI). Dallas, TX: Hayes; 2017 Mar 9. Annual Review 2021 Mar 31.

Hayes. Clinical Utility Evaluation. Genetic Testing For Fragile X-Associated Tremor/Ataxia Syndrome (FXTAS). Dallas, TX: Hayes; 2017 Mar 30. Annual Review 2021 Mar 31.

Hayes. Clinical Utility Evaluation. Genetic Testing For Fragile X Syndrome. Dallas, TX: Hayes; 2017 Feb 16. Annual Review 2021 Mar 31.

Hayes. Laboratory Test Insights. Fragile X-Associated Tremor/Ataxia Syndrome (FXTAS): CGG Repeat Analysis. Dallas, TX: Hayes; 2018 Dec 6.

Hayes. Precision Medicine Insights. Expanded Carrier Screening. Dallas, TX: Hayes; 2020 Aug 17. Hersh JH, Saul RA; Committee on Genetics. Health supervision for children with fragile X syndrome. Pediatrics. 2011 May; 127(5):994-1006. doi: 10.1542/peds.2010-3500. Epub 2011 Apr 25. PMID: 21518720.

International Society of Psychiatric Genetics (ISPG). Genetic Testing and Psychiatric Disorders. 2019 Mar 11.

Lozao R, Azarang A, Wilaisakditipakorn T, Hagerman R. Fragile X syndrome: A review of clinical management. Intractable Rare Dis Res. 2016 Aug;5(3):145–57. doi: 10.5582/irdr.2016.01048. PMID: 27672537.

Maortua H, Martínez-Bouzas C, García-Ribes A, Martínez MJ, Guillen E, Domingo MR, Calvo MT, Guitart M, Gabau E, Botella MP, Gener B, Rubio I, López-Aríztegui MA, Tejada MI. MECP2 gene study in a large cohort: testing of 240 female patients and 861 healthy controls (519 females and 342 males).

J Mol Diagn. 2013 Sep; 15(5):723-9. doi: 10.1016/j.jmoldx.2013.05.002. Epub 2013 Jun 26. PMID: 23810759.

McGrew SG, Peters BR, Crittendon JA, Veenstra-Vanderweele J. Diagnostic yield of chromosomal microarray analysis in an autism primary care practice: which guidelines to implement? J Autism Dev Disord. 2012 Aug;42(8):1582-91. doi: 10.1007/s10803-011-1398-3. PMID: 22089167.

Miller DT, Adam MP, Aradhya S, Biesecker LG, Brothman AR, Carter NP, Church DM, Crolla JA, Eichler EE, Epstein CJ, Faucett A, Feuk L, Friedman JM, Hamosh A, Jackson L, Kaminsky EB, Kok K, Krantz ID, Kuhn RM, Lee C, Ostell JM, Rosenberg C, Scherer SW, Spinner NB, Stavropoulos DJ, Tepperberg JH,

Thorland EC, Vermeesch JR, Waggoner DJ, Watson MS, Martin CL, Ledbetter DH. Consensus Statement: Chromosomal Microarray Is a First-Tier Clinical Diagnostic Test for Individuals with Developmental Disabilities or Congenital Anomalies. Am J Hum Genet. 2010 May 14;86(5):749-64. doi: 10.1016/j.ajhg.2010.04.006. PMID: 20466091.

Moeschler JB, Shevell M; Committee on Genetics. Comprehensive evaluation of the child with intellectual disability or global developmental delays. Pediatrics. 2014 Sep;134(3):e903-18. doi: 10.1542/peds.2014-1839. PMID: 25157020.

National Human Genome Research Institute. National Institutes of Health. Health Professional Genetics Resources Online.

National Institute for Health and Care Excellence (NICE). Autism spectrum disorder in under 19s: recognition, referral and diagnosis. CG128. 2011 Sep. Last Updated 2017 Dec 20.

National Society of Genetic Counselors (NSGC). Finucane B, Abrams L, Cronister A, Archibald AD, Bennett RL, McConkie-Rosell A. Genetic Counseling and Testing for FMR1 Gene Mutations: Practice Guidelines of the NSGC. J Genet Couns. 2012 Dec; 21(6):752-60. doi: 10.1007/s10897-012-9524-8. Epub 2012 Jul 14. PMID: 22797890.

National Society of Genetic Counselors (NSGC). NSGC Practice Guidelines.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Saul RA, Tarleton JC. FMR1-Related Disorders. In: Adam MP, Ardinger HH, Pagon RA, Wallace SE, Bean LJH, Stephens K, Amemiya A, editors. GeneReviews®[Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. 1998 Jun 16 [updated 2012 Apr 26]. PMID: 20301558.

Shen Y, Dies KA, Holm IA, Bridgemohan C, Sobeih MM, Caronna EB, Miller KJ, Frazier JA, Silverstein I, Picker J, Weissman L, Raffalli P, Jeste S, Demmer LA, Peters HK, Brewster SJ, Kowalczyk SJ, Rosen-

Sheidley B, McGowan C, Duda AW 3rd, Lincoln SA, Lowe KR, Schonwald A, Robbins M, Hisama F, Wolff R, Becker R, Nasir R, Urion DK, Milunsky JM, Rappaport L, Gusella JF, Walsh CA, Wu BL, Miller DT; Autism Consortium Clinical Genetics/DNA Diagnostics Collaboration. Clinical genetic testing for patients with autism spectrum disorders. Pediatrics. 2010 Apr; 125(4):e727-35. doi: 10.1542/peds.2009-1684. Epub 2010 Mar 15. PMID: 20231187.

Society of Obstetricians and Gynecologists of Canada (SOGC) and Canadian College of Medical Geneticists (CCMG). Wilson RD, De Bie I, Armour CM, Brown RN, Campagnolo C, Carroll JC, Okun N, Nelson T, Zwingerman R, Audibert F, Brock JA, Brown RN, Campagnolo C, Carroll JC, De Bie I, Johnson JA, Okun N, Pastruck M, Vallée-Pouliot K, Wilson RD, Zwingerman R, Armour C, Chitayat D, De Bie I, Fernandez S, Kim R, Lavoie J, Leonard N, Nelson T, Taylor S, Van Allen M, Van Karnebeek C. Joint SOGC-CCMG Opinion for Reproductive Genetic Carrier Screening: An Update for All Canadian Providers of Maternity and Reproductive Healthcare in the Era of Direct-to-Consumer Testing. J Obstet Gynaecol Can. 2016 Aug;38(8):742-762.e3. doi: 10.1016/j.jogc.2016.06.008. PMID: 27638987.

Tarpey PS, Smith R, Pleasance E, Whibley A, Edkins S, Hardy C, O'Meara S, Latimer C, Dicks E, Menzies A, Stephens P, Blow M, Greenman C, Xue Y, Tyler-Smith C, Thompson D, Gray K, Andrews J, Barthorpe S, Buck G, Cole J, Dunmore R, Jones D, Maddison M, Mironenko T, Turner R, Turrell K, Varian J, West S, Widaa S, Wray P, Teague J, Butler A, Jenkinson A, Jia M, Richardson D, Shepherd R, Wooster R, Tejada MI, Martinez F, Carvill G, Goliath R, de Brouwer AP, van Bokhoven H, Van Esch H, Chelly J, Raynaud M, Ropers HH, Abidi FE, Srivastava AK, Cox J, Luo Y, Mallya U, Moon J, Parnau J, Mohammed S, Tolmie JL, Shoubridge C, Corbett M, Gardner A, Haan E, Rujirabanjerd S, Shaw M, Vandeleur L, Fullston T, Easton DF, Boyle J, Partington M, Hackett A, Field M, Skinner C, Stevenson RE, Bobrow M, Turner G, Schwartz CE, Gecz J, Raymond FL, Futreal PA, Stratton MR. A systematic, large-scale resequencing screen of X-chromosome coding exons in mental retardation. Nat Genet. 2009 May; 41(5):535-43. doi: 10.1038/ng.367. Epub 2009 Apr 19. PMID: 19377476.

Tassone F. Newborn screening for fragile X syndrome. JAMA Neurol. 2014 Mar; 71(3):355-9. doi: 10.1001/jamaneurol.2013.4808. PMID: 24395328.

Tsafrir A, Altarescu G, Margalioth E, Brooks B, Renbaum P, Levy-Lahad E, Rabinowitz R, Varshaver I, Eldar-Geva T. PGD for fragile X syndrome: ovarian function is the main determinant of success. Hum Reprod. 2010 Oct;25(10):2629-36. doi: 10.1093/humrep/deq203. Epub 2010 Aug 16. PMID: 20713414.

#### **Next Review Date**

Not applicable

#### **Retired Date**

11/01/22

## **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	03/01/14 Version 1	Director of Medical Policy as Chair of	MPCTAC and QIC
Internal Approval:		MPCTAC	
05/18/11: Medical Policy, Criteria, and			
Technology Assessment Committee			
(MPCTAC)			
06/30/11: Quality Improvement			
Committee (QIC)			

<sup>\*</sup>Effective date for QHP commercial product: 01/01/12

Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisio	ns History		
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
01/01/20	Review for effective date 02/01/20. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	02/01/20 Version 15	01/15/20: MPCTAC
02/01/21	Review for effective date 03/01/21. Updated the Policy Statement and References sections. Administrative changes made to the Applicable Coding section.	03/01/21 Version 16	02/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and	12/01/21 Version 17	11/17/21: MPCTAC

<sup>\*</sup>Effective date for NH Medicaid product: 01/01/13

<sup>\*</sup>Effective date for Senior Care Options product: 01/01/16

<sup>\*</sup>Effective date for NH Medicare Advantage HMO product: 01/01/22

	Exclusions, Applicable Coding, and References sections.		
12/01/21	Review for effective date 01/01/22. Industry-wide code revision made to the Applicable Coding section.	01/01/22 Version 18	Not applicable because industry-wide code revision; 12/15/21: MPCTAC review
01/01/22	Review for effective date 02/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, and References sections.	02/01/22 Version 19	01/19/22: MPCTAC
12/01/11	Added new 2012 codes.	Version 2	12/01/11: MPCTAC 12/01/11: QIC
05/01/12	References updated, applicable CPT codes added, and clinical guidelines revised to clarify that a first degree relative is a biological parent, biological child, or biological sibling (rather than parent, child, or sibling).	Version 3	05/16/12: MPCTAC 06/27/12: QIC
07/30/12	Off cycle review for Well Sense Health Plan. Revised Summary, Medical Policy Statement, and Definitions sections.	Version 4	08/03/12: MPCTAC 09/05/12: QIC
09/01/12	References updated and referenced  Experimental and Investigational Treatment and the Preimplantation Genetic Testing policies.	Version 5	09/19/12: MPCTAC 10/24/12: QIC
08/14/13 and 08/15/13	Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 09/01/12 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 09/19/12 and QIC on 10/24/12 for applicable Plan products.	Version 6	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC
10/01/13 and 11/01/13	Review for effective date 03/01/14. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised criteria in Medical Policy Statement section. Revised language in Applicable Coding section and revised applicable code list.	03/01/14 Version 7	10/16/13: MPCTAC 11/20/13: MPCTAC 12/19/13: QIC
01/30/14	Review for effective date 04/01/14. Added ICD10 diagnosis code equivalents of existing ICD9 diagnosis codes.	04/01/14 Version 8	01/27/14: MPCTAC 01/30/14: QIC
07/01/14	Review for effective date 10/01/14. Updated Summary section and introductory paragraph in the Applicable Coding section. Added CPT	10/01/14 Version 9	07/21/14: MPCTAC (electronic vote) 07/24/14: QIC (electronic vote)

	codes 81404, 81405, and 88248 to the		
11/01/14	applicable code list.  Review for effective date 03/01/15. Added CPT code 81401 as an applicable code.  Updated criteria in the Medical Policy Statement and Limitations sections. Revised Summary, Definitions, Clinical Background Information, and References sections.  Changed review calendar.	03/01/15 Version 10	11/19/14: MPCTAC 12/10/14: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.	01/01/16 Version 11	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
01/01/16	Review for effective date 05/01/16. Revised language in the Applicable Coding section and updated list of waived pregnancy diagnosis codes and corresponding procedure codes. Updated Summary, Definitions, Clinical Background Information, and References sections. Revised criteria in the Medical Policy Statement and Limitations sections.	05/01/16 Version 12	01/20/16: MPCTAC 02/10/16: QIC
09/28/16	Review for effective date 11/01/16. Administrative changes made to clarify language related to gender. Added definitions.	11/01/16 Version 13	09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
01/01/17	Review for effective date 05/01/17. Revised ICD-10 pregnancy diagnosis codes in the Applicable Coding section. Updated criteria in the Limitations section. Revised Summary, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement section.	05/01/17 Version 14	01/18/17: MPCTAC 02/08/17: QIC
08/09/17	Revision effective 10/01/17. Industry-wide updates to the ICD-10 diagnosis codes included in the Applicable Coding section.	10/01/17 Version 15	Not applicable because industry-wide updates to ICD-10 diagnosis codes.
01/01/18	Review for effective date 02/01/18. Updated Summary, References, and Reference to Applicable Laws and Regulations sections. Administrative changes made to the Medical Policy Statement and Applicable Coding sections.	02/01/18 Version 16	01/17/18: MPCTAC
01/01/19	Review for effective date 04/01/19. Industry-wide code updates made in the Applicable Coding section with revised Plan notes.	04/01/19 Version 17	01/16/19: MPCTAC

	Administrative changes made to the Policy Summary, Limitations, Definitions, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement section.		
02/01/19	Review fore effective date 04/01/19. Administrative changes made to the Medical Policy Statement section to clarify guidelines. Updated Plan notes in the Applicable Coding section (without revising the applicable code list). Revised the Policy Summary and Other Applicable Policies sections.	04/01/19 Version 18	02/20/19: MPCTAC
06/01/19	Review for effective date 07/01/19. Revised language in the Policy Summary, Medical Policy Statement, and Applicable Coding section to clarify that the prior authorization waiver for the specified primary pregnancy diagnosis codes only applies to genetic tests ordered, administered, and processed by participating providers and participating laboratories.	07/01/19 Version 19	06/19/19: MPCTAC
07/01/19	Review for effective date 10/01/19. Medical policy criteria retired and applicable InterQual® criteria adopted. Administrative changes made to the Policy Summary, Description of Item or Service, and Other Applicable Policies sections. Updated Plan notes in the Applicable Coding section. Maintained diagnosis code list for prior authorization pregnancy waiver and updated corresponding procedure code list.	10/01/19 Version 20	07/17/19: MPCTAC
09/01/19	Review for effective date 12/01/19. Added high-risk diagnosis code in the Applicable Coding section.	12/01/19 Version 21	09/18/19: MPCTAC
01/01/20	Review for effective date 02/01/20. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	02/01/20 Version 22	01/15/20: MPCTAC
02/01/21	Review for effective date 03/01/21. Updated the Policy Statement and References sections. Administrative changes made to the Applicable Coding section.	03/01/21 Version 23	02/17/21: MPCTAC

11/01/21	Review for effective date 12/01/21. Adopted	12/01/21	11/17/21: MPCTAC
	new medical policy template; removed	Version 24	
	administrative sections, the Medical Policy		
	Statement section renamed the Clinical		
	Criteria section, and the Limitations section		
	renamed the Limitations and Exclusions		
	section. Added Well Sense Medicare		
	Advantage HMO as an applicable product		
	effective 01/01/22. Administrative changes		
	made to the Policy Summary, Applicable		
	Coding, and References sections.		
01/01/22	Review for effective date 02/01/22.	02/01/22	01/19/22: MPCTAC
	Administrative changes made to the Policy	Version 25	
	Summary, Clinical Criteria, Limitations and		
	Exclusions, and References sections.		
08/01/22	Review for policy retired date 11/01/22.	11/01/22	08/26/22: MPCTAC
	Revised the Policy Summary, Clinical Criteria,	Version 26	(electronic vote)
	Limitations and Exclusions, and Applicable		
	Coding sections. InterQual medical necessity		
	criteria and medical policy retired on 11/01/22.		
	Plan prior authorization waivers removed after		
	10/31/22. AIM medical necessity criteria		
	adopted for genetic testing on 11/01/22. Plan		
	prior authorization waivers removed after		
	10/31/22. AIM prior authorization is required		
	for genetic testing as of 11/01/22, even when		
	applicable codes are not listed in this Plan		
	policy.		



Medical Policy - Policy Retired and AIM Criteria Adopted as of 11/01/22

## **Genetic Testing for Hereditary Thrombophilia**

**Policy Number**: OCA 3.728

Version Number: 14

Policy Retired Date: 11/01/22

## **Impacted Products**

#### 

- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers genetic testing for hereditary thrombophilia to be medically necessary to identify predisposition to thrombosis if AIM clinical appropriateness guidelines are met. Prior authorization from AIM Specialty Health is required for genetic testing.

#### **Clinical Criteria**

No medical policy criteria.

#### **Limitations and Exclusions**

None.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 190.3 includes guidelines for the use of cytogenetic studies. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested

service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for genetic testing, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions
81240	F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis, 20210G>A variant
81241	F5 (coagulation factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant

#### References

Abu-Asab NS, Ayesh SK, Ateeq RO, Nassar SM, El-Sharif WA. Association of Inherited Thrombophilia with Recurrent Pregnancy Loss in Palestinian Women. Obstet Gynecol Int. 2011;2011:689684. doi: 10.1155/2011/689684. PMID: 21765836.

American College of Medical Genetics and Genomics (ACMG). ACMG Board of Directors. Direct-to-consumer genetic testing: a revised position statement of the ACMGC. Genet Med. 2016 Feb;18(2):207-8. doi: 10.1038/gim.2015.190. Epub 2015 Dec 17. PMID: 26681314.

American College of Medical Genetics and Genomics (ACMG). ACMG News. ACMG Provides Recommendations on Genetic Testing Through the Choosing Wisely® Campaign. 2015 Jul 10.

American College of Medical Genetics and Genomics (ACMG). Grody WW, Griffin JH, Taylor AK, Korf BR, Heit JA; ACMG Factor V Leiden Working Group. ACMG Consensus Statement on Factor V Leiden Mutation Testing. 2007 May 14.

American College of Medical Genetics and Genomics (ACMG). Hickey SE, Curry CJ, Toriello HV. ACMG Practice Guideline: lack of evidence for MTHFR polymorphism testing. Genet Med. 2013 Feb;15(2):153-6. doi: 10.1038/gim.2012.165. Epub 2013 Jan 3. PMID: 23288205.

American College of Medical Genetics and Genomics (ACMG). Practice Guidelines.

American College of Medical Genetics and Genomics (ACMG). Zhang S, Taylor AK, Huang X, Luo B, Spector EB, Fang P, Richards S, ACMG Laboratory Quality Assurance Committee. ACMG Standards and Guidelines. Venous thromboembolism laboratory testing (factor V Leiden and factor II c.\*97G>A), 2018 update: a technical standard of the ACMG. Genet Med. 2018 Oct 5;20:1489–98.

The American College of Obstetricians and Gynecologists (ACOG). ACOG's Clinical Guidelines

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 197: Inherited Thrombophilias in Pregnancy. Obstet Gynecol. 2018 Jul;132(1):e18-e34. doi: 10.1097/AOG.0000000000002703. PMID: 29939939.

The American College of Obstetricians and Gynecologists (ACOG). Thromboembolism and Inherited Thrombophilias in Pregnancy: Resource Overview.

American Heart Association (AHA)/American Stroke Association (ASA). Ferriero DM, Fullerton HJ, Bernard TJ, Billinghurst L, Daniels SR, DeBaun MR, deVeber G, Ichord RN, Jordan LC, Massicotte P, Meldau J, Roach ES, Smith ER, American Heart Association Stroke Council and Council on Cardiovascular and Stroke Nursing. Management of Stroke in Neonates and Children: A Scientific Statement from the AHA/ASA. Stroke. 2019;50(3):e51. PMID: 30686119.

American Society of Hematology (ASH). Choosing Wisely. 2013 Dec 4.

American Society for Reproductive Medicine (ASRM). The Practice Committee of ASRM. Evaluation and treatment of recurrent pregnancy loss: a committee opinion. Fertil Steril. 2012 Nov;98(5):1103-11. doi: 10.1016/j.fertnstert.2012.06.048. Epub 2012 Jul 24. PMID: 22835448.

American Society for Reproductive Medicine (ASRM). Practice Committee Documents.

Ashraf N, Visweshwar N, Jaglal M, Sokol L, Laber D. Evolving paradigm in thrombophilia screening. Blood Coagul Fibrinolysis. 2019 May 24. doi: 10.1097/MBC.000000000000809. PMID: 31145103.

Battinelli EM, Marshall A, Connors JM. The role of thrombophilia in pregnancy. Thrombosis. 2013;2013:516420. doi: 10.1155/2013/516420. Epub 2013 Dec 18. PMID: 24455235.

Bauer KA. Factor V Leiden and activated protein C resistance. UpToDate. 2021 Feb 23.

Bauer KA. Gene test interpretation: Factor V Leiden. UpToDate. 2021 Apr 22

Bauer KA. Protein C deficiency. UpToDate. 2021 Nov 16.

Bauer KA. Protein S deficiency. UpToDate. 2021 Nov 16.

Bauer KA. Prothrombin G20210A. UpToDate. 2021 Dec 20.

Bauer KA. Screening for inherited thrombophilia in asymptomatic adults. UpToDate. 2021 Aug 16.

Beckman MG, Hooper WC, Critchley SE, Ortel TL. Venous thromboembolism: a public health concern. Am J Prev Med. 2010 Apr;38(4 Suppl):S495-501. doi: 10.1016/j.amepre.2009.12.017. PMID: 20331949.

Bezemer ID, Doggen CJ, Vos HL, Rosendaal FR. No association between the common MTHFR 677C->T polymorphism and venous thrombosis: results from the MEGA study. Arch Intern Med. 2007 Mar 12;167(5):497-501. doi: 10.1001/archinte.167.5.497. PMID: 17353498.

Byrnes JR, Wolberg AS. Newly-Recognized Roles of Factor XIII in Thrombosis. Semin Thromb Hemost. 2016 Jun;42(4):445-54. doi: 10.1055/s-0036-1571343. Epub 2016 Apr 7. PMID: 27056150.

Campbell RA, Machlus KR, Wolberg AS. Smoking out the cause of thrombosis. Arterioscler Thromb Vasc Biol. 2010 Jan;30(1):7-8. doi: 10.1161/ATVBAHA.109.198051. PMID: 20018940.

Carroll BJ, Piazza G. Hypercoagulable states in arterial and venous thrombosis: When, how and who to test? Vasc Med. 2018 Aug;23(4):388-99. DOI: 10.1177/1358863X18755927. PMID: 30045685.

Centers for Disease Control and Prevention (CDC). Chen B, Gagnon M, Shahangian S, Anderson NL, Howerton DA, Howerton DA, Boone DJ. Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions. MMWR 2009;58(No. RR-6):1-43.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Cytogenetic Studies (190.3). Effective Date 1998 Jul 16.

Centers for Medicare & Medicaid Services (CMS). Update on Mapping the Landscape of Genetic Tests for Non-Cancer Diseases/Conditions. Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. Final Report. 2012 May 22.

Chaturvedi S, McCrae KR. The antiphospholipid syndrome: still an enigma. Hematology Am Soc Hematol Educ Program. 2015;2015:53–60. doi: 10.1182/asheducation-2015.1.53. PMID: 26637701.

College of American Pathologists (CAP). CAP Guidelines.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Genetic Testing for Hereditary Thrombophilia

Connors JM. Thrombophilia Testing and Venous Thrombosis. N Engl J Med. 2017 Sep 21;377(12):1177-87. doi: 10.1056/NEJMra1700365. PMID: 28930509.

Cox N, Johnson SA, Vazquez S, Fleming RP, Rondina MT, Kaplan D, Chauv S, Fontaine GV, Stevens SM, Woller S, Witt DM. Patterns and Appropriateness of Thrombophilia Testing in an Academic Medical Center. J Hosp Med. 2017 Sep;12(9):705-9. doi: 10.12788/jhm.2804. PMID: 28914273.

Croles FN, Nasserinejad K, Duvekot JJ, Kruip MJ, Meijer K, Leebeek FW. Pregnancy, thrombophilia, and the risk of a first venous thrombosis: systematic review and bayesian meta-analysis. BMJ. 2017 Oct 26;359:j4452. doi: 10.1136/bmj.j4452. PMID: 29074563.

De Stefano V, Rossi E. Testing for inherited thrombophilia and consequences for antithrombotic prophylaxis in patients with venous thromboembolism and their relatives. A review of the Guidelines from Scientific Societies and Working Groups. Thromb Haemost. 2013 Oct;110(4):697-705. doi: 10.1160/TH13-01-0011. Epub 2013 Jul 11. PMID: 23846575.

Dizon-Townson D, Miller C, Momirova V, Sibai B, Spong CY, Wendel G Jr, Wenstrom K, Samuels P, Caritis S, Sorokin Y, Miodovnik M, O'Sullivan MJ, Conway D, Wapner RJ, Gabbe SG. Impact of smoking during pregnancy on functional coagulation testing. Am J Perinatol. 2012 Mar;29(3):225-30. doi: 10.1055/s-0031-1285097. Epub 2011 Aug 4. PMID: 21818732.

Dizon-Townson D, Miller C, Sibai B, Spong CY, Thom E, Wendel G Jr, Wenstrom K, Samuels P, Cotroneo MA, Moawad A, Sorokin Y, Meis P, Miodovnik M, O'Sullivan MJ, Conway D, Wapner RJ, Gabbe SG; National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. The relationship of the factor V Leiden mutation and pregnancy outcomes for mother and fetus. Obstet Gynecol. 2005 Sep;106(3):517-24. PMID: 16135581.

El-Galaly TC, Kristensen SR, Overvad K, Steffensen R, Tjønneland A, Severinsen MT. Interaction between blood type, smoking and factor V Leiden mutation and risk of venous thromboembolism: a Danish case-cohort study. J Thromb Haemost. 2012 Oct;10(10):2191-3. doi: 10.1111/j.1538-7836.2012.04772.x. PMID: 22577971.

El Hachem H, Crepaux V, May-Panloup P, Descamps P, Legendre G, Bouet PE. Recurrent pregnancy loss: current perspectives. Int J Womens Health. 2017 May 17;9:331-345. doi: 10.2147/IJWH.S100817. eCollection 2017. PMID: 28553146.

Enga KF, Braekkan SK, Hansen-Krone IJ, le Cessie S, Rosendaal FR, Hansen JB. Cigarette smoking and the risk of venous thromboembolism: the Tromsø Study. J Thromb Haemost. 2012 Oct;10(10):2068-74. doi: 10.1111/j.1538-7836.2012.04880.x. PMID: 22882779.

European Society of Human Reproduction and Embryology (ESHRE). ESHRE Guideline Group on Recurrent Pregnancy Loss (RPL), Atik RB, Christiansen OB, Elson J, Kolte AM, Lewis S, Middeldorp S,

Nelen W, Peramo B, Quenby S, Vermeulen N, Goddijin M. ESHRE guideline: recurrent pregnancy loss. Human Reproductive Open. 2018 Apr 6;2018(2):1-12. doi:10.1093/hropen/hoy004. PMID: 31486805.

Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group. Recommendations from the EGAPP Working Group. Does the use of Oncotype DX tumor gene expression profiling to guide treatment decisions improve outcomes in patients with breast cancer? Genet Med. 2016 Aug;18(8):770–9. doi: 10.1038/gim.2015.173. Epub 2015 Dec 17. PMID: 26681310. Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group. Recommendations from the EGAPP Working Group. Routine testing for Factor V Leiden (R506Q) and prothrombin (20210G>A) mutations in adults with a history of idiopathic venous thromboembolism and their adult family members. Genet Med. 2011 Jan;13(1):67–76. doi: 10.1097/ GIM.0b013e3181fbe46f. PMID: 21150787.

Fox C, Smith SE. Ischemic stroke in children: Clinical presentation, evaluation, and diagnosis. UpToDate. 2020 Oct 1.

Gelfand AA, Croen LA, Torres AR, Wu YW. Genetic Risk Factors for Perinatal Arterial Ischemic Stroke. Pediatr Neurol. 2013 Jan;48(1):36–41. doi: 10.1016/j.pediatrneurol.2012.09.016. PMID: 23290018.

Genetics Home Reference. U.S. National Library of Medicine. Help Me Understand Genetics.

Genetic Home Reference. U.S. National Library of Medicine. What are Single Nucleotide Polymorphisms (SNPs)?

Genetics Home Reference. U.S. National Library of Medicine. What are the types of genetic tests?

Genetics Home Reference, U.S. National Library of Medicine. What is genetic testing?

Germain M, Chasman DI, de Haan H, Tang W, Lindström S, Weng LC, de Andrade M, de Visser MC, Wiggins KL, Suchon P, Saut N, Smadja DM, Le Gal G, van Hylckama Vlieg A, Di Narzo A, Hao K, Nelson CP, Rocanin-Arjo A, Folkersen L, Monajemi R, Rose LM, Brody JA, Slagboom E, Aïssi D, Gagnon F, Deleuze JF, Deloukas P, Tzourio C, Dartigues JF, Berr C, Taylor KD, Civelek M, Eriksson P; Cardiogenics Consortium., Psaty BM, Houwing-Duitermaat J, Goodall AH, Cambien F, Kraft P, Amouyel P, Samani NJ, Basu S, Ridker PM, Rosendaal FR, Kabrhel C, Folsom AR, Heit J, Reitsma PH, Trégouët DA, Smith NL, Morange PE. Meta-analysis of 65,734 individuals identifies TSPAN15 and SLC44A2 as two susceptibility loci for venous thromboembolism. Am J Hum Genet. 2015 Apr 2;96(4):532-42. PMID: 25772935.

German Society of Gynecology and Obstetrics (DGGG), the Austrian Society of Gynecology and Obstetrics (ÖGGG) and the Swiss Society of Gynecology and Obstetrics (SGGG). Toth B, Würfel W, Bohlmann M, Zschocke J, Rudnik-Schöneborn S, Nawroth F, Schleußner E, Rogenhofer N, Wischmann T, von Wolff M, Hancke K, von Otte S, Kuon R, Feil K, Tempfer C. Recurrent Miscarriage: Diagnostic and Therapeutic Procedures. Guideline of the DGGG, OEGGG and SGGG (S2k-Level, AWMF Registry

Number 015/050). Geburtshilfe Frauenheilkd. 2018 Apr;78(4):364-381. doi: 10.1055/a-0586-4568. Epub 2018 Apr 27. PMID: 29720743.

Ghaznavi H, Soheili Z, Samiei S, Soltanpour MS. Association of Methylenetetrahydrofolate Reductase C677T Polymorphism with Hyperhomocysteinemia and Deep Vein Thrombosis in the Iranian Population. Vasc Specialist Int. 2015 Dec;31(4):109–14. doi: 10.5758/vsi.2015.31.4.109. Epub 2015 Dec 31. PMID: 26719836.

Gupta A, Sarode R, Nagalla S. Thrombophilia Testing in Provoked Venous Thromboembolism: A Teachable Moment. JAMA Intern Med. 2017 Aug 1;177(8):1195-1196. doi: 10.1001/jamainternmed.2017.1815. PMID: 28586816.

Hayes. Clinical Utility Evaluation. Genetic Testing for Common Forms of Hereditary Thrombophilia in Adults with Unprovoked Venous Thromboembolism. Dallas, TX: Hayes; 2019 May 21. Annual Review 2021 Jun 28.

Hayes. Clinical Utility Evaluation. Genetic Testing for Common Forms of Hereditary Thrombophilia in Pediatric Patients with Unprovoked Venous Thromboembolism. Dallas, TX: Hayes; 2019 Aug 1. Annual Review 2021 Jun 28.

Hayes. Clinical Utility Evaluation. Genetic Testing for Factor V Leiden in Women with Unexplained Recurrent Pregnancy Loss. Dallas, TX: Hayes; 2018 Dec 19. Annual Review 2020 Nov 19.

Heleen van Ommen C, Middeldorp S. Thrombophilia in childhood: to test or not to test. Semin Thromb Hemost. 2011 Oct;37(7):794-801. doi: 10.1055/s-0031-1297170. Epub 2011 Dec 20. PMID: 22187402.

Hicks LK, Bering H, Carson KR, Kleinerman J, Kukreti V, Ma A, Mueller BU, O'Brien SH, Pasquini M, Sarode R, Solberg L Jr, Haynes AE, Crowther MA. The ASH Choosing Wisely®campaign: five hematologic tests and treatments to question. Blood. 2013 Dec 5;122(24):3879-83. doi: 10.1182/blood-2013-07-518423. Epub 2013 Dec 4. PMID: 24307720.

Hiltunen L, Rautanen A, Rasi V, Kaaja R, Kere J, Krusius T, Vahtera E, Paunio M. An unfavorable combination of Factor V Leiden with age, weight, and blood group causes high risk of pregnancy-associated venous thrombosis: a population-based nested case-control study. Thromb Res. 2007;119(4):423-32. Epub 2006 Jun 12. PMID: 16765424.

Horton AL, Momirova V, Dizon-Townson D, Wenstrom K, Wendel G, Samuels P, Sibai B, Spong CY, Cotroneo M, Sorokin Y, Miodovnik M, O'Sullivan MJ, Conway D, Wapner RJ; Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network (MFMU). Family history of venous thromboembolism and identifying factor V Leiden carriers during pregnancy. Obstet Gynecol. 2010 Mar;115(3):521-5. doi: 10.1097/AOG.0b013e3181d018a8. PMID: 20177282.

Jiang B, Ryan KA, Hamedani A, Cheng Y, Sparks MJ, Koontz D, Bean CJ, Gallagher M, Hooper WC, McArdle PF, O'Connell JR, Stine OC, Wozniak MA, Stern BJ, Mitchell BD, Kittner SJ, Cole JW. Prothrombin G20210A mutation is associated with young-onset stroke: the genetics of early-onset stroke study and meta-analysis. Stroke. 2014 Apr;45(4):961-7. doi: 10.1161/STROKEAHA.113.004063. Epub 2014 Mar 11. PMID: 24619398.

Johns Hopkins Medicine. Health Library. Cerebral Venous Sinus Thrombosis (CVST).

Kearon C, Ageno W, Cannegieter SC, Cosmi B, Geersing GJ, Kyrle PA; Subcommittees on Control of Anticoagulation, and Predictive and Diagnostic Variables in Thrombotic Disease. Categorization of patients as having provoked or unprovoked venous thromboembolism: guidance from the Scientific and Standardization Committee (SSC) of the International Society on Thrombosis and Hemostasis (ISTH). J Thromb Haemost. 2016 Jul;14(7):1480-3. doi: 10.1111/jth.13336. Epub 2016 Jun 7. PMID: 27428935.

Keijzer MB, Borm GF, Blom HJ, Bos GM, Rosendaal FR, den Heijer M. No interaction between factor V Leiden and hyperhomocysteinemia or MTHFR 677TT genotype in venous thrombosis. Results of a meta-analysis of published studies and a large case-only study. Thromb Haemost. 2007 Jan;97(1):32-7. PMID: 17200768.

Kenet G, Ltkhoff LK, Albisetti M, Bernard T, Bonduel M, Brandao L, Chabrier S, Chan A, deVeber G, Fiedler B, Fullerton HJ, Goldenberg NA, Grabowski E, Gunther G, Heller C, Holzhauer S, Iorio A, Journeycake J, Junker R, Kirkham FJ, Kurnik K, Lynch JK, Male C, Manco-Johnson M, Mesters R, Monagle P, van Ommen CH, Raffini L, Rostsy K, Simioni P, Strter RD, Young G, Nowak-Gttl U. Impact of thrombophilia on risk of arterial ischemic stroke or cerebral sinovenous thrombosis in neonates and children: a systematic review and meta-analysis of observational studies. Circulation. 2010 Apr 27;121(16):1838-47. doi: 10.1161/CIRCULATIONAHA.109.913673. Epub 2010 Apr 12. PMID: 20385928.

Kenet G, Nowak-Göttl U. Venous thromboembolism in neonates and children. Best Pract Res Clin Haematol. 2012 Sep;25(3):333-44. doi: 10.1016/j.beha.2012.07.001. Epub 2012 Aug 15. PMID: 22959549.

Kirton A, Shroff M, Pontigon AM, deVeber G. Risk factors and presentations of periventricular venous infarction vs. arterial presumed perinatal ischemic stroke. Arch Neurol. 2010 Jul;67(7):842-8. doi: 10.1001/archneurol.2010.140. PMID: 20625091.

Kist WJ, Janssen NG, Kalk JJ, Hague WM, Dekker GA, de Vries Jl. Thrombophilias and adverse pregnancy outcome - A confounded problem! Thromb Haemost. 2008 Jan;99(1):77-85. doi: 10.1160/TH07-05-0373. PMID: 18217138.

Kovalevsky G, Gracia CR, Berlin JA, Sammel MD, Barnhart KT. Evaluation of the association between hereditary thrombophilias and recurrent pregnancy loss: a meta-analysis. Arch Intern Med. 2004 Mar 8;164(5):558-63. doi: 10.1001/archinte.164.5.558. PMID: 15006834.

Kujovich JL. Factor V Leiden Thrombophilia. GeneReviews® [Internet]. University of Washington, Seattle;1993-2018. 1999 May 14. Updated 2018 Jan 4.

Kujovich JL. Prothrombin-Related Thrombophila. GeneReviews® [Internet]. University of Washington, Seattle;1993-2018. 2006 Jul 25. Updated 2014 Aug 14.

Laugesaar R, Kahre T, Kolk A, Uustalu U, Kool P, Talvik T. Factor V Leiden and prothrombin 20210G>A [corrected] mutation and paediatric ischaemic stroke: a case-control study and two meta-analyses. Acta Paediatr. 2010 Aug;99(8):1168-74. doi: 10.1111/j.1651-2227.2010.01784.x. Epub 2010 Mar 2. Erratum in: Acta Paediatr. 2010 Jul;99(7):1112. PMID: 20337781.

Lehman LL, Rivkin MJ. Perinatal arterial ischemic stroke: presentation, risk factors, evaluation, and outcome. Pediatr Neurol. 2014 Dec;51(6):760-8. doi: 10.1016/j.pediatrneurol.2014.07.031. Epub 2014 Aug 14. PMID: 25444092.

Lissalde-Lavigne G, Fabbro-Peray P, Cochery-Nouvellon E, Mercier E, Ripart-Neveu S, Balducchi JP, Daurès JP, Perneger T, Quéré I, Dauzat M, Marès P, Gris JC. Factor V Leiden and prothrombin G20210A polymorphisms as risk factors for miscarriage during a first intended pregnancy: the matched case-control 'NOHA first' study. J Thromb Haemost. 2005 Oct;3(10):2178-84. doi: 10.1111/j.1538-7836.2005.01581.x. PMID: 16194196

Lockwood CJ, Bauer KA. Inherited thrombophilias in pregnancy. UpToDate. 2020 Mar 31.

Lockwood C, Wendel G; Committee on Practice Bulletins – Obstetrics. Practice bulletin no. 124: inherited thrombophilias in pregnancy. Obstet Gynecol. 2011 Sep;118(3):730-40. doi: 10.1097/AOG.0b013e3182310c6f. PMID: 21860314.

Lopes L, Jacob GP. Thrombophilia testing in pregnancy: should we agree to disagree? J Perinat Med. 2015 Mar;43(2):269-72. doi: 10.1515/jpm-2014-0075. PMID: 24945420.

Madjunkova S, Volk M, Peterlin B, Plaseska-Karanfilska D. Detection of thrombophilic mutations related to spontaneous abortions by a multiplex SNaPshot method. Genet Test Mol Biomarkers. 2012 Apr;16(4):259-64. doi: 10.1089/gtmb.2011.0173. Epub 2011 Oct 24. PMID: 22023244.

Marchiori A, Mosena L, Prins MH, Prandoni P. The risk of recurrent venous thromboembolism among heterozygous carriers of factor V Leiden or prothrombin G20210A mutation. A systematic review of prospective studies. Haematologica. 2007 Aug;92(8):1107-14. PMID: 17650440.

Mester JL, Schreiber AH, Moran RT. Genetic counselors: your partners in clinical practice. Cleve Clin J Med. 2012 Aug;79(8):560-8. doi: 10.3949/ccjm.79a.11091. PMID: 22854435.

Muwakkit SA, Majdalani M, Hourani R, Mahfouz RA, Otrock ZK, Bilalian C, Chan AK, Abboud M, Mikati MA. Inherited thrombophilia in childhood arterial stroke: data from Lebanon. Pediatr Neurol. 2011 Sep;45(3):155-8. doi: 10.1016/j.pediatrneurol.2011.03.002. PMID: 21824561.

National Human Genome Research Institute. National Institutes of Health. Health Professional Genetics Resources Online.

National Human Genome Research Institute. National Institutes of Health. About Factor V Leiden Thrombophilia.

National Institute for Health and Clinical Excellence (NICE). Venous thromboembolic diseases: diagnosis, management and thrombophilia testing. NICE Guideline [NG158]. 2020 Mar 26.

National Society of Genetic Counselors (NSGC). NSGC Practice Guidelines.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

O'Brien SH. Perinatal thrombosis: implications for mothers and neonates. Hematology Am Soc Hematol Educ Program. 2015;2015:48–52. doi: 10.1182/asheducation-2015.1.48. PMID: 26637700.

Ormesher L, Simcox LE, Tower C, Greer IA. 'To test or not to test', the arguments for and against thrombophilia testing in obstetrics. Obstet Med. 2017 Jun;10(2):61-6. doi: 10.1177/1753495X17695696. Epub 2017 Mar 8. PMID: 28680464.

Pletcher BA, Toriello HV, Noblin SJ, Seaver LH, Driscoll DA, Bennett RL, Gross SJ. Indications for genetic referral: a guide for healthcare providers. Genet Med. 2007 Jun;9(6):385-9. doi: 10.1097GIM.0b013e318064e70c. PMID: 17575505.

Pruthi RK. Optimal utilization of thrombophilia testing. Int J Lab Hematol. 2017 May;39 Suppl 1:104-10. doi: 10.1111/ijlh.12672. PMID: 28447412.

Raffini L. Thrombophilia testing in children and adolescents. UpToDate. 2021 Jun 09.

Rennert H, DeSimone RA. Transfusion Medicine and Hemostasis: Clinical and Laboratory Aspects, Third Edition, 2019. Elsevier Inc. ISBN 978-0-12-813726-0. Doi:10.1016/C2015-0-05783-5.

Saracco P, Bagna R, Gentilomo C, Magarotto M, Viano A, Magnetti F, Giordano P, Luciani M, Molinari AC, Suppiej A, Ramenghi LA, Simioni P; Neonatal Working Group of Registro Italiano Trombosi Infantili (RITI). Clinical Data of Neonatal Systemic Thrombosis. J Pediatr. 2016 Apr;171:60-6. doi: 10.1016/j.jpeds.2015.12.035. Epub 2016 Jan 16. PMID: 26787378.

Sarecka-Hujar B, Kopyta I, Skrzypek M, Sordyl J. Association Between the 20210G>A Prothrombin Gene Polymorphism and Arterial Ischemic Stroke in Children and Young Adults-Two Meta-analyses of 3586 Cases and 6440 Control Subjects in Total. Pediatr Neurol. 2017 Apr;69:93-101. doi: 10.1016/j.pediatrneurol.2016.12.013. Epub 2017 Jan 4. PMID: 28160964.

Saxonhouse MA. Thrombosis in the Neonatal Intensive Care Unit.Clin Perinatol. 2015 Sep;42(3):651-73. doi: 10.1016/j.clp.2015.04.010. PMID: 26250924.

Segal JB, Brotman DJ, Emadi A, Necochea AJ, Samal L, Wilson LM, Crim MT, Bass EB. Outcomes of genetic testing in adults with a history of venous thromboembolism. Evid Rep Technol Assess (Full Rep). 2009 Jun;(180):1-162. PMID: 20629476.

Segers K, Dahlbäck B, Nicolaes GA. Coagulation factor V and thrombophilia: background and mechanisms. Thromb Haemost. 2007 Sep;98(3):530-42. PMID: 17849041.

Sergi C, Al Jishi T, Walker M. Factor V Leiden mutation in women with early recurrent pregnancy loss: a meta-analysis and systematic review of the causal association. Arch Gynecol Obstet. 2015 Mar;291(3):671-9. doi: 10.1007/s00404-014-3443-x. Epub 2014 Sep 6. PMID: 25193429.

Shen YM, Tsai J, Taiwo E, Gavva C, Yates SG, Patel V, Frenkel E, Sarode R. Analysis of Thrombophilia Test Ordering Practices at an Academic Center: A Proposal for Appropriate Testing to Reduce Harm and Cost. PLoS One. 2016 May 13;11(5):e0155326. doi: 10.1371/journal.pone.0155326. eCollection 2016. PMID: 27176603.

Silver RM, Saade GR, Thorsten V, Parker CB, Reddy UM, Drews-Botsch C, Conway D, Coustan D, Dudley DJ, Bukowski R, Rowland Hogue CJ, Pinar H, Varner MW, Goldenberg R, Willinger M. Factor V Leiden, prothrombin G20210A, and methylene tetrahydrofolate reductase mutations and stillbirth: the Stillbirth Collaborative Research Network. Am J Obstet Gynecol. 2016 Oct;215(4):468.e1-468.e17. doi: 10.1016/j.ajog.2016.04.026. Epub 2016 Apr 27. PMID: 27131585.

Silver RM, Zhao Y, Spong CY, Sibai B, Wendel G Jr, Wenstrom K, Samuels P, Caritis SN, Sorokin Y, Miodovnik M, O'Sullivan MJ, Conway D, Wapner RJ; Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units (NICHD MFMU) Network. Prothrombin gene G20210A mutation and obstetric complications. Child Health and Human Development Maternal-Fetal Medicine Units (NICHD MFMU) Network. Obstet Gynecol. 2010 Jan;115(1):14-20. doi: 10.1097/AOG.0b013e3181c88918. PMID: 20027028.

Simone B, De Stefano V, Leoncini E, Zacho J, Martinelli I, Emmerich J, Rossi E, Folsom AR, Almawi WY, Scarabin PY, den Heijer M, Cushman M, Penco S, Vaya A, Angchaisuksiri P, Okumus G, Gemmati D, Cima S, Akar N, Oguzulgen KI, Ducros V, Lichy C, Fernandez-Miranda C, Szczeklik A, Nieto JA, Torres JD, Le Cam-Duchez V, Ivanov P, Cantu-Brito C, Shmeleva VM, Stegnar M, Ogunyemi D, Eid SS, Nicolotti N, De Feo E, Ricciardi W, Boccia S. Risk of venous thromboembolism associated with single and combined effects of Factor V Leiden, Prothrombin 20210A and Methylenetethraydrofolate

reductase C677T: a meta-analysis involving over 11,000 cases and 21,000 controls. Eur J Epidemiol. 2013 Aug;28(8):621-47. doi: 10.1007/s10654-013-9825-8. Epub 2013 Jul 31. PMID: 23900608.

Stevens SM, Woller SC, Bauer KA, Kasthuri R, Cushman M, Streiff M, Lim W, Douketis JD.Guidance for the evaluation and treatment of hereditary and acquired thrombophilia. J Thromb Thrombolysis. 2016 Jan;41(1):154-64. doi: 10.1007/s11239-015-1316-1. PMID: 26780744.

#### **Next Review Date**

Not applicable

### **Retired Date**

11/01/22

## **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

## **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	03/01/14	Director of	MPCTAC and QIC
Internal Approval:	Version 1	Medical Policy as Chair of MPCTAC	
11/20/13: Medical Policy, Criteria, and		Chair of Mil CTAC	
Technology Assessment Committee			
(MPCTAC)			
12/03/13: MPCTAC (electronic vote)			
12/19/13: Quality Improvement			
Committee (QIC)			

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
11/01/14	Review for effective date 03/01/15. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Summary, Definitions, and References sections. Changed review calendar.	03/0/15 Version 2	11/19/14: MPCTAC 12/10/14: QIC
11/01/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Updated Summary and language in the Applicable Coding section without changing criteria or the applicable code list.	01/01/16 Version 3	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
01/01/16	Review for effective date 05/01/16. Updated Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised criteria in the Limitations section.	05/01/16 Version 4	01/20/16: MPCTAC 02/10/16: QIC
09/28/16	Review for effective date 11/01/16. Administrative changes to clarify language related to gender.	11/01/16 Version 5	09/30/16: MPCTAC (electronic vote) 10/12/16: QIC

<sup>\*</sup>Effective Date for NH Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for NH Medicare Advantage HMO Product: 01/01/22 \* Effective date for NH Medicare Advantage HMO product: 01/01/22

01/01/17	Review for effective date 05/01/17. Updated	05/01/17	01/18/17: MPCTAC
3,3,1	Summary, Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections.	Version 6	02/08/17: QIC
01/01/18	Review for effective date 04/01/18. Updated Definitions and References sections. Revised Medical Policy Statement and Limitations sections. Updated Plan note in the Applicable Coding section.	04/01/18 Version 7	01/17/18: MPCTAC
01/01/19	Review for effective date 04/01/19. Administrative changes made to the Policy Summary, Limitations, Definitions, Applicable Coding, Clinical Background Information, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement section.	04/01/19 Version 8	01/16/19: MPCTAC
07/01/19	Review for effective 10/01/19. Administrative changes made to the Policy Summary, Limitations, Applicable Coding, References, and Other Applicable Policies sections.	10/01/19 Version 9	07/17/19: MPCTAC
01/01/20	Review for effective date 04/01/20. Criteria revised in the Limitations section.  Administrative changes made to the Medical Policy Statement, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.	04/01/20 Version 10	01/15/20: MPCTAC
02/01/21	Review for effective date 03/01/21.  Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Definitions, Clinical Background Information, and References sections.	03/01/21 Version 11	02/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitation and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 12	11/17/21: MPCTAC

01/01/22	Review for effective date 02/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, and References sections.	02/01/22 Version 13	01/19/22: MPCTAC
08/01/22	Review for policy retired date 11/01/22. Revised the Policy Summary, Clinical Criteria, Limitations and Exclusions, and Applicable Coding sections. Medical policy retired on 11/01/22. AIM medical necessity criteria adopted for genetic testing on 11/01/22. AIM prior authorization is required for genetic testing as of 11/01/22, even when applicable codes are not listed in this Plan policy.	11/01/22 Version 27	08/26/22: MPCTAC (electronic vote)



Medical Policy - Policy Retired and AIM Criteria Adopted as of 11/01/22

Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, Facet Arthroplasty, Lysis of Epidural Adhesions, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

Policy Number: OCA 3.713 Version Number: 23

Policy Retired Date: 11/01/22

## **Impacted Products**

- **⋈** All Products
- ⋈ NH Medicare Advantage
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO

Note: Disclaimer and audit information is located at the end of this document.

## **Policy Summary**

Effective 11/01/22, the Plan will use AIM clinical appropriateness guidelines to determine the medical necessity of musculoskeletal procedures and interventional pain management services. Prior authorization from AIM Specialty Health is required for these services.

### **Clinical Criteria**

No medical policy criteria.

### **Limitations and Exclusions**

The Plan does NOT reimburse for a minimally invasive procedure (and related devices that include but are not limited to interbody cages, screws, spacers, and/or other fixation devices) when used as a

stand-alone surgical treatment of pain associated with disc disease, back pain, and/or for any other indication because the clinical utility and clinical validity of these procedures have not been sufficiently established. The Plan does NOT reimburse additionally for these unproven minimally invasive procedures/techniques (and associated devices) when used with a standard, open spinal procedure and/or with established conservative, nonsurgical treatment(s) because these minimally invasive procedures and devices are considered experimental and investigation or NOT medically necessary by the Plan.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 150.11 and NCD 150.13 include guidelines for minimally invasive procedures for the treatment of back pain. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO or New Hampshire Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for musculoskeletal procedures and interventional pain management services, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Codes	Code Descriptions	
63052	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with	
	decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or	
	lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; single	
	vertebral segment (List separately in addition to code for primary procedure	
63053	Laminectomy, facetectomy, or foraminotomy (unilateral or bilateral with	
	decompression of spinal cord, cauda equina and/or nerve root[s] [e.g., spinal or	
	lateral recess stenosis]), during posterior interbody arthrodesis, lumbar; each	
	additional segment (List separately in addition to code for primary procedure)	

### References

Abjornson C, Yoon BJV, Callanan T, Shein D, Grinberg S, Cammisa FP. Spinal Stenosis in the Absence of Spondylolisthesis: Can Interlaminar Stabilization at Single and Multi-levels Provide Sustainable Relief? Int J Spine Surg. 2018 Jan;12(1): 64–9. doi: 10.14444/5011. PMID: 30280085.

Abrishamkar S, Kouchakzadeh M, Mirhosseini A, Tabesh H, Rezvani M, Moayednia A, Ganjeifar B, Mahabadi A, Yousefi E, Kooshki AM. Comparison of open surgical discectomy versus plasma-laser nucleoplasty in patients with single lumbar disc herniation. J Res Med Sci. 2015 Dec;20(12):1133-7. doi: 10.4103/1735-1995.172979. PMID: 26958046.

Adogwa O, Carr K, Thompson P, Hoang K, Darlington T, Perez E, Fatemi P, Gottfried O, Cheng J, Isaacs RE. A prospective, multi-institutional comparative effectiveness study of lumbar spine surgery in morbidly obese patients: does minimally invasive transforaminal lumbar interbody fusion result in superior outcomes? World Neurosurg. 2015 May;83(5):860-6. doi: 10.1016/j.wneu.2014.12.034. Epub 2014 Dec 19. PMID: 25535070.

Ahn Y, Moon KS, Kang BU, Hur SM, Kim JD. Laser-assisted posterior cervical foraminotomy and discectomy for lateral and foraminal cervical disc herniation. Photomed Laser Surg. 2012 Sep;30(9):510-5. doi: 10.1089/pho.2012.3246. Epub 2012 Jul 13. PMID: 22793668.

Allegri M, Montella S, Salici F, Valente A, Marchesini M, Compagnone C, Baciarello M, Manferdini ME, Fanelli G. Mechanisms of low back pain: a guide for diagnosis and therapy. Version 2. F1000Res. 2016 Jun 28 [revised 2016 Jan 1]; 5. pii: F1000 Faculty Rev-1530. eCollection 2016. doi: 10.12688/f1000research.8105.2. PMID: 27408698.

American Academy of Orthopaedic Surgeons (AAOS). Clinical Practice Guidelines.

American Academy of Orthopaedic Surgeons (AAOS). Ortholnfo. Anterior Lumbar Interbody Fusion.

American Academy of Orthopaedic Surgeons (AAOS). Ortholnfo. Lumbar Spinal Stenosis.

American Academy of Orthopaedic Surgeons (AAOS). Ortholnfo. Minimally Invasive Spine Surgery.

American Association of Neurological Surgeons (AANS). AANS Position Statements.

American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS). AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. J Neurosurg Spine. 2014 Jul;21(1):23–30.

American Association of Neurological Surgeons (AANS). Patients. Lumbar Spinal Stenosis. December 2011.

American Association of Neurological Surgeons (AANS). Patients. Minimally Invasive Spine Surgery.

American College of Physicians (ACP), American Pain Society (APS). Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK; Clinical Efficacy Assessment Committee of the ACP; ACP; APS Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the ACP and the APS. Ann Intern Med. 2007 Oct 2; 147(7):478-91. Erratum in: Ann Intern Med. 2008 Feb 5;148(3):247-8. PMID: 17909209.

American College of Physicians (ACP). Clinical Guidelines & Recommendations.

American College of Radiology (ACR). ACR Appropriateness Criteria.

American College of Radiology (ACR). ACR Appropriateness Criteria. Chronic Back Pain: Suspected Sarcoilitis/Spondyloarthropasty. 2016.

American College of Radiology (ACR). ACR Appropriateness Criteria. Low Back Pain. 2015.

American Pain Society (APS). Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical Interventional Therapies for Low Back Pain: a Review of the Evidence for an American Pain Society Clinical Practice Guideline. Spine. 2009 May 1;34(10):1078-93. doi: 10.1097/BRS.0b013e3181a103b1. PMID: 19363456.

American Pain Society (APS). Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, Carragee EJ, Grabois M, Murphy DR, Resnick DK, Stanos SP, Shaffer WO, Wall EM; APS Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the APS. Spine (Phila Pa 1976). 2009 May 1;34(10):1066-77. doi: 10.1097/BRS.0b013e3181a1390d. PMID: 19363457.

American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA). Rosenquist RW, Benzon HT, Connis RT, De Leon-Casasola OA, Glass D, Korevaar WC, Cynwyd B, Mekhail NA, Merrill DG, NIckinovich DG, Rathnmell JP, Nai-Mei Sang C, Simon DL; ASA Task Force on Chronic Pain Management. Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA. Anesthesiology. 2010 Apr;112(4):810-33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.

American Society of Interventional Pain Physicians (ASIPP). Boswell MV, Trescot AM, Datta S, Schultz DM, Hansen HC, Abdi S, Sehgal N, Shah RV, Singh V, Benyamin RM, Patel VB, Buenaventura RM, Colson JD, Cordner HJ, Epter RS, Jasper JF, Dunbar EE, Atluri SL, Bowman RC, Deer TR, Swicegood JR, Staats PS, Smith HS, Burton AW, Kloth DS, Giordano J, Manchikanti L; ASIPP. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. Pain Physician. 2007 Jan;10(1):7-111. PMID: 17256025.

American Society of Interventional Pain Physicians (ASIPP). Interventional Pain Management (IPM) Practice Guidelines.

American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks TA, Caraway DL, Calodney AK, Cash KA, Christo PJ, Cohen SP, Colson J, Conn A, Cordner HJ, Coubarous S, Datta S, Deer TR, Diwan SA, Falco FJE, Fellows B, Geffert SC, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm II S, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel V, Racz GB, Sehgal N, Sharma M, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood J, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. Interventional Pain Management (IPM) Practice Guideline. An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part 2: Guidance and Recommendations. Pain Physician. 2013;16:S49-283.

American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, Falco FJE, Singh V, Benyamin RM, Racz GB, Helm II S, Caraway DL, Calodney AK, Snook LT, Smith HS, Gupta S, Ward SP, Grider JS, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: introduction and general considerations. Pain Physician 2013 Apr;16(2 Suppl):S1-48. PMID: 23615882.

Bae J, Lee SM, Lee SH, Shin SH, Kim HJ, Kim KH. The Likelihood of Reaching Substantial Clinical Benefit after an Interlaminar Dynamic Spacer for Chronic Low Back Pain: A Clinical and Radiologic Analysis of a Prospective Cohort. World Neurosurg. 2017 May;101:589-598. doi: 10.1016/j.wneu.2017.02.083. Epub 2017 Feb 27. PMID: 28242487.

Birnbum K. Percutaneous cervical disc decompression. Surg Radiol Anat. 2009 Jun;31(5):379-87. Epub 2009 Feb 4. doi: 10.1007/s00276-009-0462-6. PMID: 19190848.

Bonaldi G, Baruzzi F, Facchinetti A, Fachinetti P, Lunghi S. Plasma radio-frequency-based diskectomy for treatment of cervical herniated nucleus pulposus: feasibility, safety, and preliminary clinical results. AJNR Am J Neuroradiol. 2006 Nov-Dec;27(10):2104-11. PMID: 17110676.

Brito-García N, García-Pérez L, Kovacs FM, Del Pino-Sedeño T, Pérez-Ramos J, Imaz-Iglesia I, Serrano-Aguilar P. Efficacy, Effectiveness, Safety, and Cost-effectiveness of Epidural Adhesiolysis for Treating Failed Back Surgery Syndrome. A Systematic Review. Pain Med. 2019 Apr 1;20(4):692-706. doi: 10.1093/pm/pny233. PMID: 30590850.

Brouwer PA, Brand R, van den Akker-van Marle ME, Jacobs WC, Schenk B, van den Berg-Huijsmans AA, Koes BW, Arts MA, van Buchem MA, Peul WC. Percutaneous laser disc decompression versus conventional microdiscectomy for patients with sciatica: Two-year results of a randomized controlled trial. Interv Neuroradiol. 2017 Jun;23(3):313-24. doi: 10.1177/1591019917699981. Epub 2017 Apr 28. PMID: 28454511.

Brouwer PA, Peul WC, Brand R, Arts MP, Koes BW, van den Berg AA, van Buchem MA. Effectiveness of percutaneous laser disc decompression versus conventional open discectomy in the treatment of lumbar disc herniation; design of a prospective randomized controlled trial. BMC Musculoskelet Disord. 2009 May 13;10:49. doi: 10.1186/1471-2474-10-49. PMID: 19439098.

Buy X, Gangi A. Percutaneous Treatment of Intervertebral Disc Herniation. Semin Intervent Radiol. 2010 Jun;27(2):148–59. doi: 10.1055/s-0030-1253513. PMID: 21629404.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis 150.13. Version 2. 2016 Dec 7.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPs) 150.11. Version 1. 2008 Sep 29.

Cesaroni A, Nardi PV. Plasma disc decompression for contained cervical disc herniation: a randomized, controlled trial. Eur Spine J. 2010 March;19(3):477–86. doi: 10.1007/s00586-009-1189-0. Epub 2009 Nov 10. PMID: 19902277.

Cheng JS, Park P, Le H, Reisner L, Chou D, Mummaneni PV. Short-term and long-term outcomes of minimally invasive and open transforaminal lumbar interbody fusions: is there a difference? Neurosurg Focus. 2013 Aug;35(2):E6. doi: 10.3171/2013.5.FOCUS1377. PMID: 23905957.

Celestre PC, Pazmiño PR, Mikhael MM, Wolf CF, Feldman LA, Lauryssen C, Wang JC. Minimally invasive approaches to the cervical spine. Orthop Clin North Am. 2012 Jan;43(1):137-47, x. doi: 10.1016/j.ocl.2011.08.007. Epub 2011 Oct 13. PMID: 22082636.

Chou R, Deyo R, Friedly J, Skelly A, Hashimoto R, Weimer M, Fu R, Dana T, Kraegel P, Griffin J, Grusing S, Brodt ED. Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline. Ann Intern Med. 2017 Apr 4;166(7):493–505. doi: 10.7326/M16-2459. Epub 2017 Feb 14. PMID: 28192793.

Chou R. Subacute and chronic low back pain: Nonsurgical interventional treatment. UpToDate. 2021 Jun 10.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts, MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Cuellar VG, Cuellar JM, Vaccaro AR, Carragee EJ, Scuderi GJ. Accelerated degeneration after failed cervical and lumbar nucleoplasty. J Spinal Disord Tech. 2010 Dec;23(8):521-4. doi: 10.1097/BSD.0b013e3181cc90dd. PMID: 21131800.

Dahdaleh NS, Wong AP, Smith ZA, Wong RH, Lam SK, Fessler RG. Microendoscopic decompression for cervical spondylotic myelopathy. Neurosurg Focus. 2013 Jul;35(1):E8. doi: 10.3171/2013.3.FOCUS135. PMID: 23815253.

Department of Veterans Affairs (VA), Department of Defense (DOD). The Diagnosis and Treatment of Low Back Pain Work Group. VA/DoD Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain, Version 2.0, 2017.

Deukmedjian AJ, Cianciabella A, Cutright J, Deukmedjian A. Cervical Deuk Laser Disc Repair®: a novel, full-endoscopic surgical technique for the treatment of symptomatic cervical disc disease. Surg Neurol Int. 2012;3:142. doi: 10.4103/2152-7806.103884. Epub 2012 Nov 27. PMID: 23230523.

Deukmedjian AJ, Jason Cutright ST, Augusto Cianciabella PC, Deukmedjian A. Deuk Laser Disc Repair (\*) is a safe and effective treatment for symptomatic cervical disc disease. Surg Neurol Int. 2013 May 28;4:68. doi: 10.4103/2152-7806.112610. PMID: 23776754.

Deutsch H, Musacchio MJ Jr. Minimally invasive transforaminal lumbar interbody fusion with unilateral pedicle screw fixation. Neurosurg Focus. 2006;20(3):E10. PMID: 16599416.

Dohrmann GJ, Mansour N. Long-Term Results of Various Operations for Lumbar Disc Herniation: Analysis of over 39,000 Patients. Med Princ Pract. 2015;24(3):285-90. doi: 10.1159/000375499. Epub 2015 Mar 27. PMID: 25832729.

Eck JC, Hodges S, Humphreys SC. Minimally invasive lumbar spinal fusion. J Am Acad Orthop Surg. 2007 Jun;15(6):321-9. PMID: 17548881.

Epstein NE. Percutaneous cervical laser diskectomy, thermoannuloplasty, and thermonucleoplasty; comparable results without surgery. Surg Neurol Int. 2017 Jun 21;8:128. doi: 10.4103/sni.sni\_164\_17. PMID: 28713631.

Freeman BJ, Mehdian R. Intradiscal electrothermal therapy, percutaneous discectomy, and nucleoplasty: what is the current evidence? Curr Pain Headache Rep. 2008 Jan;12(1):14-21. PMID: 18417018.

Garg B, Mehta N. Minimally invasive transforaminal lumbar interbody fusion (MI-TLIF): A review of indications, technique, results and complications. J Clin Orthop Trauma. 2019 Oct;10(Suppl 1):S156-62. doi: 10.1016/j.jcot.2019.01.008. Epub 2019 Jan 14. PMID: 31695275.

Gebremariam L, Koes BW, Peul WC, Huisstede BM. Evaluation of treatment effectiveness for the herniated cervical disc: a systematic review. Spine (Phila Pa 1976). 2012 Jan 15;37(2):E109-18. doi: 10.1097/BRS.0b013e318221b5af. PMID: 21587105.

Gelalis I, Gkiatas I, Spiliotis A, Papadopoulos D, Pakos E, Vekris M, Korompilias A. Current Concepts in Intradiscal Percutaneous Minimally Invasive Procedures for Chronic Low Back Pain. Asian J Neurosurg. 2019 Jul-Sep;14(3):657-69. doi: 10.4103/ajns.AJNS\_119\_17. PMID: 31497082.

Gerdesmeyer L, Wagenpfeil S, Birkenmaier C, Veihelmann A, Hauschild M, Wagner K, Muderis MA, Gollwitzer H, Diehl P, Toepfer A. Percutaneous epidural lysis of adhesions in chronic lumbar radicular pain: a randomized, double-blind, placebo-controlled trial. Pain Physician. 2013 May-Jun;16(3):185-96. PMID: 23703406.

Gibson JN, Waddell G. Surgical interventions for lumbar disc prolapse: updated Cochrane Review. Spine (Phila Pa 1976). 2007 Jul 15;32(16):1735-47. doi: 10.1097/BRS.0b013e3180bc2431. PMID: 17632394.

Goodwin ML, Spiker WR, Brodke DS, Lawrence BD. Failure of facet replacement system with metal-on-metal bearing surface and subsequent discovery of cobalt allergy: report of 2 cases. J Neurosurg Spine. 2018 Jul;29(1):81-4. doi: 10.3171/2017.10.SPINE17862. Epub 2018 Apr 13.

Haldeman S, Carroll L, Cassidy JD. Findings from the bone and joint decade 2000 to 2010 task force on neck pain and its associated disorders. J Occup Environ Med. 2010 Apr;52(4):424-7. doi: 10.1097/JOM.0b013e3181d44f3b. PMID: 20357682.

Halim W, Wullems JA, Lim T, Aukes HA, van der Weegen W, Vissers KC, Gültuna I, Chua NH. The long-term efficacy and safety of percutaneous cervical nucleoplasty in patients with a contained herniated disk. Pain Pract. 2013 Jun; 13(5):364-71. doi: 10.1111/papr.12003. Epub 2012 Oct 31. PMID: 23113964.

Hayes. Evolving Evidence Review. Superion Interspinous Spacer System (Vertiflex) for Treatment of Neurogenic Claudication Caused by Spinal Stenosis. Dallas, TX: Hayes; 2021 Sep 17.

Hayes. Health Technology Assessment. Coflex Interlaminar Stabilization Device (Surgalign Spine Technologies Inc.) for Treatment of Lumbar Spinal Stenosis. Dallas, TX: Hayes; 2018 Sep 21. Annual Review 2021 Oct 13.

Hayes. Health Technology Assessment. Expandable Interbody Cages for Lumbar Spinal Fusion. Dallas, TX: Hayes; 2021 Jun 22.

Hayes. Health Technology Assessment. Minimally Invasive Lumbar Decompression (Mild; Vertos Medical Inc.) Device Kit for Treatment of Lumbar Spinal Stenosis. Dallas, TX: Hayes; 2019 Mar 26. Annual Review 2021 May 27.

Hayes. Health Technology Assessment. Percutaneous Laser Disc Decompression for Lumbar Disc Herniation. Dallas, TX: Hayes; 2018 Mar 28. Annual Review 2021 May 04.

Heemskerk JL, Oluwadara Akinduro O, Clifton W, Quiñones-Hinojosa A, Abode-Iyamah KO. Long-term clinical outcome of minimally invasive versus open single-level transforaminal lumbar interbody fusion for degenerative lumbar diseases: a meta-analysis. Spine J. 2021 Dec;21(12):2049-65. doi: 10.1016/j.spinee.2021.07.006. Epub 2021 Jul 14.

Hellinger S. The full endoscopic anterior cervical fusion: a new horizon for selective percutaneous endoscopic cervical decompression. Acta Neurochir Suppl. 2011;108:203-7. doi: 10.1007/978-3-211-99370-5\_31. PMID: 21107960.

Helm S 2nd, Racz GB, Gerdesmeyer L, Justiz R, Hayek SM, Kaplan ED, El Terany MA, Knezevic NN. Percutaneous and Endoscopic Adhesiolysis in Managing Low Back and Lower Extremity Pain: A Systematic Review and Meta-analysis. Pain Physician. 2016 Feb;19(2):E245–82. PMID: 26815254.

Helm S, Benyamin RM, Chopra P, Deer TR, Justiz R. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: a systematic review. Pain Physician. Jul-Aug 2012;15(4):E435-62. PMID: 22828693.

Hirsch JA, Singh V, Falco FJ, Benyamin RM, Manchikanti L. Automated percutaneous lumbar discectomy for the contained herniated lumbar disc: a systematic assessment of evidence. Pain Physician. 2009 May-Jun;12(3):601-20. PMID: 19461826.

Hong Park C, Ho Lee S. Epidurographic Findings Following Percutaneous Epidural Adhesiolysis Failed to Correlate with Level of Pain Reduction in Patients with Lumbar Spinal Stenosis. Pain Med. 2017 May 1;18(5):842-5. doi: 10.1093/pm/pnw244. PMID: 27651508.

International Society for the Advancement of Spine Surgery (ISASS). Guyer R, Musacchio M, Cammisa FP, Lorio MP. ISASS Recommendations/Coverage Criteria for Decompression with Interlaminar Stabilization - Coverage Indications, Limitations, and/or Medical Necessity. Int J Spine Surg. 2016;10:41. doi: 10.14444/3041. PMID: 28377855.

Jiang W, Sun B, Sheng Q, Song X, Zheng Y, Wang L. Feasibility and efficacy of percutaneous lateral lumbar discectomy in the treatment of patients with lumbar disc herniation: a preliminary experience. Biomed Res Int. 2015;2015:378612. doi: 10.1155/2015/378612. Epub 2015 Jan 28. PMID: 25695066.

Kaushal M, Sen R. Posterior endoscopic discectomy: Results in 300 patients. Indian J Orthop. 2012 Jan-Feb;46(1):81–5. doi: 10.4103/0019-5413.91640. PMID: 22345812.

Kelekis AD, Filippiadis DK, Martin JB, Brountzos E. Standards of practice: quality assurance guidelines for percutaneous treatments of intervertebral discs. Cardiovasc Intervent Radiol. 2010 Oct;33(5):909-13. doi: 10.1007/s00270-010-9952-5. Epub 2010 Jul 30. PMID: 20676639.

Keorochana G, Setrkraising K, Woratanarat P, Arirachakaran A, Kongtharvonskul J. Clinical outcomes after minimally invasive transforaminal lumbar interbody fusion and lateral lumbar interbody fusion for treatment of degenerative lumbar disease: a systematic review and meta-analysis. Neurosurg Rev. 2018 Jul;41(3):755-70. doi: 10.1007/s10143-016-0806-8. Epub 2016 Dec 24. PMID: 28013419.

Kreiner DS, MacVicar J, Duszynski B, Nampiaparampil DE. The mild® procedure: a systematic review of the current literature. Pain Med. 2014 Feb;15(2):196–205. doi: 10.1111/pme.12305. Epub 2013 Dec 5. PMID: 24308292.

Kvarstein G, Måwe L, Indahl A, Hol PK, Tennøe B, Digernes R, Stubhaug A, Tønnessen TI, Beivik H. A randomized double-blind controlled trial of intra-annular radiofrequency thermal disc therapy--a 12-month follow-up. Pain. 2009 Oct;145(3):279-86. doi: 10.1016/j.pain.2009.05.001. Epub 2009 Aug 3. PMID: 19647940.

Lawrence MM, Hayek SM. Minimally invasive lumbar decompression: a treatment for lumbar spinal stenosis. Curr Opin Anaesthesiol. 2013 Oct;26(5):573-9. doi: 10.1097/01.aco.0000432520.24210.54. PMID: 23963231.

Lee LY, Idris Z, Beng TB, Young TY, Chek WC, Abdullah JM, Hieng WS. Outcomes of Minimally Invasive Surgery Compared to Open Posterior Lumbar Instrumentation and Fusion. Asian J Neurosurg. 2017 Oct-Dec;12(4):620-37. doi: 10.4103/ajns.AJNS\_331\_16. PMID: 29114274.

Liao C, Ren Q, Chu L, Shi L, Yu Q, Yan Z, Yu K, Liu C, Wu W, Xiong Y, Deng Z, Chen L. Modified posterior percutaneous endoscopic cervical discectomy for lateral cervical disc herniation: the vertical anchoring technique. Eur Spine J. 2018 Jun;27(6):1460–8. doi: 10.1007/s00586-018-5527-y. Epub 2018 Feb 24. PMID: 29478117.

Liliang PC, Lu K, Liang CL, Chen YW, Tsai YD, Tu YK. Nucleoplasty for treating lumbar disk degenerative low back pain: an outcome prediction analysis. J Pain Res. 2016;9:893–8. eCollection 2016. doi: 10.2147/JPR.S116533. PMID: 27826211.

Lim JH, Lee HJ, Lee SH. Application of percutaneous cervical nucleoplasty using the navigable disc decompression device in patient of cervical herniated intervertebral disc: a case report. Ann Rehabil Med. 2013 Oct;37(5):730–4. doi: 10.5535/arm.2013.37.5.730. Epub 2013 Oct 29. PMID: 24236264.

Lopez AJ, Scheer JK, Dahdaleh NS, Patel AA, Smith ZA. Lumbar Spinous Process Fixation and Fusion: A Systematic Review and Critical Analysis of an Emerging Spinal Technology. Clin Spine Surg. 2017 Nov;30(9):E1279-88. doi: 10.1097/BSD.0000000000000011. PMID: 27438402.

Lo WL, Lin CM, Yeh YS, Su YK, Tseng YY, Yang ST, Lin JW. Comparing miniopen and minimally invasive transforaminal interbody fusion in single-level lumbar degeneration. Biomed Res Int. 2015;2015:168384. doi: 10.1155/2015/168384. Epub 2015 Jan 5. PMID: 25629037.

Lu Y, Guzman JZ, Purmesseur D, latridis JC, Hecht AC, Quresshi SA, Cho SK. Nonoperative management of discogenic back pain: a systematic review. Spine (Phila Pa 1976). 2014 Jul 15;39(16):1314–24. doi: 10.1097/BRS.000000000000001. PMID: 24827515.

Manchikanti L, Falco FJ, Benyamin RM, Caraway DL, Kaye AD, Helm S 2nd, Wargo BW, Hansen H, Parr AT, Singh V, Swicegood JR, Smith HS, Schultz DM, Malla Y, Hirsch JA. Assessment of bleeding risk of interventional techniques: a best evidence synthesis of practice patterns and perioperative management of anticoagulant and antithrombotic therapy. Pain Physician. 2013 Apr;16(2 Suppl):SE261-318. PMID: 23615893.

Manchikanti L, Pampati V, Falco FJ, Hirsch JA. Growth of spinal interventional pain management techniques: analysis of utilization trends and Medicare expenditures 2000 to 2008. Spine (Phila Pa 1976). 2013 Jan 15;38(2):157-68. doi: 10.1097/BRS.0b013e318267f463. PMID: 22781007.

Manchikanti L, Singh V, Calodney AK, Helm S 2nd, Deer TR, Benyamin RM, Falco FJE, Hirsch JA. Percutaneous lumbar mechanical disc decompression utilizing Dekompressor®: an Update of current evidence. Pain Physician. 2013 Apr;16(2 Suppl):SE1-24. PMID: 23615884.

Manchikanti L, Singh V, Cash KA, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing post lumbar surgery syndrome: 2-year follow-up of a randomized, controlled trial. J Pain Res. 2012;5:597–608. doi: 10.2147/JPR.S38999. PMID: 23293536.

Manchikanti L, Singh V, Falco FJE, Calodney AK, Onyewu O, Helm S 2nd, Benyamin RM, Hirsch JA. An updated review of automated percutaneous mechanical lumbar discectomy for the contained herniated lumbar disc. Pain Physician. 2013 Apr;16(2 Suppl):SE151-84. PMID: 23615890.

Maurer P, Block JE, Squillante D. Intradiscal electrothermal therapy (IDET) provides effective symptom relief in patients with discogenic low back pain. J Spinal Disord Tech. 2008 Feb;21(1):55-62. doi: 10.1097/BSD.0b013e31812f4f29. PMID: 18418138.

McCormack BM, Bundoc RC, Ver MR, Ignacio JMF, Berven SH, Eyster EF. Percutaneous posterior cervical fusion with the DTRAX Facet System for single-level radiculopathy: results in 60 patients. J Neurosurg Spine. 2013 Mar;18(3):245-54. doi: 10.3171/2012.12.SPINE12477. Epub 2013 Jan 18. PMID: 23330952.

Mummaneni PV, Dhall SS, Eck JC, Groff MW, Ghogawala Z, Watters WC 3rd, Dailey AT, Resnick DK, Choudhri TF, Sharan A, Wang JC, Kaiser MG. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 11: interbody techniques for lumbar fusion. J Neurosurg Spine. 2014 Jul;21(1):67-74. doi: 10.3171/2014.4.SPINE14276. PMID: 24980588.

Nandyala SV, Fineberg SJ, Pelton M, Singh K. Minimally invasive transforaminal lumbar interbody fusion: one surgeon's learning curve. Spine J. 2014 Aug 1;14(8):1460-5. doi: 10.1016/j.spinee.2013.08.045. Epub 2013 Oct 3. PMID: 24290313.

National Institute for Health and Clinical Excellence (NICE). Automated percutaneous mechanical lumbar discectomy. Interventional Procedures Guidance IP141. 2005 Nov 23.

National Institute for Health and Clinical Excellence (NICE). Interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication. Interventional procedures guidance (IPG). IPG 365, 2010 Nov 24.

National Institute for Health and Clinical Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. NICE guideline NG59. 2016 Nov 30. Updated 2020 Dec 11.

National Institute for Health and Clinical Excellence (NICE). Non-rigid stabilization procedures for the treatment of low back pain. Interventional procedures guidance (IPG). IPG 366. 2010 Nov 24.

National Institute for Health and Care Excellence (NICE). Percutaneous endoscopic laser cervical discectomy. Interventional procedures guidance (IPG). IPG 303. 2009 Jun 24.

National Institute for Health and Care Excellence (NICE). Percutaneous endoscopic laser lumbar discectomy. Interventional procedures guidance (IPG). IPG300. 2009 May 27.

National Institute for Health and Care Excellence (NICE). Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. Interventional procedures guidance (IPG). IPG83. 2004 Aug 25.

National Institute for Health and Care Excellence (NICE). Therapeutic endoscopic division of epidural adhesions. Interventional procedure guidance (IPG). IPG333. 2010 Feb 24.

National Institute for Health and Clinical Excellence (NICE). Transaxial interbody lumbosacral fusion for severe chronic low back pain. Interventional procedure guidance (IPG). IPG620. 2018 Jul 25.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

North American Spine Society (NASS). Clinical Guidelines.

North American Spine Society (NASS). Current Coverage Policy Recommendations.

North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and Treatment of Low Back Pain. 2020. Endorsed by the American Academy of Physical Medicine and Rehabilitation (AAPM&R) and American Association of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS).

North American Spine Society (NASS). NASS Coverage Policy Recommendations: Interspinous Fixation with Fusion. Revised 2019 Dec.

North American Spine Society (NASS). NASS Guidelines. Diagnosis and Treatment of Adult Isthmic Spondylolisthesis. Diagnosis and Treatment of Degenerative Spondylolisthesis. Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy. Antibiotic Prophylaxis in Spine Surgery.

North American Spine Society (NASS). NASS Guidelines. Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis. Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis. Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders. Antithrombotic Therapies in Spine Surgery.

Nunley PD, Deer TR, Benyamin RM, Staats PS, Block JE. Interspinous process decompression is associated with a reduction in opioid analgesia in patients with lumbar spinal stenosis. J Pain Res. 2018 Nov 20;11:2943-8. doi: 10.2147/JPR.S182322. eCollection 2018.PMID: 30538533.

Official Disability Guidelines (ODG). Treatment Guidelines.

Oktenoglu T, Ozer AF, Sasani M, Ataker Y, Gomleksiz C, Celebi I. Posterior Transpedicular Dynamic Stabilization versus Total Disc Replacement in the Treatment of Lumbar Painful Degenerative Disc Disease: A Comparison of Clinical Results. Adv Orthop. 2013;2013:874090. doi: 10.1155/2013/874090. Epub 2013 Jan 17. PMID: 23401784.

Omidi-Kashani F, Hasankhani EG, Ashjazadeh A. Lumbar spinal stenosis: who should be fused? An updated review. Asian Spine J. 2014 Aug;8(4):521–30. doi: 10.4184/asj.2014.8.4.521. Epub 2014 Aug 19. PMID: 25187873.

Pan Z, Ha Y, Yi S, Cao K. Efficacy of Transforaminal Endoscopic Spine System (TESSYS) Technique in Treating Lumbar Disc Herniation. Med Sci Monit. 2016 Feb 18;22:530–9. PMID: 26887645.

Park CH, Lee SH, Lee SC. Preliminary results of the clinical effectiveness of percutaneous adhesiolysis using a Racz catheter in the management of chronic pain due to cervical central stenosis. Pain Physician. 2013 Jul-Aug;16(4):353-8. PMID: 23877451.

Park P, Foley KT. Minimally invasive transforaminal lumbar interbody fusion with reduction of spondylolisthesis: technique and outcomes after a minimum of 2 years' follow-up. Neurosurg Focus. 2008;25(2):E16. doi: 10.3171/FOC/2008/25/8/E16. PMID: 18673045.

Patel VB, Wasserman R, Imani F. Interventional Therapies for Chronic Low Back Pain: A Focused Review (Efficacy and Outcomes). Anesth Pain Med. 2015 Aug 22; 5(4):e29716. doi: 10.5812/aapm.29716. PMID: 26484298.

Pearson AM. Fusion in degenerative spondylolisthesis: how to reconcile conflicting evidence. J Spine Surg. 2016 Jun;2(2):143-5. doi: 10.21037/jss.2016.06.02. PMID: 27683712.

Peng BG. Pathophysiology, diagnosis, and treatment of discogenic low back pain. World J Orthop. 2013 Apr 18;4(2):42–52. doi: 10.5312/wjo.v4.i2.42 PMID: 23610750.

Popov V, Anderson DG. Minimal invasive decompression for lumbar spinal stenosis. Adv Orthop. 2012;2012:645321. doi: 10.1155/2012/645321. PMID: 22548182.

Price JP, Dawson JM, Schwender JD, Schellhas KP. Clinical and Radiologic Comparison of Minimally Invasive Surgery with Traditional Open Transforaminal Lumbar Interbody Fusion: A Review of 452 Patients from a Single Center. Clin Spine Surg. 2018 Mar;31(2):E121-6. doi: 10.1097/BSD.000000000000581. PMID: 28945642.

Rasouli MR, Rahimi-Movaghar V, Shokraneh F, Moradi-Lakeh M, Chou R. Minimally invasive discectomy versus microdiscectomy/open discectomy for symptomatic lumbar disc herniation. Cochrane Database Syst Rev. 2014 Sep 4;(9):CD010328. doi: 10.1002/14651858.CD010328.pub2. PMID: 25184502.

Schaufele MK. Single level lumbar disc herniations resulting in radicular pain: pain and functional outcomes after treatment with targeted disc decompression. Pain Med. 2008 Oct;9(7):835-43. doi: 10.1111/j.1526-4637.2008.00516.x. PMID: 18950438.

Scheufler KM, Dohmen H, Vougioukas VI. Percutaneous transforaminal lumbar interbody fusion for the treatment of degenerative lumbar instability. Neurosurgery. 2007 Apr;60(4 Suppl 2):203-12; discussion 212-213. Doi: 10.1227/01.NEU.0000255388.03088.B7. PMID: 17415155.

Sjovold SG, Zhu Q, Bowden A, Larsoon CR, de Bakker PM, Villarraga ML, Ochoa JA, Rosler DM, Cripton PA. Biomechanical evaluation of the Total Facet Arthroplasty System® (TFAS®): Loading as compared to a rigid posterior instrumentation system. Eur Spine J. 2012;21(8):1660-73. doi: 10.1007/s00586-012-2253-8. PMID: 22407270.

Smorgick Y, Mirovsky Y, Floman Y, Rand N, Millgram M, Anekstein Y. Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis. J Neurosurg Spine. 2019 Oct 4:1-6. doi: 10.3171/2019.7.SPINE19150. PMID: 31585417.

Spine Intervention Society (SIS) Bogduk N, ed. ISIS Practice Guidelines. Practice Guidelines for the Spinal Diagnostic and Treatment Procedures. (Formerly known as International Spine Intervention Society/ISIS.) Second Edition. San Francisco. 2013.

Spoor AB, Öner FC. Minimally invasive spine surgery in chronic low back pain patients. J Neurosurg Sci. 2013 Sep;57(3):203-18. PMID: 23877267.

Sclafani JA, Kim CW. Complications associated with the initial learning curve of minimally invasive spine surgery: a systematic review. Clin Orthop Relat Res. 2014 Jun;472(6):1711-7. doi: 10.1007/s11999-014-3495-z. PMID: 24510358.

Singh V, Manchikanti L, Calodney AK, Staats PS, Falco FJE, Caraway DL, Hirsch JA, Cohen SP. Percutaneous Lumbar Laser Disc Decompression: An Update of Current Evidence. Pain Physician. 2013 Apr;16(2 Suppl):SE229-60. PMID: 23615885.

Smorgick Y, Mirovsky Y, Floman Y, Rand N, Millgram M, Anekstein Y. Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis. J Neurosurg Spine. 2019 Oct:4;:1-6. doi: 10.3171/2019.7.SPINE19150. PMID: 31585417.

Stagni S, de Santis F, Cirillo L, Dall'Olio M, Princiotta C, Simonetti L, Stafa A, Leonardi M. A minimally invasive treatment for lumbar disc herniation: DiscoGel® chemonucleolysis in patients unresponsive to chemonucleolysis with oxygen-ozone. Interv Neuroradiol. 2012 Mar;18(1):97–104. Epub 2012 Mar 16. doi: 10.1177/159101991201800113. PMID: 22440607.

Taba HA, Williams SK. Lateral Lumbar Interbody Fusion. Neurosurg Clin N Am. 2020 Jan; 31(1):33-42. doi: 10.1016/j.nec.2019.08.004. Epub 2019 Oct 24. PMID: 31739927.

Tan JH, Liu G, Ng R, Kumar N, Wong HK, Liu G. Is MIS-TLIF superior to open TLIF in obese patients? A systematic review and meta-analysis. Eur Spine J. 2018 Aug;27(8):1877-86. doi: 10.1007/s00586-018-5630-0. Epub 2018 Jun 1. PMID: 29858673.

Timmermann J, Hahn M, Krueger K. Short-term follow-up: micro-invasive therapy of the cervical herniated disk by percutaneous nucleotomy. J Back Musculoskelet Rehabil. 2011;24(2):89-93. doi: 10.3233/BMR-2011-0280. PMID: 21558613.

Tsou HK, Chao SC, Kao TH, Yiin JJ, Hsu HC, Shen CC, Chen HT. Intradiscal electrothermal therapy in the treatment of chronic low back pain: experience with 93 patients. Surg Neurol Int. 2010 Aug 4;1:37. doi: 10.4103/2152-7806.67107. Erratum in: Surg Neurol Int. 2012; 3:38. PMID: 20847918. Urits I, Schwartz RH, Brinkman J, Foster L, Miro P, Berger AA, Kassem H, Kaye AD, Manchikanti L, Viswanath O. An Evidence Based Review of Epidurolysis for the Management of Epidural Adhesions. Psychopharmacol Bull. 2020 Oct 15;50(4 Suppl 1):74-90. PMID: 33633419.

U.S. Food and Drug Administration (FDA). 510(k) Premarket Notification. eXtreme Lateral Interbody Fusion (XLIF; NuVasive Inc.). K140162 AP Expandable XLIF System (NuVasive, Inc.) Approved 2014 Jul 2. K130820 AP Expandable Lumbar Interbody System (NuVasive, Inc.) Approved 2013 Aug 8. K132601 CoRoent Sterile System (NuVasive, Inc.) Approved 2013 Dec 24.

Villavicencio AT, Burneikiene S, Bulsara KR, et al. Perioperative complications in transforaminal lumbar interbody fusion versus anterior-posterior reconstruction for lumbar disc degeneration and instability. J Spinal Disord Tech. 2006 Apr;19(2):92-7. doi: 10.1097/01.bsd.0000185277.14484.4e. PMID: 16760781.

Villavicencio AT, Burneikiene S, Roeca CM, Nelson EL, Mason A. Minimally invasive versus open transforaminal lumbar interbody fusion. Surg Neurol Int. 2010 May 31;1:12. doi: 10.4103/2152-7806.63905. PMID: 20657693.

Wu AM, Hu ZC, Li XB, Feng ZH, Chen D, Xu H, Huang QS, Lin Y, Wang XY, Zhang K, Zhao J, Ni WF. Comparison of minimally invasive and open transforaminal lumbar interbody fusion in the treatment of single segmental lumbar spondylolisthesis: minimum two-year follow up. Ann Transl Med. 2018 Mar;6(6):105. doi: 10.21037/atm.2018.02.11. PMID: 29707554.

Yang Y, Liu ZY, Zhang LM, Pang M, Chhantyal K, Wu WB, Chen ZH, Luo CX, Rong LM, Liu B. Microendoscopy-Assisted Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion for Lumbar Degenerative Diseases: 5-Year Outcomes. World Neurosurg. 2018 Aug;116:e602-10. doi: 10.1016/j.wneu.2018.05.049. Epub 2018 May 17. PMID: 29778600.

Yoshihara H, Yoneoka D. National trends in the surgical treatment for lumbar degenerative disc disease: United States, 2000 to 2009. Spine J. 2015 Feb 1;15(2):265-71. doi: 10.1016/j.spinee.2014.09.026. Epub 2014 Oct 2.PMID: 25281920.

### **Next Review Date**

Not applicable

#### **Retired Date**

11/01/22

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	09/01/09	Director of	MPCTAC, QIC, and
Internal Approval:	Version 1	Medical Policy as Chair of MPCTAC	UMC
05/26/09: Medical Policy, Criteria, and			
Technology Assessment Committee			
(MPCTAC) 05/26/09: Utilization Management			
Committee (UMC)			
06/24/09: Quality Improvement Committee			
(QIC)			

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

### Policy Title:

- 1. Effective 09/01/09, this policy replaced the IDET policy. Policy title from 09/01/09 to 05/31/16 was Thermal Intradiscal and Other Minimally Invasive Surgical Treatments for Back Pain.
- 2. Policy renamed Minimally Invasive Procedures for Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures to Remove Disc Material) as of 06/01/16.
- 3. Policy title from 03/01/17 to 05/31/21 was Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material).
- 4. From 06/01/21 to 10/31/22, policy tile was Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, Facet Arthroplasty, Lysis of Epidural Adhesions, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material). Policy retired as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
04/01/10	Annual review. Updated references.	Version 2	04/27/10: MPCTAC 05/26/10: QIC
04/01/11	Annual review. No changes to criteria. Updated references.	Version 3	04/20/11: MPCTAC 05/25/11: QIC

<sup>\*</sup>Effective Date for New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

04/01/12	Annual review. Updated criteria, updated	Version 4	04/18/12: MPCTAC
, ,	coding, updated references.		06/27/12: QIC
07/29/12	Off cycle review for NH product. Revised	Version 5	08/03/12: MPCTAC
	Summary statement, revised Medical Policy		09/05/12: QIC
	Statement, revised language in Applicable		
	Coding section, revised Limitations.		
02/01/13	Annual review for effective date 06/01/13.	06/01/13	02/20/13: MPCTAC
	References updated, updated code	Version 6	03/21/13: QIC
	definitions, revised introductory paragraph in		
	Applicable Coding section, revised Summary		
	section and referenced Experimental and		
	Investigational Treatment policy,		
	reformatted Description of Item or Service		
	section, revised the Medical Policy		
	Statement section (formerly named the		
	Clinical Guideline Statement section) and		
	Limitations section, moved list of experimental and investigation procedures		
	from the Medical Policy Statement section		
	to the Limitations section and added		
	procedures, added definition for		
	nociceptors, changed name of policy		
	category from "Clinical Coverage		
	Guidelines" to "Medical Policy."		
08/14/13 and	Off cycle review for NH product and merged	Version 7	08/14/13: MPCTAC
08/15/13	policy format. Incorporate policy revisions		(electronic vote)
	dated 02/01/13 (as specified above) for the		08/15/13: QIC
	NH Medicaid product; these policy revisions		
	were approved by MPCTAC on 02/20/13		
	and QIC on 03/21/13 for applicable Plan		
	products.		
02/01/14	Annual review for effective 03/01/14. Added	03/01/14	02/19/14: MPCTAC
	arthroscopic microdiscectomy (AMD) and	Version 8	02/26/14: QIC
	examples of percutaneous discectomy		
	devices to the Description of Item or Service		
	section. Updated references.		
02/01/15	Annual review for effective date 04/01/15.	04/01/15	02/18/15: MPCTAC
	Updated references. Removed	Version 9	03/11/15: QIC
	Commonwealth Care, Commonwealth		
	Choice, and Employer Choice from the list of		
	applicable products because the products are no longer available.		
11/25/15	Review for effective date 01/01/16. Updated	01/01/16	11/18/15: MPCTAC
11/23/13	template with list of applicable products and	Version 10	11/25/15: MPCTAC
	notes. Revised language in the Applicable	A 61 21011 10	(electronic vote)
	Coding section.		12/09/15: QIC
1	County Section.	i	12/03/13. WIC

02/01/16	Review for effective date 06/01/16.	06/01/16	02/17/16: MPCTAC
02/01/10		Version 11	
	Updated Summary, Description of Item or	version ii	03/09/16: QIC
	Service, Limitations, Definitions, Clinical		
	Background Information, References, and		
	Reference to Applicable Laws and		
	Regulations sections. Added experimental		
	and investigational codes to the applicable		
	code list and revised the policy title.		
12/01/16	Review for effective date 04/01/17. Revised	03/01/17	12/21/16: MPCTAC
	title. Updated Summary, Description of Item	Version 12	01/11/17: QIC
	or Service, Definitions, Clinical Background		
	Information, and References sections.		
	Revised criteria in the Medical Policy		
	Statement and Limitations sections.		
	Revised the language and code list in the		
	Applicable Coding section.		
03/01/17	Review for effective date 06/07/17.	06/07/17	03/15/17: MPCTAC
	Updated Summary, References, and Other	Version 13	
	Applicable Policies sections. Administrative		
	changes made to the Medical Policy		
	Statement section. Updated applicable		
	code list and added Plan notes to the		
	Applicable Coding section.		
02/01/18	Review for effective date 03/01/18.	03/01/18	02/21/18: MPCTAC
, ,	Updated References and Other Applicable	Version 14	, ,
	Policies sections.		
02/01/19	Review for effective date 03/01/19.	03/01/19	02/20/19: MPCTAC
, ,	Administrative changes made to the Policy	Version 15	, ,
	Summary, Description of Item or Service,		
	References, Other Applicable Policies, and		
	Reference to Applicable Laws and		
	Regulations sections.		
02/01/20	Review for effective date 05/01/20.	05/01/20	02/19/20: MPCTAC
7 7 7 - *	Administrative changes made to the	Version 16	, , , , , , , , , , , , , , , , , , , ,
	Description of Item or Service, Clinical		
	Background Information, References, and		
	Reference to Applicable Laws and		
	Regulations sections. Code added and Plan		
	notes revised in the Applicable Coding		
	section.		
03/01/21	Review for effective date 06/01/21.	06/01/21	03/17/21: MPCTAC
03/01/21		Version 17	03/1/21. WIFCTAC
	Administrative changes made to the Policy	VEISION 1/	
	Summary, Description of Item or Service,		
	Medical Policy Statement, and References		
	sections. Revised the policy title. Criteria		
	revised in the Limitations section. Coding		
	updated in the Applicable Coding section.		

0.0 (01 (01	D. '. ((()' . 1 . 00 /01/01 0 . 1	00 (01 (01	OC /1C /21 NADOTA C
06/01/21	Review for effective date 09/01/21. Codes removed from Applicable Coding section when InterQual criteria used to determine medical necessity. Administrative changes made to the Policy Summary, Description of Item or Service, Medical Policy Statement, Limitations, References, and Other Applicable Policies sections. Updated medical necessity criteria with the use of applicable InterQual criteria, when available.	09/01/21 Version 18	06/16/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitation and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 19	11/17/21: MPCTAC
12/01/21	Review for effective date 01/01/22. Industry-wide code updates made in the Applicable Coding section.	01/01/22 Version 20	Not applicable because industry-wide code changes. 12/15/21: MPCTAC review
02/01/22	Review for effective date 03/01/22. Administrative changes made to the Policy Summary, Applicable Coding, and References sections.	03/01/22 Version 21	02/16/22: MPCTAC
05/01/22	Review for effective date 08/01/22. Codes added to the Applicable Coding section.	08/01/22 Version 22	05/11/22: MPCTAC (electronic vote)
08/01/22	Review for policy retired date 11/01/22. The Plan will adopt on 11/01/22 the AIM clinical appropriateness guidelines for musculoskeletal services, including joint surgery, spine surgery, and interventional pain management services; AIM prior authorization is required for those services as of 11/01/22, even when applicable codes are not listed in this Plan policy. Criteria revised in the Clinical Criteria and Limitations and Exclusions sections.  Administrative changes made to the Policy Summary section. Coding revised in the Applicable Coding section.	11/01/22 Version 23	08/26/22: MPCTAC (electronic vote)



### Medical Policy

# **Non-Emergency Transportation Services**

**Policy Number:** OCA 3.191 **Version Number:** 23

**Version Effective Date:** 11/01/22

# **Impacted Products**

$\square$ All Pro	ducts
-------------------	-------

☑ NH Medicaid

☐ NH Medicare Advantage

☑ MA MassHealth ACO

☑ MA MassHealth MCO

☐ MA Qualified Health Plans/Employer Choice Direct

☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers non-emergency transportation services medically necessary when Plan criteria are met according to applicable state regulations and benefit coverage. Prior authorization is required. The Plan does NOT require prior authorization for emergency ambulance transportation (including ground, air, and/or sea emergency transport) and/or ground ambulance transport when a member is transported between two (2) inpatient facilities where the admission to each inpatient facility is authorized by the Plan.

Coordinated Transportation Solutions, Inc. (CTS) manages the travel arrangements for non-emergent sea transport, non-emergent air transport, and non-emergent ground transportation for NH Medicaid members, SCO members, and NH Medicare Advantage HMO members. CTS may be contacted directly at 1-844-909-RIDE for NH Medicaid members and 1-844-458-6226 for NH Medicare Advantage members. When requesting transportation services for a MA Senior Care Options member, call 1-855-833-8125. Hearing impaired members may dial 711 to be connected to an operator who will then connect the member to CTS. Review the following notification guidelines:

#### 1. MA MassHealth Members:

a. Non-Emergency Transportation Services Managed Directly by MassHealth: Nonemergency transport by land transport, chair car, taxi, and common carriers that generally are pre-arranged to transport a member to and from covered medical care in Massachusetts or within 50 miles or less of the Massachusetts border are covered directly by MassHealth (rather than the Plan) and may require authorization directly from MassHealth; this includes ground ambulance transport when a member is transported between two (2) inpatient facilities. The Plan will assist in the coordination of these services. (This MassHealth coverage guideline does NOT apply to SCO members with MassHealth benefits.)

- b. Non-Emergency Transportation Services Managed by the Plan: All other types of covered non-emergency transportation services that require prior authorization are managed by the Plan (i.e., transportation greater than 50 miles outside of the Massachusetts border). Verify member benefits and eligibility for the type of non-emergency transportation requested (and corresponding services) in addition to obtaining prior authorization for services. When a code is NOT payable by the Plan for a MassHealth member, contact MassHealth rather than the Plan for coverage guidelines.
- 2. MA Qualified Health Plans (QHP) Members: Non-emergency transportation services are NOT routinely covered for QHP members. Benefit exceptions do require Plan prior authorization and may include requests for non-emergency sea and/or non-emergency air transportation according to standard medical necessity criteria used for all Plan products. The Plan does cover transportation services when a QHP member is transported between two (2) inpatient facilities where the admission to each inpatient facility is authorized by the Plan.
- 3. MA Senior Care Options (SCO) Members: CTS will manage the travel arrangements for non-emergency transportation services for SCO members.
- 4. NH Medicaid Members: Contact CTS directly rather than the Plan for requests for non-emergent sea transport, non-emergent air transport, non-emergent chair car/wheelchair van transport, non-emergent ground transport, and/or medically necessary general transportation services for the Plan's NH Medicaid members, including both member and provider requests for service. This includes all non-emergent transportation and associated transportation services (even if the corresponding code are not listed in this policy's Applicable Coding section). Transportation services are not covered outside the United States and its territories.
- 5. NH Medicare Advantage HMO Members: Prior authorization is NOT required for covered nonemergency transportation services provided to NH Medicare Advantage members as a supplemental benefit. Review the member's benefit documents for coverage guidelines and maximum number of trips included in the transportation supplemental benefit. Benefit exceptions do require Plan prior authorization.

### Clinical Criteria for MA MassHealth Product

Contact the Plan for requests for non-emergency transportation services. Applicable medical necessity criteria must be met in EITHER item 1 or item 2:

1. Non-Emergent Sea Transportation or Non-Emergent Air Transportation:

BOTH criteria must be met in item a and item b:

a. Transport is to a contracted or Plan authorized medically appropriate acute care medical facility predetermined and authorized by the Plan; AND

Note: Commercial airline charges may be authorized for the member in lieu of air transportation services only when the Plan determines that the member could be safely and less expensively transported on a commercial airline accompanied by necessary medical attendants.

- b. ANY criteria is met in items (1) through (3):
  - (1) Member's medical condition requires medical attention during transport and EITHER:
    - (a) The use of ground transportation is contraindicated; OR
    - (b) Ground transportation is inappropriate to ensure the member's safe transfer; OR
  - (2) An ill or injured member who received urgent or emergent care outside the service area is determined to be medically stable for transport back to the Plan service area but requires medical attention during transport to ensure a safe return; OR
  - (3) The time needed to provide transport for a patient by land, or the instability of transportation by land, poses a threat to the member's condition or survival; OR
- 2. Other Types of Plan Authorized Non-Emergency Transportation:

Criteria are met in either item a or item b:

a. Non-Emergent Chair Car or Non-Emergent Wheelchair Van Transportation: ±

ALL criteria are met in items (1) through (4):

- (1) Member requires transportation to and/or from a covered medical, dental, and/or behavioral health service (including transport from an inpatient facility when the Plan has authorized the admission unless the reason for the transport is that the originating facility does not have the medically necessary diagnostic or therapeutic service); AND
- (2) Member's medical condition prevents safe transportation by any other means and this method of transportation is the least intensive, medically necessary method; AND

- (3) Member is unable to safely transfer from a wheelchair to a vehicle with or without assistance; AND
- (4) Member is unable to ambulate with or without assistance or a device; OR
- b. Non-Emergent Ground Transportation:

ALL criteria are met in items (1) through (3):

- (1) Member requires transportation to and/or from a covered medical, dental, or behavioral health service (including transport from an inpatient facility when the Plan has authorized the admission unless the reason for the transport is that the originating facility does not have the medically necessary diagnostic or therapeutic service); AND
- (2) Member's medical condition prevents safe transport by any other means and this method of transportation is the least intensive, medically necessary method; AND
- (3) ANY criteria are met in items (a) through (h):
  - (a) Member is bed confined (defined as unable to get out of bed without assistance, unable to ambulate, and unable to sit in a chair or wheelchair); OR
  - (b) Member cannot safely sit upright while seated in a wheelchair; OR
  - (c) Member can tolerate a wheelchair but is medically unstable; OR
  - (d) Member requires oxygen and oxygen saturation level monitoring, in the absence of a portable oxygen system, to treat hypoxemia, syncope, airway obstruction and/or chest pain; OR
  - (e) Member requires isolation due to communicable disease or hazardous material exposure; OR
  - (f) Member has a major orthopedic device that specifically precludes the member from sitting in a wheelchair van or chair car; examples may include backboard, halo-traction, Spica cast, use of pins and traction; OR
  - (g) Member requires special positioning to prevent further injury (i.e., decubiti or other wound, contracture, post-op hip fracture, severe pain, or the member's size and/or medical condition is such that more than one person is needed for transfer); OR
  - (h) Member is at risk of harming him/herself or others.

# Clinical Criteria for MA Senior Care Options (SCO) Product

Contact the Plan for requests for non-emergency transportation services. After Plan approval, CTS may serve as the Plan's designee to coordinate travel arrangements for covered non-emergent transport and general transport services. The requested transportation must be a component of the member's individualized care plan and applicable medical necessity criteria must be met in EITHER item 1 or item 2:

1. Non-Emergent Sea Transportation or Non-Emergent Air Transportation:

BOTH criteria must be met in item a and item b:

- a. Non-emergent sea transportation or non-emergent air transportation is prescribed by the member's primary care provider or treating provider; AND
- b. Ground transportation is contraindicated, inappropriate to ensure the member's safe transfer, or cannot be used to access the member; OR
- 2. Other Types of Plan Authorized Non-Emergency Transportation:

ANY criteria must be met in items a through c:

a. Non-Emergent Chair Car or Non-Emergent Wheelchair Van Transportation:

ALL criteria must be met in items (1) through (4):

- (1) Member requires non-emergent chair care or non-emergent wheelchair van transportation to a covered medical, dental, or behavioral health service, and/or transport to a pharmacy when it is a covered destination according to the CMS Medicare Benefit Policy Manual in effect at the time of the prior authorization request, or the transportation service is authorized by the Plan for care management and integration of medically necessary services for the member's individualized care plan; AND
- (2) Member's medical condition prevents safe transportation by any other means and this method of transportation is the least intensive, medically necessary method; AND
- (3) Member is unable to safely transfer from a wheelchair to a vehicle with or without assistance; AND
- (4) Member is unable to ambulate with or without assistance or a device; OR
- b. Non-Emergent Ground Ambulance Transportation:

BOTH criteria must be met in items (1) and (2):

Non-Emergency Transportation Services

- (1) Member's medical condition prevents safe transportation by any other means and this method of transportation is the least intensive, medically necessary method; AND
- (2) Member meets ANY criteria in items (a) through (i):
  - (a) Member requires non-emergent ground transportation to a covered medical, dental, or behavioral health service and/or transport to a pharmacy when it is a covered destination according to the CMS Medicare Benefit Policy Manual in effect at the time of the prior authorization request, or the transportation service is authorized by the Plan for care management and integration of medically necessary services for the member's individualized care plan; OR
  - (b) Member is bed confined (defined as unable to get out of bed without assistance, unable to ambulate, and unable to sit in a chair or wheelchair); OR
  - (c) Member cannot safely sit upright while seated in a wheelchair; OR
  - (d) Member can tolerate a wheelchair but is medically unstable; OR
  - (e) Member requires oxygen and oxygen saturation level monitoring, in the absence of a portable oxygen system, to treat hypoxemia, syncope, airway obstruction and/or chest pain; OR
  - (f) Member requires isolation due to communicable disease or hazardous material exposure; OR
  - (g) Member has a major orthopedic device that specifically precludes the member from sitting in a wheelchair van or chair car; examples may include backboard, halo-traction, Spica cast, use of pins and traction; OR
  - (h) Member requires special positioning to prevent further injury (i.e., decubiti or other wound, contracture, post-op hip fracture, severe pain, or the member's size and/or medical condition is such that more than one person is needed for transfer); OR
  - (i) Member is at risk of harming him/herself or others; OR

#### c. General Transportation:

Member requires general transportation services (excluding coverage for private transportation services that may include but are not limited to a taxi service, private car service, and/or transportation provided by a member, family member, friend, volunteer, and/or significant other) to a covered medical, dental, or behavioral health service and/or transport to a pharmacy when it is a covered destination according to the CMS Medicare

Benefit Policy Manual in effect at the time of the prior authorization request, or the transportation service is authorized by the Plan for care management and integration of medically necessary services for the member's individualized care plan. General transportation services must be authorized by the Plan for the mode of transportation and indication for transport, arrangements are coordinated by the Plan's Care Management staff (or CTS as the Plan's designee), and the transportation service is covered.

## **Clinical Criteria for NH Medicaid Product**

Contact CTS directly rather than the Plan for requests for covered non-emergent transport and/or medically necessary general transportation services for NH Medicaid members. CTS will coordinate covered and medically necessary transportation on behalf of Plan members (and will direct requests to the Plan's Care Management staff for medically necessary non-emergent transportation requests over 100 miles one way for a NH Medicaid member).

Applicable medical necessity criteria must be met in EITHER item 1 or item 2:

1. Non-Emergent Sea Transportation or Non-Emergent Air Transportation:

Non-emergent sea transport or non-emergent air transport to and/or from medically necessary care is covered when BOTH criteria are met in item a and item b:

- a. Transport is to a contracted or Plan authorized medically appropriate acute care medical facility predetermined and authorized by the Plan; AND
- b. ANY criteria is met in items (1) through (4):
  - (1) Member's medical condition requires medical attention during transport and ANY criteria is met in item (a) or item (b):
    - (a) The use of ground transportation is contraindicated; OR
    - (b) Ground transportation is inappropriate to ensure the member's safe transfer; OR
  - (2) An ill or injured member who received urgent or emergent care outside the service area is determined to be medically stable for transport back to the Plan service area but requires medical attention during transport to ensure a safe return; OR
  - (3) The time needed to provide transport for a patient by land, or the instability of transportation by land, poses a threat to the member's condition or survival; OR
  - (4) The non-emergent sea transportation or non-emergent air transportation is prescribed by the member's primary care provider or treating provider and ground transportation is contraindicated, inappropriate to ensure the member's safe transfer, or cannot be used to access the member; OR

Non-Emergency Transportation Services

Note: Commercial airline charges may be authorized for the member in lieu of air transportation services only when the Plan determines that the member could be safely and less expensively transported on a commercial airline accompanied by necessary medical attendants. Coverage for transportation services complies with applicable New Hampshire regulations (including He-W 572).

2. Other Types of Plan Authorized Non-Emergent Transportation:

ANY criteria must be met in items a through c:

a. Non-Emergent Chair Car or Non-Emergent Wheelchair Van Transportation:

ALL criteria must be met in items (1) through (4):

- (1) Member requires transportation to and/or from a covered medical, dental, or behavioral health service (including transport from an inpatient facility when the Plan has authorized the admission unless the reason for the transport is that the originating facility does not have the medically necessary diagnostic and/or therapeutic service), with coverage according to the member's benefit document and applicable New Hampshire regulations (including He-W 572); AND
- (2) Member's medical condition prevents safe transportation by any other means and this method of transportation is the least intensive, medically necessary method; AND
- (3) Member is unable to safely transfer from a wheelchair to a vehicle with or without assistance; AND
- (4) Member is unable to ambulate with or without assistance or a device; OR
- b. Non-Emergent Ground Transportation:

ALL criteria must be met in items (1) through (3):

- (1) Member requires transportation to and/or from a covered medical, dental, or behavioral health service (including transport from an inpatient facility when the Plan has authorized the admission unless the reason for the transport is that the originating facility does not have the medically necessary diagnostic and/or therapeutic service), with coverage according to the member's benefit document and applicable New Hampshire regulations (including He-W 572and He-W 574); AND
- (2) Member's medical condition prevents safe transportation by any other means and this method of transportation is the least intensive, medically necessary method; AND
- (3) Member meets ANY criteria in items (a) through (k):

Non-Emergency Transportation Services

- (a) The non-emergent ground transportation is prescribed by the member's primary care provider or treating provider; OR
- (b) Member is bed confined (defined as unable to get out of bed without assistance, unable to ambulate, and unable to sit in a chair or wheelchair); OR
- (c) Member cannot safely sit upright while seated in a wheelchair and must be transported in a supine position; OR
- (d) Member can tolerate a wheelchair but is medically unstable; OR
- (e) Member requires oxygen and oxygen saturation level monitoring, in the absence of a portable oxygen system, to treat hypoxemia, syncope, airway obstruction and/or chest pain; OR
- (f) Member requires isolation due to communicable disease or hazardous material exposure; OR
- (g) Member has a major orthopedic device that specifically precludes the member from sitting in a wheelchair van or chair car; examples may include backboard, halo-traction, Spica cast, use of pins and traction; OR
- (h) Member requires special positioning to prevent further injury (i.e., decubiti or other wound, contracture, post-op hip fracture, severe pain, or the member's size and/or medical condition is such that more than one person is needed for transfer); OR
- (i) Member is at risk of harming him/herself or others and requires restraints during transport; OR
- (j) Member requires skilled/trained monitoring with life support equipment during transport, which may include but is not limited to a member with ANY conditions in items I through vi:
  - i. Member is comatose; OR
  - ii. Member requires airway monitoring; OR
  - iii. Member requires cardiac monitoring; OR
  - iv. Member is dependent on a ventilator; OR
  - v. Member requires suctioning; OR

- vi. Member requires the supply and/or regulation of oxygen; OR
- (k) Member requires skilled/trained monitoring during transport for ANY conditions in items i through vi:
  - i. Member is comatose; OR
  - ii. Member requires airway monitoring; OR
  - iii. Member requires cardiac monitoring; OR
  - iv. Member is dependent on a ventilator; OR
  - v. Member requires suctioning; OR
  - vi. Member requires the supply and/or regulation of oxygen; OR
- c. General Transportation:

General transportation services are covered and consider medically necessary when the Plan's NH Medicaid member requires general transportation services to a covered medical, dental, or behavioral health service, and/or transport to a pharmacy (if the pharmacy does not provide free delivery services to the member's home) ONLY when the transportation is authorized by CTS (as the Plan's designee) in advance. Requests for transportation services must be submitted to CTS at least 48 hours before the member's non-urgent appointment time. CTS will accept an urgent request for transportation services with less than 48-hour notification when the treating provider's office has validated that that the member requires an urgent appointment. CTS must prospectively authorize the mode of transportation and indication for transport, and arrangements must be coordinated by CTS. General transportation services are covered for a NH Medicaid member for healthcare services when the member is not able to obtain free transportation (or not eligible for transportation from another agency), as specified in the member's applicable benefit document and according to applicable New Hampshire regulations (including He-W 572 and He-W 574). The member is responsible for submitting prior authorization requests in advance to CTS for general transportation services, and the member must comply with all reimbursement guidelines. Covered general transportation services may include public transportation (including bus and/or train) and transportation provided by a CTS provider authorized to transport the member (with mileage reimbursement for the driver according to CTS quidelines). See the New Hampshire Medicaid Member Handbook rather than this policy for Plan rules for transportation coordination and reimbursement for the Friends and Family Mileage Reimbursement Program and Request a Ride Program.

### **Limitations and Exclusions**

The following transportation services are NOT covered:

- 1. Transportation to and/or from medical appointments, dental appointments, behavioral health appointments, and/or transport to a pharmacy EXCEPT when the specific transportation service is covered and authorized by the Plan or CTS as the Plan's designee.
- 2. Private transportation services (such as taxi service, private car service, and/or transportation provided by a member, family member, friend, volunteer, and/or significant other) UNLESS authorized by the Plan or CTS as the Plan's designee as a medically necessary service and a component of the member's individualized treatment plan.
- 3. Public transportation UNLESS authorized by the Plan or CTS as the Plan's designee as a medically necessary service and component of the member's individualized treatment plan.
- 4. Transport, non-emergent chair car or non-emergent wheelchair van transportation, or covered general transportation solely for the convenience or preference of a member or the member's family member (unless authorized by the Plan as a medically necessary service and a component of the member's individualized treatment plan).
- 5. Transport, non-emergent chair car or non-emergent wheelchair van transportation when an alternative method of transportation is available and can be utilized without endangering the member's health status unless authorized by the Plan or CTS as the Plan's designee as a medically necessary service and a component of the member's individualized treatment plan.
- 6. Transport for the purpose of seeking a non-covered service unless authorized by the Plan or CTS as the Plan's designee as a medically necessary service and a component of the member's individualized treatment plan.
- 7. Transport for any purpose other than to receive covered healthcare services from a network provider.

### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

# **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification

of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

HCPCS Codes	Description: The following transportation codes REQUIRE prior authorization.	
	Contact CTS for all non-emergency transport for SCO and NH Medicaid members.	
A0021	Ambulance service, outside state per mile, transport (Medicaid only)	
	Plan note: Code is NOT payable for the Plan's SCO members.	
A0100	Nonemergency transportation; taxi	
A0110	Nonemergency transportation and bus, intra- or interstate carrier	
A0120	Nonemergency transportation: mini-bus, mountain area transports, or other transportation systems	
A0130	Nonemergency transportation: wheelchair van	
A0170	Transportation ancillary: parking fees, tolls, other	
	Plan note: Payable by the Plan for NH Medicaid and SCO members if related to emergency ambulance services and is dependent on the primary transportation code.	
A0426	Ambulance service, advanced life support, non-emergency transport, level 1 (ALS 1)	
A0428	Ambulance service, basic life support, non-emergency transport (BLS)	
	Plan note: Ground ambulance transport is covered and does NOT require prior authorization when a member is transported between two (2) inpatient facilities where the admission to each inpatient facility is authorized by the Plan.	
A0998	Ambulance response and treatment, no transport	
A0999	Unlisted ambulance service	
S0215	Non-emergency transportation; mileage, per mile	
	Plan note: Code is NOT payable for members with MassHealth Family Assistance coverage.	
T2001	Nonemergency transportation; patient attendant/escort	
	Plan note: Code is NOT payable for members with MassHealth Family Assistance coverage.	
T2005	Non-emergency transportation; stretcher van	
T2049	Non-emergency transportation; stretcher van, mileage; per mile	

## References

American College of Emergency Physicians. EMTALA Main Points.

Centers for Medicare & Medicaid Services (CMS). Ambulances Services Center.

Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual. Publication Number 100-02. Transmittal 130. Change Request 7058. Definition of Ambulance Services. 2010 Jul 29.

Centers for Medicare & Medicaid Services (CMS). Medicare Benefit Policy Manual. Publication Number 100-02. Chapter 10 – Ambulance Services.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Centers for Medicare & Medicaid Services (CMS). Welcome to the Medicare Coverage Database.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

### **Next Review Date**

03/01/23

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Non-Emergency Transportation Services

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	01/01/12	Director of Medical	MPCTAC and QIC
	Version 1	Policy as Chair of	
Internal Approval:		MPCTAC	
06/29/11: Medical Policy, Criteria,			
and Technology Assessment			
Committee (MPCTAC)			
07/27/11: Quality Improvement			
Committee (QIC)			

- \* Effective Date for QHP and MassHealth Products: 01/01/12.
- \* Effective Date for NH Medicaid Product: 07/01/14.
- \* Effective Date for SCO Product: 01/01/16.

Effective 06/01/22 policy title changed from Emergency Transportation Services to *Non-Emergent Transportation Services* until 05/31/22. As of 06/01/22, policy title changed to *Non-Emergency Transportation Services*.

### Transportation Vendor:

- From 06/01/20 to 06/30/22, One Call Government Solutions, LLC (One Call) managed the travel arrangements for non-emergent sea transport, non-emergent air transport, and non-emergent ground transportation for New Hampshire Medicaid members and Senior Care Options members.
- Prior to 06/01/20 and as of 07/01/22, Coordinated Transportation Solutions, Inc. (CTS) manages the travel arrangements for non-emergent sea transport, non-emergent air transport, and non-emergent ground transportation for New Hampshire Medicaid and Senior Care Options members.

Policy Revisio	Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by	
07/01/12	Updated reference, revised language in Applicable Code section, included list of applicable codes, added detail on the when to reference the Plan's Reimbursement Guidelines: Transportation policy. Included clarification on limitations on the use of ambulance transport (i.e., limitation when ambulance transport is solely for convenience, when another alternative is safe and available, and/or use with non-covered services).	Version 2	06/20/12: MPCTAC 07/18/12: MPCTAC 08/22/12: QIC	

Non-Emergency Transportation Services

Policy Revisi	ons History		
11/01/12	Added Commonwealth Care to list of applicable products (to comply with EOC), removed "Guidelines" from title, updated Summary and References sections, reformatted Medical Policy Statement section, added references to sea ambulance (as appropriate).	Version 3	11/21/12: MPCTAC 12/20/12: QIC
03/01/13	Review, deleted redundant text in the Summary section, revised Description of Item or Service section, moved medical criteria from the Summary section to the Medical Policy Statement section (formerly named Clinical Guideline Statement section), updated applicable code list and references, and changed name of policy category from "Clinical Coverage Guidelines" to "Medical Policy."	Version 4	03/20/13: MPCTAC 04/18/13: QIC
03/01/14	Review for effective date 07/01/14. Added New Hampshire Medicaid as an applicable product for this policy and included criteria for New Hampshire Medicaid product.  Updated references, applicable code list (adding HCPCS codes S9960 and S9961), and revised language in the Applicable Coding section. Revised Summary section and added note to policy header. Added reference to Coordinated Transportation Solutions, Inc. (CTS), the Plan's external partner who manages the travel arrangements for non-emergent sea transport, non-emergent air transport, and non-emergent ground transportation for New Hampshire Medicaid members. Reformatted and revised criteria for BMC HealthNet Plan products, allowing the approval of transport to a Plan authorized acute care medical facility (as well as a contracted facility).	07/01/14 Version 5	03/19/14: MPCTAC 04/16/14: QIC
06/30/14	Off cycle review for effective date 10/01/14. Removed the following codes from the applicable code list: A0425, A0430, A0431, A0434, A0435, and A0436 (since these codes may be used with emergency transport and Plan prior authorization will not be required).	10/01/14 Version 6	06/30/14: MPCTAC (electronic vote) 07/09/14: QIC

Policy Revisi	ions History		
10/31/14	Off cycle review for effective date 12/01/14. Added MassHealth as an applicable product. Updated Summary, Medical Policy Statement, and Limitations sections without changing criteria.	12/01/14 Version 7	10/31/14: MPCTAC (electronic vote) 11/12/14: QIC
03/01/15	Review for effective date 05/01/15. Updated references. Revised the Limitations section to reference the member's applicable benefit document without changing the service limitations. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.	05/01/15 Version 8	03/18/15: MPCTAC 04/08/15: QIC
11/01/15	Review for effective date 0 1/01/16. Updated product applicability template and note.  Administrative changes made to the Summary, Limitations, and BMC HealthNet Plan Medical Policy Statement sections to reference the Senior Care Options (SCO) product and interface with Coordinated Transportation Solutions, Inc. (CTS) to manage the travel arrangements for covered non-emergent transport for SCO members. Revised language in the Applicable Coding section.	01/01/16 Version 9	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
05/01/16	Review for effective date 09/01/16. Updated Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Administrative changes made to the Summary, Description of Item or Service, Applicable Coding, and Definitions sections. Criteria changes made in the Medical Policy Statement and Limitations sections. Updated applicable code list.	09/01/16 Version 10	05/31/16: MPCTAC (electronic vote) 06/08/16: QIC
04/01/17	Review for effective date 07/08/17. Updated Summary section. Administrative changes made to the Medical Policy Statement section. Revised the code list, revised Plan notes for applicable codes, and administrative changes made to the Applicable Coding section.	07/08/17 Version 11	04/28/17: MPCTAC
02/01/18	Review for effective date 05/01/18.  Administrative changes made to the Policy Summary and Other Applicable Policies sections. Updated criteria in the Medical	05/01/18 Version 12	02/21/18: MPCTAC

Delieu Beriei	ana Historia		
Policy Revisi	ons History		
	Policy Statement and Limitations sections. Revised applicable code list.		
04/01/18	Review for effective date 05/01/18. Updated Plan notes (administrative changes only) in the Applicable Coding section.	05/01/18 Version 13	04/18/18: MPCTAC
09/01/18	Review for effective date 12/01/18. Revised criteria in the Medical Policy Statement for BMC HealthNet Plan Product, Senior Care Options Product, and New Hampshire Medicaid Product sections. Updated the Definitions and the Other Applicable Policies sections.	12/01/18 Version 14	09/19/18: MPCTAC
03/01/19	Review for effective date 04/01/19.  Administrative changes made to the Medical Policy Statement for New Hampshire Medicaid Product section and the Limitations section. Updated the Plan notes in the Applicable Coding section and revised the Other Applicable Policies section and the Applicable Laws and Regulations section.	04/01/19 Version 15	03/20/19: MPCTAC
11/01/19	Review for effective date 01/01/20. Plan note effective 01/01/20 added to the Applicable Coding section. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	01/01/20 Version 16	11/20/19: MPCTAC
04/01/20	Review for effective date 06/01/20. The Plan has partnered with the non-emergency medical transportation vendor, One Call Government Solutions, LLC (One Call). One Call replaces Coordinated Transportation Solutions, Inc. (CTS) effective 06/01/20 as the manager of travel arrangements for non-emergent sea transport, non-emergent air transport, and non-emergent ground transportation for members enrolled in the Plan's New Hampshire Medicaid product or the Senior Care Options product.  Administrative changes made to the Policy Summary, Medical Policy Statement for Senior Care Options Products, Medical Policy Statement for New Hampshire Medicaid Product, Limitations, and Applicable Coding sections.	06/01/20 Version 17	04/15/20: MPCTAC
01/01/21	Review for effective date 04/01/21. Plan notes and coding revised in the Applicable	04/01/21 Version 18	01/19/21: MPCTAC (electronic vote)

Policy Revis	ions History		
	Coding section. Administrative change made to the Other Applicable Policies section.		
02/01/21	Review for effective date 05/01/21. Revised the coding in the Applicable Coding section.	05/01/21 Version 19	02/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 20	11/30/21: MPCTAC (electronic vote)
04/01/22	Review for effective date 05/01/22.  Emergency transportation and facility-to-facility transport do not require prior authorization so services removed from the Clinical Criteria for MassHealth Product and Clinical Criteria for New Hampshire Medicaid Product sections. Administrative changes made to the Policy Summary, Applicable Coding, and References sections. QHP was removed as an applicable product from the policy but no material changes to coverage. Revised the policy title.	05/01/22 Version 21	04/20/22: MPCTAC
06/01/22	Review for effective date 07/01/22.  Administrative changes made to the Policy Summary, Clinical Criteria for MA Senior Care Options Product, Clinical Criteria for NH Medicaid Product, Limitations and Exclusions, and Applicable Coding sections.	07/01/22 Version 22	06/15/22: MPCTAC
08/01/22	Review for effective date 11/01/22. Removed CPT code A0434 from the Applicable Coding section.	11/01/22 Version 23	08/26/22: MPCTAC (electronic vote)



Medical Policy - Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 11/01/22

# Occupational Therapy in the Outpatient Setting

Policy Number: OCA 3.543 Version Number: 25 Policy Retired Date: 11/01/22
Impacted Products
☐ All Products
NH Medicaid     ■ NH
<ul><li>☑ NH Medicare Advantage</li><li>☐ MA MassHealth ACO</li></ul>
<ul><li>☐ MA MassHealth ACO</li><li>☐ MA MassHealth MCO</li></ul>
☐ MA Qualified Health Plans/Employer Choice Direct
☐ MA Senior Care Options
Note: Disclaimer and audit information is located at the end of this document.
Policy Summary
The Plan considers outpatient occupational therapy (OT) medically necessary, including habilitative services and/or rehabilitative services, when AIM clinical appropriateness guidelines are met for an adult or pediatric member or are required EPSDT services for a member age 20 or younger on the date of service. Prior authorization from AIM Specialty Health is required for outpatient OT after the initial evaluation. OT must be provided within the scope of practice of the treating professional and/or paraprofessional and follow all applicable state licensing and supervisory requirements.
Clinical Criteria
No medical policy criteria.
Limitations and Exclusions
None.
Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for NH Medicare Advantage members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, LCD L34427 includes medically necessary indications for occupational therapy. Verify CMS guidelines in in effect on the date of the prior authorization request. When there is no guidance from CMS on the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for occupational therapy, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

<b>CPT Codes</b>	Code Descriptions	
97010	Application of a modality to 1 or more areas; hot or cold packs	
97012	Application of a modality to 1 or more areas; traction, mechanical	
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)	
97016	Application of a modality to 1 or more areas; vasopneumatic devices	
97018	Application of a modality to 1 or more areas; paraffin bath	
97022	Application of a modality to 1 or more areas; whirlpool	
97024	Application of a modality to 1 or more areas; diathermy (e.g., microwave)	
97026	Application of a modality to 1 or more areas; infrared	
97028	Application of a modality to 1 or more areas; ultraviolet	
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes	
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes	
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes	
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes	
97036	Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes	
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility	
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities	
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises	
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)	
97124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion)	

97129	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes
97130	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97150	Therapeutic procedure(s), group (2 or more individuals)
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; an update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and a revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes
97535	Self-care/home management training (e.g., activities of daily living [ADL] and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
97537	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes by provider, each 15 minutes
97545	Work hardening/conditioning; initial 2 hours
97546	Work hardening/conditioning; each additional hour (List separately in addition to code for primary procedure)
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
97761	Prosthetic training, upper and/or lower extremity(ies), initial prosthetic(s) encounter each 15 minutes

97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower	
	extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15	
	minutes	

## References

American Academy of Pediatrics (AAP). 2020 Recommendations for Preventive Pediatric Health Care. Committee on Practice and Ambulatory Medicine and Bright Futures Periodicity Schedule Workgroup. Pediatrics. 2020 Mar;145(3):e20200013. doi: 10.1542/peds.2020-0013

American Occupational Therapy Association (AOTA). Guidelines for Supervision, Roles, and Responsibilities During the Delivery of Occupational Therapy Services. Am J Occup Ther. 2020 Nov-Dec;7413410020. doi: 10.5014/ajot.2020.74S3004.

American Occupational Therapy Association (AOTA). Occupational Therapy Using a Sensory Integration-Based Approach with Adult Populations.

American Occupational Therapy Association (AOTA). Practice Guidelines.

American Occupational Therapy Association (AOTA). Scope of Practice: Questions & Answers

Centers for Medicare & Medicaid Services (CMS). Early and Periodic Screening, Diagnostic and Treatment (EPSDT). Medicaid.gov.

Centers for Medicare & Medicaid Services (CMS). EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents. 2014 Jun.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Outpatient Physical and Occupational Therapy Services A56566. 2019 Dec 19. Revision Effective Date 2020 Oct 1. National Government Services, Inc.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Outpatient Physical and Occupational Therapy Services L33631. 2015 Oct 1. Revision Effective Date 2020 Jan 1. National Government Services, Inc.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Hayes. Health Technology Assessment. Cognitive Rehabilitation Therapy for Traumatic Brain Injury (TBI). Dallas, TX: Hayes; 2017 Sep 26. Annual Review 2021 Feb 8.

Hayes. Health Technology Assessment. Occupational Therapy for Attention-Deficit/Hyperactivity Disorder (ADHD). Dallas, TX: Hayes; 2017 Mar 16. Annual Review 2021 May 12.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. NH Medicaid Program.

New Hampshire Department of Health and Human Services. Provider Notices

New Hampshire Medicaid. Therapies. Physical, Occupational, Speech. Provider Manual. Volume II. 2017 Dec 1.

New Hampshire Office of Professional Licensure and Certification. Office of Licensed Allied Health Professionals. Laws and Administrative Rules Governing Licensed Allied Health Professionals.

## **Next Review Date**

Not applicable

## **Retired Date**

11/01/22

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.		
Occupational Therapy in the Outpatient Setting (NH Products)		

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	10/16/05	Director of Medical Policy as	Quality and Clinical
	Version 1	Chair of Medical Policy,	Management
Internal Approval:		Criteria, and Technology	Committee
09/16/05		Assessment Committee	(Q&CMC)
		(MPCTAC)	

<sup>\*</sup>Effective Date for NH Medicaid Product: 01/01/13

Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
02/07/06	Added definitions for modality and visit. Defined coverage for visits, evaluations and units billed.	Version 2	02/07/06: Q&CMC
07/06/06	Removed verbiage regarding reimbursement for evaluation and modality services.	Version 3	07/06/06: Q&CMC
03/27/07	Policy archived.	Not applicable	Not specified
10/14/08	Policy reviewed and clinical criteria updated, effective date of revised policy is 12/16/08.	12/16/08 Version 4	11/10/08: MPCTAC 12/16/08: Quality Improvement Committee (QIC)
09/22/09	No changes.	Version 5	09/22/09: MPCTAC 10/28/09: QIC
10/01/10	Updated template and references, no changes to criteria	Version 6	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Added Commercial benefit limitations, updated references and coding.	Version 7	10/19/11: MPCTAC 11/29/11: QIC
08/01/12	Off cycle review for the NH Medicaid product, revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introductory paragraph, updated code list, revised limitations, deleted references to contracts and EOCs that are not applicable.	Version 8	08/13/12: MPCTAC 09/06/12: QIC
11/01/12	Review for effective date 03/01/13. Updated references and revised Summary section.	03/01/13 Version 9	11/21/12: MPCTAC 12/20/12: QIC

<sup>\*</sup>Effective Date for NH Medicare Advantage HMO Product: 01/01/22

	Moved medical criteria from Summary section		
	to Clinical Guidelines Statement section.		
	Moved services not considered medically		
	necessary from the Clinical Guidelines		
	Statement section to the Limitations section.		
	Updated applicable coding list and references.		
	Removed duplicate text in the Clinical		
	Background Information section. Referenced		
	Plan reimbursement policy 4.609 for		
	occupational therapy reimbursement guidelines.		
	Updated language in introductory paragraph of		
	Applicable Coding section. Removed		
	"Guideline" from title.		
00/14/12		\/i10	00 /14 /12: MDCTAC
08/14/13 and	Off cycle review for the NH Medicaid product	Version 10	08/14/13: MPCTAC
08/15/13	and merged policy format. Incorporate policy		(electronic vote)
	revisions dated 11/01/12 (as specified above) for		08/15/13: QIC
	the NH Medicaid product; these policy revisions		
	were approved by MPCTAC on 11/21/12 and QIC		
	on 12/20/12 for applicable Plan products.		
11/01/13,	Review for effective date 05/01/14. Updated	05/01/14	02/11/14: MPCTAC
12/01/13,	code definitions, introductory paragraph in	Version 11	02/18/14: QIC
01/01/14, and	Applicable Coding section, and the applicable		
02/01/14	code lists for the MA products and the NH		
	Medicaid product. Updated references.		
	Removed prior authorization waiver for the first		
	32 units of OT for the NH Medicaid product.		
	Add criterion in the Medical Policy Statement		
	sections for the MA products and NH Medicaid		
	product requiring an updated physician		
	prescription and supporting clinical		
	documentation after 20 OT visits per treatment		
	episode. Revised Limitations.		
09/08/14	For NH Medicaid product only, waived prior	10/01/14	09/17/14: MPCTAC
, ,	authorization of first eight (8) 15-minute	Version 11	09/301/14: QIC
	treatment units per member per servicing	Addendum A	
	provider per calendar year.		
11/04/14 and	Review for effective date 01/11/15. Summary	01/11/15	11/06/14: MPCTAC
11/19/14	and Medical Policy Statement sections updated	Version 12	(electronic vote)
1.7.137.1.1	with guidelines specified in version 11, addendum	V 0101011 12	11/11/14: QIC
	A. Policy renumbered OCA 3.543 to include		(electronic vote)
	occupational therapy in the outpatient setting		11/19/14: MPCTAC
	for NH Medicaid members age 21 or older.		12/10/14: QIC
	Summary, Limitations, and References sections		12/10/17. QIC
	updated. (OT services formerly included in		
	policy number OCA 3.53 for all adult and		
	pediatric members.) Change in review calendar.		

12/03/15	Review for effective date 01/01/16. Updated	01/01/16	12/03/15: MPCTAC
12/ 03/ 13	template and Summary section. Administrative changes made to the Medical Policy Statement section and Limitations sections without changing criteria. Revised language in the Applicable Coding section. Added definitions.	Version 13	(electronic vote) 12/09/15: QIC
12/01/16	Review for effective date 02/01/17. Industry-wide revisions of applicable codes. Clarified existing criteria in the Medical Policy Statement section.	02/01/17 Version 14	12/21/16: MPCTAC 01/11/17: QIC
12/01/17	Review for effective 01/01/18. Industry-wide updates to codes included in the Applicable Coding section. Annual review of policy with administrative changes made to the Definitions and Reference sections.	01/01/18 Version 15	12/20/17: MPCTAC
02/01/18	Review for effective date 03/01/18. Administrative changes made to the Policy Summary and Limitations sections.	03/01/18 Version 16	02/21/18: MPCTAC
11/01/18	Review for effective date 12/01/18. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Definitions, Applicable Coding, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/18 Version 17	11/21/18: MPCTAC
03/01/19	Review for effective date 07/01/19. Criteria and prior authorization guidelines revised in the Medical Policy Statement section.  Administrative changes made to the Limitations and Reference to Applicable Laws and Regulations sections.	07/01/19 Version 18	03/20/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide updates to codes included in the Applicable Coding section.	01/01/20 Version 19	Not applicable because industry-wide code changes
11/01/19	Review for effective date 02/01/20. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to the References Reference to Applicable Laws and Regulations sections.	O2/01/20 Version 20  Renumbered to version 20 to implement industry-wide code updates effective O1/01/20 in version 19	11/20/19: MPCTAC

12/01/19	Review for effective 02/01/20. Industry-wide updates to codes effective 01/01/20 included in the Applicable Coding section of the policy version 20 effective 02/01/20.	02/01/20 Version 21	Not applicable because industry-wide code changes
12/01/19	Review for effective date 03/01/20. Revised in the Medical Policy Statement section the definition of a servicing OT provider for the prior authorization waiver.	03/01/20 Version 22	12/18/19: MPCTAC
11/01/20	Review for effective date 12/01/20. Updated the References section. Administrative change made to the Applicable Coding section.	12/01/20 Version 23	11/18/20: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary and References sections. Criteria revised in the Clinical Criteria and Limitations and Exclusions sections. Medical policy criteria retired and InterQual criteria will continue to be used to determine medical necessity.	12/01/21 Version 24	11/17/21: MPCTAC
08/01/22	Review for effective date 11/01/22.  Administrative changes made to the Policy Summary and Applicable Coding sections. InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and Limitations and Exclusions sections retired on 11/01/22. AIM criteria adopted for outpatient OT on 11/01/22. Plan prior authorization waivers removed after 10/31/22. AIM prior authorization is required for outpatient OT after the initial evaluation as of 11/01/22, even when applicable codes are not listed in this Plan policy.	11/01/22 Version 25	08/26/22: MPCTAC (electronic vote)



Medical Policy - Policy Retired and AIM Criteria Adopted as of 11/01/22

# Osteochondral Treatments for Defects of the Knee, Talus, or Other Joints

Policy Number: OCA 3.965

**Version Number**: 19

**Policy Retired Date**: 11/01/22

## **Impacted Products**

- **⋈** All Products
- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers autologous chondrocyte implantation (ACI)/matrix-induced autologous chondrocyte implantation (MACI), osteochondral autograft transplantation (OATS/autologous mosaicplasty), and osteochondral allograft transplantation procedures medically necessary for the treatment of osteochondral defects when AIM clinical appropriateness guidelines are met. Prior authorization from AIM Specialty Health is required for musculoskeletal procedures and interventional pain management services.

## **Clinical Criteria**

No medical policy criteria.

## **Limitations and Exclusions**

None.

## **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and NH Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO or NH Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

# **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for this service, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT/HCPCS Codes	Code Descriptions	
27412	Autologous chondrocyte implantation, knee	
27415	Osteochondral allograft, knee, open	
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of	
	autograft[s])	
28446	Open osteochondral autograft, talus (includes obtaining grafts[s])	
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty)	
	(includes harvesting of the autograft[s])	
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)	
J7330	Autologous cultured chondrocytes, implant	
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)	

## References

Aae TF, Randsborg PH, Lurås H, Årøen A, Lian ØB. Microfracture is more cost-effective than autologous chondrocyte implantation: a review of level 1 and level 2 studies with 5 year follow-up. Knee Surg Sports Traumatol Arthrosc. 2018 Apr;26(4):1044-52. doi: 10.1007/s00167-017-4802-5. Epub 2017 Nov 11. PMID: 29128878.

Ahmad J, Jones K. Comparison of Osteochondral Autografts and Allografts for Treatment of Recurrent or Large Talar Osteochondral Lesions. Foot Ankle Int. 2016 Jan;37(1):40-50. doi: 10.1177/1071100715603191. Epub 2015 Sep 2. PMID: 26333683.

American Academy of Orthopaedic Surgeons (AAOS). Carey JL, Shea KG. AAOS Appropriate Use Criteria: Management of Osteochondritis Dissecans of the Femoral Condyle. J Am Acad Orthop Surg. 2016 Sep;24(9):e105-11. doi: 10.5435/JAAOS-D-16-00227. PMID: 27479836.

American Academy of Orthopaedic Surgeons (AAOS). Chambers HG, Shea KG, Anderson AF, Brunelle TJ, Carey JL, Ganley TJ, Paterno MV, Weiss JM, Sanders JO, Watters WC 3rd, Goldberg MJ, Keith MW, Turkelson CM, Wies JL, Raymond L, Boyer KM, Hitchcock K, Anderson S, Sluka P, Boone C, Patel N; American Academy of Orthopedic Surgeons. The Diagnosis and Treatment of Osteochondritis Dissecans. Guideline and Evidence Report. J Am Acad Orthop Surg. 2011 May;19(5):297-306. doi: 10.5435/00124635-201105000-00007. PMID: 21536629.

American Academy of Orthopaedic Surgeons (AAOS). Ortholnfo. Diseases & Conditions. Patellofemoral Arthritis. 2018 Jan.

American Academy of Orthopaedic Surgeons (AAOS). Ortholnfo. Treatment. Articular Cartilage Restoration. 2009 Feb.

American Orthopaedic Foot & Ankle Society (AOFAS). Position Statement: The Use of Osteochondral Transplantation for the Treatment of Osteochondral Lesions of the Talus. 2018 Apr 12.

Astur DC, Arliani GG, Binz M, Astur N, Kaleka CC, Amaro JT, Pochini A, Cohen M. Autologous osteochondral transplantation for treating patellar chondral injuries: evaluation, treatment, and outcomes of a two-year follow-up study. J Bone Joint Surg Am. 2014 May 21;96(10):816-23. doi: 10.2106/JBJS.M.00312. PMID: 24875022.

Basad E, Ishaque B, Bachmann G, Stürz H, Steinmeyer J. Matrix-induced autologous chondrocyte implantation versus microfracture in the treatment of cartilage defects of the knee: a 2-year randomized study. Knee Surg Sports Traumatol Arthrosc. 2010 Apr;18(4):519-27. doi: 10.1007/s00167-009-1028-1. PMID: 20062969.

Basad E, Wissing FR, Fehrenbach P, Rickert M, Steinmeyer J, Ishaque B. Matrix-induced autologous chondrocyte implantation (MACI) in the knee: clinical outcomes and challenges. Knee Surg Sports Traumatol Arthrosc. 2015 Dec;23(12):3729-35. doi: 10.1007/s00167-014-3295-8. Epub 2014 Sep 14. PMID: 25218576.

Baums MH, Schultz W, Kostuj T, Klinger HM. Cartilage repair techniques of the talus: An update. World J Orthop. 2014 Jul 18;5(3):171–9. doi: 10.5312/wjo.v5.i3.171. eCollection 2014 Jul 18. PMID: 25035819.

Benthien JP, Schwaninger M, Behrens P. We do not have evidence based methods for the treatment of cartilage defects in the knee. Knee Surg Sports Traumatol Arthrosc. 2011 Apr;19(4):543-52. doi: 10.1007/s00167-010-1271-5. Epub 2010 Nov 18. PMID: 21085933.

Bexkens R, Ogink PT, Doornberg JN, Kerkhoffs GMMJ, Eygendaal D, Oh LS, van den Bekerom MPJ. Donor-site morbidity after osteochondral autologous transplantation for osteochondritis dissecans of the capitellum: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc. 2017 Jul;25(7):2237-46. doi: 10.1007/s00167-017-4516-8. Epub 2017 Apr 8. PMID: 28391550.

Bhosale AM, Myint P, Roberts S, Menage J, Harrison P, Ashton B, Smith T, McCall I, Richardson JB. Combined autologous chondrocyte implantation and allogenic meniscus transplantation: a biological knee replacement. Knee. 2007 Oct;14(5):361-8. Epub 2007 Aug 6. doi: 10.1016/j.knee.2007. 07.002. PMID: 17689085.

Brittberg M. Cell carriers as the next generation of cell therapy for cartilage repair: A review of the matrix-induced autologous chondrocyte implantation procedure. Am J Sports Med. 2010 Jun;38(6):1259-71. doi: 10.1177/0363546509346395. Epub 2009 Dec 4. PMID: 19966108.

Camp CL, Stuart MJ, Krych AJ. Current Concepts of Articular Cartilage Restoration Techniques in the Knee. Sports Health. 2014 May;6(3):265–73. doi: 10.1177/1941738113508917. Erratum in: Sports Health. 2014 Nov; 6(6):NP1. PMID: 24790697.

Chen L, Shi Y, Zhang X, Hu X, Shao Z, Dai L, Ju X, Ao Y, Wang J. CaAlg hydrogel containing bone morphogenetic protein 4-enhanced adipose-derived stem cells combined with osteochondral mosaicplasty facilitated the repair of large osteochondral defects. Knee Surg Sports Traumatol Arthrosc. 2019 Nov;27(11):3668-78. doi: 10.1007/s00167-019-05418-1. Epub 2019 Mar 28. PMID: 30923857.

Christensen BB, Olesen ML, Lind M, Foldager CB. Autologous cartilage chip transplantation improves repair tissue composition compared with marrow stimulation. Am J Sports Med. 2017 Jun;45(7):1490-6. doi: 10.1177/0363546517694617. Epub 2017 Mar 20. PMID: 28319418.

Coetzee JC, Giza E, Schon LC, Berlet GC, Neufeld S, Stone RM, Wilson EL. Treatment of osteochondral lesions of the talus with particulated juvenile cartilage. Foot Ankle Int. 2013 Sep;34(9):1205-11. doi: 10.1177/1071100713485739. Epub 2013 Apr 10. PMID: 23576118.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

De Caro F, Bisicchia S, Amendola A, Ding L. Large Fresh Osteochondral Allografts of the Knee: A Systematic Clinical and Basic Science Review of the Literature. Arthroscopy. 2015 Apr;31(4):757-65. doi: 10.1016/j.arthro.2014.11.025. Epub 2015 Feb 3. PMID: 25660010.

Devitt BM, Bell SW, Webster KE, Feller JA, Whitehead TS. Surgical treatments of cartilage defects of the knee: Systematic review of randomised controlled trials. Knee. 2017 Jun;24(3):508-17. doi: 10.1016/j.knee.2016.12.002. Epub 2017 Feb 8. PMID: 28189406.

Dunkin BS, Lattermann. New and Emerging Techniques in Cartilage Repair: MACI. Oper Tech Sports Med. 2013 Jun 1;21(2):100–7. doi: 10.1053/j.otsm.2013.03.003. PMID: 24072960.

Durur-Subasi I, Durur-Karakaya A, Yildirim OS. Osteochondral Lesions of Major Joints. Eurasian J Med. 2015 Jun;47(2):138-44. doi: 10.5152/eurasianjmed.2015.50. PMID: 26180500.

Ebert JR, Lloyd DG, Ackland T, Wood DJ. Knee biomechanics during walking gait following matrix-induced autologous chondrocyte implantation. Clin Biomech (Bristol, Avon). 2010 Dec;25(10):1011-7. doi: 10.1016/j.clinbiomech.2010.07.004. Epub 2010 Aug 7. PMID: 20692745.

Ebert JR, Smith A, Edwards PK, Hambly K, Wood DJ, Ackland TR. Factors predictive of outcome 5 years after matrix-induced autologous chondrocyte implantation in the tibiofemoral joint. Am J Sports Med. 2013 Jun;41(6):1245-54. doi: 10.1177/0363546513484696. Epub 2013 Apr 25. PMID: 23618699.

Engen CN, Årøen A, Engebretsen L. Incidence of knee cartilage surgery in Norway, 2008–2011. BMJ Open. 2015 Nov 30;5(11):e008423. doi: 10.1136/bmjopen-2015-008423. PMID: 26621511.

Farr J, Cole B, Dhawan A, Kercher J, Sherman S. Clinical cartilage restoration: evolution and overview. Clin Orthop Relat Res. 2011 Oct;469(10):2696–705. doi: 10.1007/s11999-010-1764-z. PMID: 21240578.

Farr J, Gracitelli GC, Shah N, Chang EY, Gomoll AH. High Failure Rate of a Decellularized Osteochondral Allograft for the Treatment of Cartilage Lesions. Am J Sports Med. 2016 Aug;44(8):2015-22. doi: 10.1177/0363546516645086. Epub 2016 May 13. PMID: 27179056.

Farr J, Tabet SK, Margerrison E, Cole BJ. Clinical, Radiographic, and Histological Outcomes After Cartilage Repair With Particulated Juvenile Articular Cartilage: A 2-Year Prospective Study. Am J Sports Med. 2014 Jun;42(6):1417-25. doi: 10.1177/0363546514528671. Epub 2014 Apr 9. PMID: 24718790.

Fortier LA, Chapman HS, Pownder SL, Roller BL, Cross JA, Cook JL, Cole BJ. BioCartilage Improves Cartilage Repair Compared With Microfracture Alone in an Equine Model of Full-Thickness Cartilage Loss. Am J Sports Med. 2016 Sep;44(9):2366-74. doi: 10.1177/0363546516648644. Epub 2016 Jun 13. PMID: 27298478.

Genovese E, Ronga M, Angeretti MG, Novario R, Leonardi A, Albrizio M, Callegari L, Fugazzola C. Matrix-induced autologous chondrocyte implantation of the knee: Mid-term and long-term follow-up by MR arthrography. Skeletal Radiol. 2011;40(1):47–56. Skeletal Radiol. 2011 Jan;40(1):47–56. doi: 10.1007/s00256-010-0939-8. Epub 2010 May 6. PMID: 20446086.

Georgiannos D, Bisbinas I, Badekas A. Osteochondral transplantation of autologous graft for the treatment of osteochondral lesions of talus: 5- to 7-year follow-up. Knee Surg Sports Traumatol Arthrosc. 2016 Dec; 24(12):3722-9. Epub 2014 Oct 19. PMID: 25326766.

Gianakos AL, Yasui Y, Hannon CP, Kennedy JG. Current management of talar osteochondral lesions. World J Orthop. 2017 Jan 18;8(1):12-20. doi: 10.5312/wjo.v8.i1.12. eCollection 2017 Jan 18. PMID: 28144574.

Giannini S, Buda R, Battaglia M, Cavallo M, Ruffilli A, Ramponi L, Pagliazzi G, Vannini F. One-step repair in talar osteochondral lesions: 4-year clinical results and t2-mapping capability in outcome prediction. Am J Sports Med. 2013 Mar;41(3):511-8. doi: 10.1177/0363546512467622. Epub 2012 Dec 5. PMID: 23221772.

Giuliani JR, Pickett A. Cell-based chondral restoration. Curr Rev Musculoskelet Med. 2015 Dec;8(4):436–42. Published online 2015 Sep 26. doi: 10.1007/s12178-015-9301-z. PMID: 26408149.

Giza E, Sullivan M, Ocel D, Lundeen G, Mitchell ME, Veris L, Walton J. Matrix-induced autologous chondrocyte implantation of talus articular defects. Foot Ankle Int. 2010 Sep;31(9):747-53. doi: 10.3113/FAI.2010.0747. PMID: 20880476.

Haleem AM, Ross KA, Smyth NA, Duke GL, Deyer TW, Do HT, Kennedy JG. Double-Plug Autologous Osteochondral Transplantation Shows Equal Functional Outcomes Compared With Single-Plug Procedures in Lesions of the Talar Dome: A Minimum 5-Year Clinical Follow-up. Am J Sports Med. 2014 Aug;42(8):1888-95. doi: 10.1177/0363546514535068. Epub 2014 Jun 19. PMID: 24948585.

Hayes. Clinical Research Response. BioCartilage (Arthrex) for Orthopedic Indications. Dallas, TX: Hayes; 2021 Feb 9.

Hayes. Comparative Effectiveness Review. Comparative Effectiveness Review of Mosaicplasty for Treatment of Articular Cartilage Injuries. Dallas, TX: Hayes; 2017 May 4. Annual Review 2021 Jun 17.

Hayes. Comparative Effectiveness Review. Comparative Effectiveness Review of Stem Cell Therapy for Joint Pain. Dallas, TX: Hayes; 2018 Jul 12. Annual Review 2021 Aug 24.

Hayes. Health Technology Assessment. DeNovo NT Natural Tissue Graft (Zimmer Inc.) for Articular Cartilage Repair of the Knee or Ankle. Dallas, TX: Hayes; 2019 Dec 23. Annual Review 2021 Apr 20.

Hergenroeder AC, Harvey BS. Management of osteochondritis dissecans (OCD). UpToDate. 2021 Jun 28.

Hergenroeder AC, Harvey BS. Osteochondritis dissecans (OCD): Clinical manifestations and diagnosis. UpToDate. 2021 Nov 29.

Hoburg A, Löer I, Körsmeier K, Siebold R, Niemeyer P, Fickert S, Ruhnau K. Matrix-Associated Autologous Chondrocyte Implantation Is an Effective Treatment at Midterm Follow-up in Adolescents and Young Adults. Orthop J Sports Med. 2019 Apr 25;7(4):2325967119841077. doi: 10.1177/2325967119841077. eCollection 2019 Apr. PMID: 31041335.

Howard JS, Mattacola CG, Mullineaux DR, English RA, Lattermann C. Patient-oriented and performance-based outcomes after knee autologous chondrocyte implantation: a timeline for the first year of recovery. J Sport Rehabil. 2014 Aug;23(3):223–34. doi: 10.1123/jsr.2013-0094. Epub 2014 Feb 28. PMID: 24589660.

Johnson CC, Johnson DJ, Garcia GH, Wang D, Pais M, Degen RM, Burge AJ, Williams RJ 3rd. High Short-Term Failure Rate Associated With Decellularized Osteochondral Allograft for Treatment of Knee Cartilage Lesions. Arthroscopy. 2017 Dec;33(12):2219-27. doi: 10.1016/j.arthro.2017.07.018. Epub 2017 Sep 28. PMID: 28967543.

Jungmann PM, Salzmann GM, Schmal H, Pestka JM, Südkamp NP, Niemeyer P. Autologous chondrocyte implantation for treatment of cartilage defects of the knee: what predicts the need for reintervention? Am J Sports Med. 2012 Jan;40(1):58-67. doi: 10.1177/0363546511423522. Epub 2011 Oct 3. PMID: 21969180.

Meyerkort D, Ebert JR, Ackland TR, Robertson WB, Fallon M, Zheng MH, Wood DJ. Matrix-induced autologous chondrocyte implantation (MACI) for chondral defects in the patellofemoral joint. Knee Surg Sports Traumatol Arthrosc. 2014 Oct; 22(10):2522-30. doi: 10.1007/s00167-014-3046-x. Epub 2014 May 11. PMID: 24817164.

Minas T, Gomoll AH, Solhpour S, Rosenberger R, Probst C, Bryant T. Autologous Chondrocyte Implantation for Joint Preservation in Patients with Early Osteoarthritis. Clin Orthop Relat Res. 2010 Jan;468(1):147–57. doi: 10.1007/s11999-009-0998-0. Epub 2009 Aug 4. PMID: 19653049.

Mistry H, Connock M, Pink J, Shyangdan D, Clar C, Royle P, Court R, Biant LC, Metcalfe A, Waugh N. Autologous chondrocyte implantation in the knee: systematic review and economic evaluation. Health Technol Assess. 2017 Feb;21(6):1-294. doi: 10.3310/hta21060. PMID: 28244303.

Mundi R, Bedi A, Chow L, Crouch S, Simunovic N, Sibilsky Enselman E, Ayeni OR. Cartilage Restoration of the Knee: A Systematic Review and Meta-analysis of Level 1 Studies. Am J Sports Med. Jul 2016;44(7):1888-95. doi: 10.1177/0363546515589167. Epub 2015 Jul 2. PMID: 26138733.

National Institute for Health and Care Excellence (NICE). Autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee. Technology appraisal guidance TA477. 2017 Oct 4.

National Institute for Health and Care Excellence (NICE). Autologous chondrocyte implantation using chondrosphere for treating symptomatic articular cartilage defects of the knee. Technology appraisal quidance TA508. 2018 Mar 7.

National Institute for Health and Care Excellence (NICE). Microstructural scaffold (patch) insertion without autologous cell implantation for repairing symptomatic chondral knee defects. Interventional procedures guidance IPG560. 2016 Jun 22.

National Institute for Health and Clinical Excellence (NICE). Mosaicplasty for symptomatic articular cartilage defects of the knee. Interventional procedure guidance IPG607. 2018 Mar 14.

Nagura I, Fujioka H, Kokubu T, Makino T, Sumi Y, Kurosaka M. Repair of osteochondral defects with a new porous synthetic polymer scaffold. J Bone Joint Surg Br. 2007 Feb;89(2):258-64. doi: 10.1302/0301-620X.89B2.17754. PMID: 17322449.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Nielsen ES, McCauley JC, Pulido PA, Bugbee WD. Return to Sport and Recreational Activity After Osteochondral Allograft Transplantation in the Knee. Am J Sports Med. 2017 Jun;45(7):1608-14. doi: 10.1177/0363546517694857. Epub 2017 Apr 4. PMID: 28375642.

Niemeyer P, Porichis S, Steinwachs M, Erggelet C, Kreuz PC, Schmal H, Uhl M, Ghanem N, Südkamp NP, Salzmann G. Long-term outcomes after first-generation autologous chondrocyte implantation for cartilage defects of the knee. Am J Sports Med. 2014 Jan;42(1):150-7. doi: 10.1177/0363546513506593. Epub 2013 Oct 21. PMID: 24145948.

Ogura T, Bryant T, Minas T. Biological Knee Reconstruction With Concomitant Autologous Chondrocyte Implantation and Meniscal Allograft Transplantation. Mid- to Long-term Outcomes. Orthop J Sports Med. 2016 Oct 19;4(10):2325967116668490. doi: 10.1177/2325967116668490. eCollection 2016 Oct.. PMID: 27803938.

Özmeriç A, Alemdaroğlu KB, Aydoğan NH. Treatment for cartilage injuries of the knee with a new treatment algorithm. World J Orthop. 2014 Nov 18; 5(5):677–84. doi: 10.5312/wjo.v5.i5.677. eCollection 2014 Nov 18. PMID: 25405097.

Pagliazzi G, Vannini F, Battaglia M, Ramponi L, Buda R. Autologous Chondrocyte Implantation for Talar Osteochondral Lesions: Comparison Between 5-Year Follow-Up Magnetic Resonance Imaging Findings and 7-Year Follow-Up Clinical Results. J Foot Ankle Surg. 2018 Mar-Apr;57(2):221-5. doi: 10.1053/j.jfas.2017.05.013. Epub 2017 Nov 14. PMID: 29146220.

Pareek A, Carey JL, Reardon PJ, Peterson L, Stuart MJ, Krych AJ. Long-Term Outcomes after Autologous Chondrocyte Implantation: A Systematic Review at Mean Follow-Up of 11.4 Years. Cartilage. 2016 Oct;7(4):298-308. doi: 10.1177/1947603516630786. Epub 2016 Mar 3. PMID: 27688838.

Perera JR, Gikas PD, Bentley G. The present state of treatments for articular cartilage defects in the knee. Ann R Coll Surg Engl. 2012 Sep;94(6):381-7. doi: 10.1308/003588412X13171221592573. PMID: 22943326.

Petersen L, Vasiliadis HS, Brittberg M, Lindahl A. Autologous Chondrocyte Implantation: A Long-term Follow-up. Am J Sports Med. 2010 Jun;38(6):1117-24. doi: 10.1177/0363546509357915. Epub 2010 Feb 24. PMID: 20181804.

Ramponi L, Yasui Y, Murawski CD, Ferkel RD, DiGiovanni CW, Kerkhoffs GMMJ, Calder JDF, Takao M, Vannini F, Choi WJ, Lee JW, Stone J, Kennedy JG. Lesion Size Is a Predictor of Clinical Outcomes After Bone Marrow Stimulation for Osteochondral Lesions of the Talus: A Systematic Review. Am J Sports Med. 2017 Jun;45(7):1698-705. doi: 10.1177/0363546516668292. Epub 2016 Nov 16. PMID: 27852595.

Richter DL, Schenck RC Jr, Wascher DC, Treme G. Knee articular cartilage repair and restoration techniques: A review of the literature. Sports Health. 2016 Mar-Apr;8(2):153-60. doi: 10.1177/1941738115611350. Epub 2015 Oct 12. PMID: 26502188.

Richter DL, Tanksley JA, Miller MD. Osteochondral Autograft Transplantation: A Review of the Surgical Technique and Outcomes. Sports Med Arthrosc Rev. 2016 Jun;24(2):74-8. doi: 10.1097/JSA.00000000000099. PMID: 27135290.

Riboh JC, Cvetanovich GL, Cole BJ, Yanke AB. Comparative efficacy of cartilage repair procedures in the knee: a network meta-analysis. Knee Surg Sports Traumatol Arthrosc. 2017 Dec; 25(12):3786-99. doi: 10.1007/s00167-016-4300-1. Epub 2016 Sep 7. PMID: 27605128.

Rosa D, Balato G, Ciaramella G, Soscia E, Improta G, Triassi M. Long-term clinical results and MRI changes after autologous chondrocyte implantation in the knee of young and active middle aged patients. J Orthop Traumatol. 2016 Mar;17(1):55-62. doi: 10.1007/s10195-015-0383-6. Epub 2015 Oct 24. PMID: 26496929.

Saltzman BM, Lin J, Lee S. Particulated Juvenile Articular Cartilage Allograft Transplantation for Osteochondral Talar Lesions. Cartilage. 2017 Jan;8(1):61-72. Edoi: 10.1177/1947603516671358. pub 2016 Sep 29. PMID: 27994721.

Salzmann GM, Baumann GA, Preiss S. Spontaneous minced cartilage procedure for unexpectedly large femoral condyle surface defect. Case Rep Orthop. 2016;2016:1498135. doi: 10.1155/2016/1498135. PMID: 27504207.

Salzmann GM, Calek AK, Preiss S. Second-generation autologous minced cartilage repair technique. Arthrosc Tech. 2017 Jan 30;6(1):e127-e131. doi: 10.1016/j.eats.2016.09.011. eCollection 2017 Feb. PMID: 28373950.

Salzmann GM, Niemeyer P, Hochrein A, Stoddart MJ, Angele P. Articular Cartilage Repair of the Knee in Children and Adolescents. Orthop J Sports Med. 2018 Mar;6(3):2325967118760190. doi:10.1177/2325967118760190. PMID: 29568785.

Savage-Elliott I, Ross KA, Smyth NA, Murawski CD, Kennedy JG. Osteochondral lesions of the talus: a current concepts review and evidence-based treatment paradigm. Foot Ankle Spec. 2014 Oct;7(5):414-22. doi: 10.1177/1938640014543362. Epub 2014 Aug 5. PMID: 25100765.

Schuette HB, Kraeutler MJ, McCarty EC. Matrix-Assisted Autologous Chondrocyte Transplantation in the Knee: A Systematic Review of Mid- to Long-Term Clinical Outcomes. Orthop J Sports Med. 2017 Jun 6;5(6):2325967117709250. doi: 10.1177/2325967117709250. eCollection 2017 Jun. PMID: 28620621.

Shimozono Y, Yasui Y, Ross AW, Kennedy JG. Osteochondral lesions of the talus in the athlete: up to date review. Curr Rev Musculoskelet Med. 2017 Mar;10(1):131-140. doi: 10.1007/s12178-017-9393-8. PMID: 28188546.

Slattery C, Kweon CY. Classifications in Brief: Outerbridge Classification of Chondral Lesions. Clin Orthop Relat Res. 2018 Oct;476(10):2101-4. doi: 10.1007/s11999.0000000000000255. PMID: 29533246.

Torrie AM, Kesler WW, Elkin J, Gallo RA. Osteochondral allograft. Curr Rev Musculoskelet Med. 2015 Dec; 8(4):413–22. doi: 10.1007/s12178-015-9298-3. PMID: 26475149.

U. S. Food and Drug Administration. MACI (Autologous Cultured Chondrocytes on a Porcine Collagen Membrane).

U. S. Food and Drug Administration. Vaccines, Blood & Biologics. 2016 Biological License Application Approvals. MACI. Approval Date 2016 Dec 13. Content current as of 2021 Mar 22.

U. S. Food and Drug Administration (FDA). Vaccines, Blood & Biologics. MACI (Autologous Cultured Chondrocytes on a Porcine Collagen Membrane). 2018 Feb 20. Content current as of 2021 Jun 30.

Vangsness CT Jr, Higgs G, Hoffman JK, Farr J, Davidson PA, Milstein F, Geraghty S. Implantation of a Novel Cryopreserved Viable Osteochondral Allograft for Articular Cartilage Repair in the Knee. J Knee Surg. 2018 Jul;31(6):528-35. doi: 10.1055/s-0037-1604138. Epub 2017 Jul 24. PMID: 28738433.

VanTienderen RJ, Dunn JC, Kusnezov N, Orr JD. Osteochondral allograft transfer for treatment of 2osteochondral lesions of the talus: a systematic review. Arthroscopy. Jan 2017;33(1):217-22. doi: 10.1016/j.arthro.2016.06.011. Epub 2016 Aug 18. PMID: 27546173.

Williams RJ 3rd, Ranawat AS, Potter HG, Carter T, Warren RF. Fresh stored allografts for the treatment of osteochondral defects of the knee. J Bone Joint Surg Am. 2007 Apr;89(4):718-26. doi: 10.2106/JBJS.F.00625. PMID: 17403792.

Wylie JD, Hartley MK, Kapron AL, Aoki SK, Maak TG. What Is the Effect of Matrices on Cartilage Repair? A Systematic Review. Clin Orthop Relat Res. 2015 May;473(5):1673–82. doi: 10.1007/s11999-015-4141-0. PMID: 25604876.

Yoon HS, Park YJ, Lee M, Choi WJ, Lee JW. Osteochondral Autologous Transplantation Is Superior to Repeat Arthroscopy for the Treatment of Osteochondral Lesions of the Talus After Failed Primary Arthroscopic Treatment. Am J Sports Med. 2014 Aug;42(8):1896-903. doi: 10.1177/0363546514535186. Epub 2014 Jun 6. PMID: 24907287.

Zengerink M, Struijs PA, Tol JL, van Dijk CN. Treatment of osteochondral lesions of the talus: A systematic review. Knee Surg Sports Traumatol Arthrosc. 2010 Feb;18(2):238-46. doi: 10.1007/s00167-009-0942-6. Epub 2009 Oct 27. PMID: 19859695.

Zhang Z, Zhong X, Ji H, Tang Z, Bai J, Yao M, Hou J, Zheng M, Wood DJ, Sun J, Zhou SF, Liu A. Matrix-induced autologous chondrocyte implantation for the treatment of chondral defects of the knees in Chinese patients. Drug Des Devel Ther. 2014 Dec 5;8:2439-48. doi: 10.2147/DDDT.S71356. eCollection 2014. PMID: 25525334.

## **Next Review Date**

Not applicable

## **Retired Date**

11/01/22

# **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original	Original Effective	Policy Owner	Original Policy
Approval Date	Date* and Version		Approved by
Regulatory Approval: N/A  Internal Approval: 07/08/08: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 07/22/08: Utilization Management Committee (UMC) 08/13/08: Quality Improvement Committee (QIC)	11/01/08 Version 1	Director of Medical Policy as Chair of MPCTAC	MPCTAC, QIC, and UMC

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

Policy title was Osteochondral Treatments for Defects of the Knee until 05/31/19. As of 06/01/19, policy title changed to Osteochondral Treatments for Defects of the Knee, Talus, or Other Joint. Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
07/28/09	No changes except updated references.	Version 2	07/28/09: MPCTAC 07/28/09: UMC 08/26/09: QIC
07/01/10	No changes except updated references.	Version 3	08/18/10: MPCTAC 09/22/10: QIC
07/01/11	No changes except updated references.	Version 4	08/17/11: MPCTAC 09/28/11: QIC
07/01/12	Updated references. No change made to applicable code list. Revised list of conservative treatment options. Added language in clinical criteria that states "acute trauma may result from falls, sports, and other sources of impact while repetitive trauma may include overuse."  Changed criteria for all three procedure types	Version 5	07/18/12: MPCTAC 08/22/12: QIC

<sup>\*</sup>Effective Date for New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for NH Medicare Advantage HMO Product: 01/01/22

	from "no history of bone cancer in the affected limb" to "no history of cancer in the bone, cartilage, fat, or muscle of the treated limb." Added note in Description of Item or Service with recommendations on age and BMI of member seeking surgical procedure. Added language in Applicable Code section.		
07/30/12	Off cycle review for New Hampshire Medicaid product. Revised Summary statement, reformatted Medical Policy Statement section, deleted reference to Carticel product.	Version 6	08/03/12: MPCTAC 09/05/12: QIC
07/01/13	Review for effective date 11/01/13. Revised text in Description of Item or Service section. Removed duplicate text in the Clinical Background Information section and added information on Carticel®, minced cartilage repair, and synthetic resorbable polymers. Moved medical guidelines (related to skeletal maturing and BMI) from Description of Item or Service to the Medical Policy Statement section. Added medical criteria, limitations, and definition of Outerbridge Grading System. Updated references.	11/01/13 Version 7	07/17/13: MPCTAC 08/15/13: QIC
04/01/14	Review for effective date 08/01/14. Revised Summary, Description of Item or Service, Definitions, and References sections. Revised criteria in the Medical Policy Statement section.	08/01/14 Version 8	04/16/14: MPCTAC 05/14/14: QIC
03/01/15	Review for effective date 05/01/15. Updated references. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.  Administrative changes made to Medical Policy Statement section and Limitation section to clarify criteria.	05/01/15 Version 9	03/18/15: MPCTAC 04/08/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.	01/01/16 Version 10	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
04/01/16	Review for effective date 06/01/16. Updated Clinical Background Information, References, and Reference to Applicable Laws and Regulations.	06/01/16 Version 11	04/20/16: MPCTAC 05/23/16: QIC
03/01/17	Review for effective date 06/07/17. Updated criteria in the Medical Policy Statement and Limitations sections. Updated References	06/07/17 Version 12	03/15/17: MPCTAC

	saction. Plan note added to the Applicable		
	section. Plan note added to the Applicable Coding section.		
02/01/18	Review for effective date 03/01/18. Updated Description of Item or Service, Definitions, References, and Other Applicable Policies sections.	03/01/18 Version 13	02/21/18: MPCTAC
03/01/19	Review for effective date 06/01/19. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, Other Applicable Policies, and References to Applicable Laws and Regulations sections. Revised Plan notes in the Applicable Coding section without revising code list. Criteria revised in the Medical Policy Statement and Limitations sections. Revised the policy title.	06/01/19 Version 14	03/20/19: MPCTAC
02/01/20	Review for effective date 05/01/20. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement and Limitations sections.	05/01/20 Version 15	02/19/20: MPCTAC
02/01/21	Review for effective date 03/01/21. Administrative changes made to the References section.	03/01/21 Version 16	02/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 17	11/17/21: MPCTAC
02/01/22	Review for effective date 03/01/22. Administrative changes made to the References section. Non-material changes made to the Clinical Criteria section (removing Outerbridge Grade criteria).	03/01/22 Version 18	02/16/22: MPCTAC
08/01/2	Review for effective date 11/01/22. The Plan will adopt on 11/01/22 the AIM clinical	11/01/22 Version 19	08/26/22: MPCTAC

appropriateness guidelines for musculoskeletal	(electronic vote)
services, including joint surgery, spine surgery,	
and interventional pain management services;	
AIM prior authorization is required for those	
services as of 11/01/22, even when applicable	
codes are not listed in this Plan policy. Criteria	
revised in the Clinical Criteria and Limitations	
and Exclusions sections. Administrative changes	
made to the Policy Summary section.	



Medical Policy - Policy Retired and AIM Criteria Adopted as of 11/01/22

# Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder

Policy Number: OCA 3.561 Version Number: 25

Dalian Datinad Data: 11/01/2

**Policy Retired Date**: 11/01/22

## Impacted Products

#### 

- ⋈ NH Medicaid
- ☑ NH Medicare Advantage
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

AIM clinical appropriateness criteria will be used to determine if non-implantable pelvic floor stimulation is considered medically necessary for the treatment of overactive bladder, urinary incontinence and/or fecal continence; this includes pelvic floor electrical stimulation (PFES) and/or pelvic floor magnetic stimulation. Prior authorization from AIM Specialty Health is required.

#### Clinical Criteria

No medical policy criteria.

## **Limitations and Exclusions**

None.

## **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and NH Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, CMS NCD 230.8 8 includes medically necessary indications for the use of a non-implantable pelvic floor electrical stimulator. No

Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder

CMS clinical criteria were identified for pelvic floor magnetic stimulation for urinary incontinence or fecal incontinence or the use of pelvic floor electrical stimulation (PFES) for fecal incontinence. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for this services, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT/HCPCS Codes	Code Descriptions
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	Note: Supervised. The application of a modality that does not require direct, one-one, patient contact by the provider.
	Plan note: Code is NOT payable for the Senior Care Options and NH Medicare Advantage HMO products.
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
E0740	Non-implanted pelvic floor electrical stimulator, complete system
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

## References

Abdelbary AM, El-Dessoukey AA, Massoud AM, Moussa AS, Zayed AS, Elsheikh MG, Ghoneima W, Abdella R, Yousef M. Combined Vaginal Pelvic Floor Electrical Stimulation (PFS) and Local Vaginal Estrogen for Treatment of Overactive Bladder (OAB) in Perimenopausal Females. Randomized Controlled Trial (RCT). Urology. 2015 Sep;86(3):482-6. doi: 10.1016/j.urology.2015.06.007. Epub 2015 Jun 30. PMID: 26135813.

Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, Cottenden A, Davila W, de Ridder D, Dmochowski R, Drake M, Dubeau C, Fry C, Hanno P, Smith JH, Herschorn S, Hosker G, Kelleher C, Koelbl H, Khoury S, Madoff R, Milsom I, Moore K, Newman D, Nitti V, Norton C, Nygaard I, Payne C, Smith A, Staskin D, Tekgul S, Thuroff J, Tubaro A, Vodusek D, Wein A, Wyndaele JJ; Members of Committees; Fourth International Consultation on Incontinence. Fourth international

consultation on incontinence recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol Urodyn. 2010;29(1):213-40. doi: 10.1002/nau.20870. PMID: 20025020.

American College of Gastroenterology (ACG). Guidelines.

The American College of Obstetricians and Gynecologists (ACOG). Clinical Guidance.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 155. Urinary Incontinence in Women. 2015. Reaffirmed 2018. Obstet Gynecol. 2015 Nov;126(5):e66-81. doi: 10.1097/AOG.000000000001148. PMID: 26488524.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 210. Fecal Incontinence. Obstet Gynecol. 2019 Apr;133(4):837-39. doi: 10.1097/AOG.00000000003188. PMID: 30913191.

The American College of Obstetricians and Gynecologists (ACOG), American Urogynecologic Society (AUGS). ACOG Committee on Gynecologic Practice. Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment. Committee Opinion Number 603. 2014 Jun. Reaffirmed 2017.

The American College of Obstetricians and Gynecologists (ACOG). Urinary Incontinence. Patient Resources.

American College of Physicians (ACP). Clinical Guidelines & Recommendations.

American College of Physicians (ACP). Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD, Shekelle P. Clinical Guidelines Committee of the ACP. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the ACP. Ann Intern Med. 2014 Sep 16;161(6):429-40. doi: 10.7326/M13-2410. PMID: 25222388.

American Gastroenterological Association (AGA). Bharucha AE, Pemberton JH, Locke GR. American Gastroenterological Association technical review on constipation. Gastroenterology. 2013 Jan;144(1):218-38. doi: 10.1053/j.gastro.2012.10.028. PMID: 23261065.

American Gastroenterological Association (AGA). Clinical Guidelines.

American Society of Colon and Rectal Surgeons (ASCRS). Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The ASCRS' Clinical Practice Guideline for the Treatment of Fecal Incontinence. Dis Colon Rectum. 2015 Jul;58(7):623–36. doi: 10.1097/DCR.00000000000397. PMID: 26200676.

American Society of Colon and Rectal Surgeons (ASCRS). Paquette IM, Varma M, Ternent C, Melton-Meaux G, Rafferty J, Feingold D, Steele SR. The ASCRS' Clinical Practice Guideline for the Evaluation

and Management of Constipation. Dis Colon Rectum 2016; 59: 479–92. doi: 10.1097/DCR.00000000000599. PMID: 27145304.

American Urogynecologic Society (AUGS). Clinical Guidance Documents.

American Urological Association (AUA). Guidelines & Policies.

American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU). Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. J Urol. 2019 Sep;202(3):558-63. doi: 10.1097/JU.0000000000000309. Epub 2019 Aug 8. PMID: 31039103.

Anderson CA, Omar MI, Campbell SE, Hunter KF, Cody JD, Glazener CM. Conservative management for postprostatectomy urinary incontinence. Cochrane Database Syst Rev. 2015 Jan 20;1:CD001843. doi: 10.1002/14651858.CD001843.pub5. PMID: 25602133.

Aydin S, Arioglu Aydin Ç, Batmaz G, Dansuk R. Effect of vaginal electrical stimulation on female sexual functions: a randomized study. J Sex Med. 2015 Feb;12(2):463-9. doi: 10.1111/jsm.12788. Epub 2014 Dec 3. PMID: 25470078.

Berghmans B, Hendriks E, Bernards A, de Bie R, Omar MI. Electrical stimulation with non-implanted electrodes for urinary incontinence in men. Cochrane Database Syst Rev. 2013 Jun 6;(6):CD001202. doi: 10.1002/14651858.CD001202.pub5. PMID: 23740763.

Canadian Urological Association. Bettez M, Tu LM, Carlson K, Corcos J, Gajewski J, Jolivet M, Bailly G. 2012 Update: Guidelines for Adult Urinary Incontinence Collaborative Consensus Document for the Canadian Urological Association. Can Urol Assoc J. 2012 Oct;6(5):354–63. doi: 10.5489/cuaj.12248. PMID: 23093627.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Posterior Tibial Nerve Stimulation for Voiding Dysfunction L33396. National Government Services, Inc. 2015 Oct 1. Revision Effective Date 2019 Oct 24.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Biofeedback Therapy for the Treatment of Urinary Incontinence 30.1.1. Effective 2001 Jul 1.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Bladder Stimulators (Pacemakers) 230.16. 1996 Oct 7.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator 230.8. Effective 2006 Jun 19.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence (230.18). Effective 2002 Jan 1.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Chêne G, Mansoor A, Jacquetin B, Mellier G, Douvier S, Sergent F, Aubard Y, Seffert P. Female urinary incontinence and intravaginal electrical stimulation: an observational prospective study. Eur J Obstet Gynecol Reprod Biol. 2013 Sep;170(1):275-80. doi: 10.1016/j.ejogrb.2013.06.011. Epub 2013 Jul 5. PMID: 23830965.

Chughtai B, Lee R, Sandhu J, Te A, Kaplan S. Conservative Treatment for Postprostatectomy Incontinence. Rev Urol. 2013;15(2):61–6. PMID: 24082844.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Correia, GN, Pereira, VS, Hirakawa, HS, Driusso, P. Effects of surface and intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2014 Feb;173:113–8. doi: 10.1016/j.ejogrb.2013.11.023. Epub 2013 Dec 4. PMID: 24382548.

Dumoulin C, Hay-Smith EJC, Mac Habée-Séguin G. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev. 2014 May 14;(5):CD005654. doi: 10.1002/14651858.CD005654.pub3. PMID: 24823491.

European Association of Urology (EAU). Blok B, Castro-Diaz D, Del Popolo G, Groen J, Hamid R, Karsenty G, Kessler TM, Pannek J, Ecclestone H, Musco S, Padilla-Fernández B, Sartori A, 't Hoen LA. Guidelines. Neuro-Urology.

European Association of Urology (EAU). Nambiar AK, Bosch R, Cruz F, Lemack GE, Thiruchelvam N, Tubaro A, Bedretdinova DA, Ambühl D, Farag F, Lombardo R, Schneider MP, Burkhard FC. EAU

Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence. Eur Urol. 2018 Apr;73(4):596-609. doi: 10.1016/j.eururo.2017.12.031. Epub 2018 Feb 3. PMID: 29398262.

European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN), North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN). Tabbers MM, DiLorenzo C, Berger MY, Faure BC, Langendam MW, Nurko S, Staiano A, Vandenplas Y, Benninga MA. Clinical Guideline. Evaluation and Treatment of Functional Constipation in Infants and Children: Evidence-Based Recommendations from ESPGHAN and NASPGHAN. J Pediatr Gastroenterol Nutr. 2014 Feb;58(2):258-74. doi:10.1097/MPG.0000000000000666. PMID: 24345831.

Faiena I, Patel N, Parihar JS, Calabrese M, Tunuguntla H. Conservative Management of Urinary Incontinence in Women. Rev Urol. 2015;17(3):129–39. PMID: 26543427.

Fernández-Cuadros ME, Nieto-Blasco J, Geanini-Yagüez A, Ciprián-Nieto D, Padilla-Fernández B, Lorenzo-Gómez MF. Male Urinary Incontinence: Associated Risk Factors and Electromyography Biofeedback Results in Quality of Life. Am J Mens Health. 2016 Nov;10(6):NP127-35. Epub 2015 Jun 30. doi: 10.1177/1557988315590653. PMID: 26130728.

Fritel X, Fauconnier A, Bader G, Cosson M, Debodinance P, Deffieux X, Denys P, Dompeyre P, Faltin D, Fatton B, Haab F, Hermieux JF, Kerdraon J, Mares P, Mellier G, Michel-Laaengh N, Nadeau C, Robain G, de Tayrac R, Jacquetin B; French College of Gynecologists and Obstetricians. Diagnosis and management of adult female stress urinary incontinence: guidelines for clinical practice from the French College of Gynecologists and Obstetricians. Eur J Obstet Gynecol Reprod Biol. 2010 Jul;151(1):14-9. doi: 10.1016/j.ejogrb.2010.02.041. Epub 2010 Mar 16. PMID: 20236751.

Fürst MC, Mendonça RR, Rodrigues AO, Matos LL, Pompeo AC, Bezerra CA. Long-term results of a clinical trial comparing isolated vaginal stimulation with combined treatment for women with stress incontinence. Einstein (Sao Paulo). 2014 Apr;12(2):168-74. doi: 10.1590/s1679-45082014ao2866. PMID: 25003921.

Ghaderi F, Oskouei AE. Physiotherapy for Women with Stress Urinary Incontinence: A Review Article. J Phys Ther Sci. 2014 Sep;26(9):1493–9. doi: 10.1589/jpts.26.1493. Epub 2014 Sep 17. PMID: 25276044.

Gilling PJ, Wilson LC, Westenberg AM, McAllister WJ, Kennett KM, Frampton CM, Bell DF, Wrigley PM, Fraundorfer MR. A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs. sham therapy in the treatment of women with stress urinary incontinence. BJU Int. 2009 May;103(10):1386-90. Epub 2009 Jan 14. doi: 10.1111/j.1464-410X.2008.08329.x. Epub 2009 Jan 14. PMID: 19154474.

Goode PS, Burgio KL, Johnson TM 2nd, Clay OJ, Roth DL, Markland AD, Burkhardt JH, Issa MM, Lloyd LK. Behavioral therapy with or without biofeedback and pelvic floor electrical stimulation for persistent postprostatectomy incontinence: a randomized controlled trial. JAMA. 2011 Jan 12;305(2):151-9. doi: 10.1001/jama.2010.1972. PMID: 21224456.

Gungor Ugurlucan F, Onal M, Aslan E, Ayyildiz Erkan H, Kizilkaya Beji N, Yalcin O. Comparison of the effects of electrical stimulation and posterior tibial nerve stimulation in the treatment of overactive bladder syndrome. Gynecol Obstet Invest. 2013;75(1):46-52. doi: 10.1159/000343756. Epub 2012 Nov 16. PMID: 23171636.

Guralnick ML, Kelly H, Engelke H, Koduri S, O'Connor RC. InTone: a novel pelvic floor rehabilitation device for urinary incontinence. Int Urogynecol J. 2015 Jan;26(1):99-106. doi: 10.1007/s00192-014-2476-9. Epub 2014 Jul 30. PMID: 25074260.

Hersh L, Salzman B. Clinical management of urinary incontinence in women. Am Fam Physician. 2013 May;87(9):634-40. Erratum in: Am Fam Physician. 2013 May 1;87(9):634-40. PMID: 23668526.

International Urogynecological Association (IUGA), International Continence Society (ICS). Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, Monga A, Petri E, Rizk DE, Sand PK, Schaer GN. An IUGA/ICS joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J. 2010 Jan;21(1):5-26. doi: 10.1007/s00192-009-0976-9. Epub 2009 Nov 25. PMID: 19937315.

Joussain C, Denys P. Electrical management of neurogenic lower urinary tract disorders. Ann Phys Rehabil Med. 2015 Sep;58(4):245–250. doi: 10.1016/j.rehab.2015.07.005. Epub 2015 Aug 25. PMID: 26321622.

Lim R, Liong ML, Leong WS, Khan NA, Yuen KH. Magnetic stimulation for stress urinary incontinence: study protocol for a randomized controlled trial. Trials. 2015 Jun 21;16:279. doi: 10.1186/s13063-015-0803-1. PMID: 26093910.

Maher RM, Caulfield B. A novel externally applied neuromuscular stimulator for the treatment of stress urinary incontinence in women-a pilot study. Neuromodulation. 2013 Nov-Dec;16(6):590-4; discussion 594. doi: 10.1111/j.1525-1403.2012.00509.x. Epub 2012 Sep 25. PMID: 23009698.

Mariotti G, Salciccia S, Innocenzi M, Gentilucci A, Fasulo A, Gentile V, Sciarra A. Recovery of Urinary Continence After Radical Prostatectomy Using Early vs. Late Pelvic Floor Electrical Stimulation and Biofeedback-associated Treatment. Urology. 2015 Jul;86(1):115-20. doi: 10.1016/j.urology.2015.02.064. PMID: 26142594.

Maternik M, Krzeminska K, Zurowska A. The management of childhood urinary incontinence. Pediatr Nephrol. 2015 Jan;30(1):41-50. doi: 10.1007/s00467-014-2791-x. Epub 2014 Mar 11. PMID: 24615564.

Morin F, Akhavizadegan H, Kavanagh A, Moore K. Dysfunctional voiding: Challenges of disease transition from childhood to adulthood. Can Urol Assoc J. 2018 Apr;12(4 Suppl 1):S42-7. doi: 10.5489/cuaj.5230. PMID: 29681274.

Moroni RM, Magnani PS, Haddad JM, Castro Rde A, Brito LG. Conservative Treatment of Stress Urinary Incontinence: A Systematic Review with Meta-analysis of Randomized Controlled Trials. Rev

Bras Ginecol Obstet. 2016 Feb;38(2):97-111. doi: 10.1055/s-0035-1571252. Epub 2016 Jan 29. PMID: 26883864.

National Institute for Health and Care Excellence (NICE). Lower urinary tract symptoms in men: management. Clinical Guideline CG97. 2010 May 23. Last Updated 2015 Jun 3.

National Institute for Health and Care Excellence (NICE). Urinary incontinence in neurological disease: assessment and management. Clinical Guideline CG148. 2012 Aug 8.

National Institute for Health and Care Excellence (NICE). Urinary incontinence and pelvic organ prolapse in women: management. NICE Guideline NG123. 2019 Apr 2. Last Updated 2019 Jun 24.

Nepple KG, Cooper CS. Management of bladder dysfunction in children. UpToDate. 2021 Jun 22.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Santos JD, Lopes RI, Koyle MA. Bladder and bowel dysfunction in children: An update on the diagnosis and treatment of a common, but underdiagnosed pediatric problem. Can Urol Assoc J. 2017 Jan-Feb;11(1-2Suppl1):S64-72. doi: 10.5489/cuaj.4411. PMID: 28265323.

Schreiner L, Santos TG, Souza AB, Nygaard CC, Silva Filho IG. Electrical stimulation for urinary incontinence in women: a systematic review. Int Braz J Urol. 2013 Jul-Aug;39(4):454-64. doi: 10.1590/S1677-5538.IBJU.2013.04.02. PMID: 24054395.

Terlikowski R, Dobrzycka B, Kinalski M, Kuryliszyn-Moskal A, Terlikowski SJ. Transvaginal electrical stimulation with surface-EMG biofeedback in managing stress urinary incontinence in women of premenopausal age: a double-blind, placebo-controlled, randomized clinical trial. Int Urogynecol J. 2013 Oct;24(10):1631-8. doi: 10.1007/s00192-013-2071-5. Epub 2013 Feb 27. PMID: 23443345.

Tugtepe H, Thomas DT, Ergun R, Kalyoncu A, Kaynak A, Kastarli C, Dagli TE. The effectiveness of transcutaneous electrical neural stimulation therapy in patients with urinary incontinence resistant to initial medical treatment or biofeedback. J Pediatr Urol. 2015 Jun;11(3):137.e1-5. doi: 10.1016/j.jpurol.2014.10.016. Epub 2015 Mar 12. PMID: 25824876.

- U.S. Food and Drug Administration (FDA). Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence Guidance for Industry and FDA Staff. 2011 Mar 8.
- U. S. Food and Drug Administration (FDA). Medical Devices. 510(k) Clearances.
- U. S. Food and Drug Administration (FDA). Medical Devices. Device Registration and Listing.

Wald A. Diagnosis and Management of Fecal Incontinence. Curr Gastroenterol Rep. 2018 Mar 26;20(3):9. doi: 10.1007/s11894-018-0614-0. PMID: 29582182.

Wallis MC, Davies EA, Thalib L, Griffiths S. Pelvic static magnetic stimulation to control urinary incontinence in older women: a randomized controlled trial. Clin Med Res. 2012 Feb;10(1):7-14. doi: 10.3121/cmr.2011.1008. Epub 2011 Aug 4. PMID: 21817123.

Yamanishi T, Mizuno T, Watanabe M, Honda M, Yoshida K. Randomized, placebo controlled study of electrical stimulation with pelvic floor muscle training for severe urinary incontinence after radical prostatectomy. J Urol. 2010 Nov;184(5):2007-12. doi: 10.1016/j.juro.2010.06.103. Epub 2010 Sep 20. PMID: 20850831.

Zhu YP, Yao XD, Zhang SL, Dai B, Ye DW. Pelvic floor electrical stimulation for postprostatectomy urinary incontinence: a meta-analysis. Urology 2012 Mar;79(3):552-5. doi: 10.1016/j.urology.2011.10.005. PMID: 22386394.

## **Next Review Date**

Not applicable

## **Retired Date**

11/01/22

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eliqibility and benefits on the date of service; medical necessity;

Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder

utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	12/03/06	Medical Policy Manager as	Quality and Clinical
	Version 1	Chair of Medical Policy,	Management
Internal Approval:		Criteria, and Technology	Committee
10/03/06		Assessment Committee	(Q&CMC)
		(MPCTAC)	

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

This policy replaced Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence medical policy, policy number OCA 3.56, as of 05/01/13 for criteria related to pelvic floor stimulation for the treatment of incontinence. The policy was titled Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence from 05/01/13 to 01/31/16. The policy title was Pelvic Floor Stimulation for the Treatment of Incontinence from 02/01/16 to 02/28/19. Effective 03/01/19, the policy title has been changed to Pelvic Floor Stimulation for the Treatment of Incontinence and/or Overactive Bladder. Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History				
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by	
09/11/07	Updated template, added coding, approved by MPCTAC.	Version 2	09/11/07: MPCTAC 09/25/07: Utilization Management Committee (UMC) 10/15/07: Quality Improvement Committee (QIC)	
09/09/08	No changes.	Version 3	09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC	
09/22/09	Updated references, no changes to criteria.	Version 4	09/22/09: MPCTAC 10/28/09: QIC	
09/01/10	Updated template and references, no changes to criteria.	Version 5	10/20/10: MPCTAC 11/22/10: QIC	

<sup>\*</sup>Effective Date for New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

10 /01 /11	Undated limitations to include that carrel nerve	Version 6	10 /10 /11, MDCTAC
10/01/11	Updated limitations to include that sacral nerve stimulation for the treatment of fecal	version 6	10/19/11: MPCTAC
			11/29/11: QIC
	incontinence and posterior tibial nerve		
	stimulation for the treatment of symptoms		
	associated with overactive bladder are		
	considered experimental and investigational.		
	Updated references and coding.		
07/20/12	Off cycle review for Well Sense Health Plan:	Version 7	08/13/12: MPCTAC
	Updated title, revised Summary statement,		09/13/12: QIC
	added posterior tibial stimulation to Description		
	of Item or Service, reformatted Medical Policy		
	Statement, updated Definitions, revised		
	language in Applicable Coding section, updated		
	code list.		
12/01/12	Separated pelvic floor electrical stimulation,	Version 8	12/19/12: MPCTAC
	sacral nerve stimulation, and posterior tibial		01/31/13: QIC
	nerve stimulation into three separate policies;		
	policy formerly titled Pelvic Floor/Sacral Nerve		
	Stimulation for Urinary Incontinence (formerly		
	policy number OCA: 3.65). Revised title and re-		
	numbered policy. Updated language in		
	Summary, Description of Item or Service,		
	Definitions, Applicable Coding, and Clinical		
	Background Information sections. Referenced		
	Posterior Tibial Nerve Stimulation, Sacral Nerve		
	Stimulation (Including Peripheral Nerve		
	Stimulation Test and Two-Stage Tined Lead		
	Procedure) for Incontinence and Urinary		
	Conditions, Biofeedback for Urinary		
	Incontinence, Experimental and Investigation		
	Treatment, and Medically Necessary policies.		
	Reformatted and added criteria in Medical		
	Policy Statement section, updated and added		
	references, and added limitations. Revised		
	applicable code list.		
12/01/13	Review for effective date 02/01/14. Updated	02/01/14	12/18/13: MPCTAC
, 5,, 15	references.	Version 9	01/21/14: QIC
12/01/14	Review for effective date 05/01/15. Updated	05/01/15	12/17/14: MPCTAC
14/01/14	references. Added ICD9/ICD10 diagnosis codes	Version 10	01/14/15: QIC
	for urinary incontinence to the Applicable	A CLOINII IO	01/1 <del>1</del> /10. QIC
	Coding section. Updated introductory		
10 /01 /15	paragraph in the Applicable Coding section.	12 /01 /15	10 /21 /1E, MDCTAC
10/01/15	Review for effective date 12/01/15. Updated	12/01/15	10/21/15: MPCTAC
	template with list of applicable products and	Version 11	11/11/15: QIC
40 (04 (77	corresponding notes.	00/01/45	40 (04 (45 ) :
10/21/15	Review for effective date 02/01/16. Updated	02/01/16	10/21/15: MPCTAC
	Summary, Description of Item or Service,	Version 12	11/11/15: QIC
	Definitions, Clinical Background Information,		

	1	T	
	and References sections. Updated criteria in the		
	Medical Policy Statement and Limitations		
	sections. Revised the title of the policy.		
11/25/15	Review for effective date 02/01/16. Revised	02/01/16	11/25/15: MPCTAC
	language in the Applicable Coding section. Plan	Version 13	(electronic vote)
	note added to HCPCS code G0283.		12/09/15: QIC
10/01/16	Review for effective date 12/01/16. Updated	12/01/16	10/19/16: MPCTAC
	Summary, Definitions, Clinical Background	Version 14	11/09/16: QIC
	Information, References, and References to		
	Applicable Laws and Regulations sections.		
	Administrative changes made to the Medical		
	Policy Statement and Limitations sections; no		
	change to criteria. Removed ICD-9 diagnosis		
	codes and Plan notes added to applicable		
	codes.		
12/01/16	Industry-wide change to applicable code	01/01/17	Not applicable
, ,	description (HCPCS code E0740) effective	Version 15	because industry-
	01/01/17.		wide change in code
			description.
10/01/17	Review for effective date 01/01/18. Revised	01/01/18	10/18/17: MPCTAC
, ,	criteria in the Medical Policy Statement and	Version 16	
	Limitations sections (designating service		
	experimental and investigational for the		
	treatment of urinary incontinence and/or fecal		
	incontinence). Administrative changes made to		
	the Policy Summary, Description of Item or		
	Service, Definitions, Clinical Background		
	Information, References, and Other Applicable		
	Policies sections. Plan notes updated in the		
	Applicable Coding section and revised code list;		
	diagnosis codes added for fecal incontinence		
	and applicable procedure codes considered		
	experimental and investigational for specified		
	indications.		
10/01/18	Review for effective date 11/01/18.	11/01/18	10/17/18: MPCTAC
10/01/18	Administrative changes made to the Policy	Version 17	10/1/10. MFCTAC
	Summary, References, and Other Applicable	Version i/	
	Policies sections. Administrative change made		
	to the Applicable Coding section (using ICD-10		
	diagnosis code range rather than individual		
12 /01 /10	diagnosis codes without changing the code list).	02/01/10	12 /10 /10. NADCTA C
12/01/18	Review for effective date 03/01/19. Revised the	03/01/19	12/19/18: MPCTAC
	policy title. Administrative changes made to the	Version 18	
	Policy Summary, Description of Item or Service,		
	Definitions, and References sections. Criteria		
	updated in the Medical Policy Statement and		
	Limitations sections. Revised the diagnosis		

	codes and Plan notes in the Applicable Coding section.		
07/01/19	Review for effective date 08/01/19. Updated the Plan notes in the Applicable Coding section.	08/01/19 Version 19	07/17/19: MPCTAC
09/01/19	Review for effective date 10/01/19. Administrative changes made to the Other Applicable Policies, References, and Reference to Applicable Laws and Regulations sections.	10/01/19 Version 20	09/18/19: MPCTAC
09/01/20	Review for effective date 10/01/20. Administrative changes made to the References and Other Applicable Policies sections.	10/01/20 Version 21	09/16/20: MPCTAC
05/01/21	Review for effective date 06/01/21. Plan note revised in the Applicable Coding section. Administrative changes made to the Policy Summary, Description of Item or Service, Medical Policy Statement, and Limitations sections.	06/01/21 Version 22	05/19/21: MPCTAC
10/01/21	Review for effective date 11/01/21. Adopted new medical policy template; removed administrative sections and the Medical Policy Statement section renamed the Clinical Criteria section.  Added NH Medicare Advantage HMO as an applicable product effective 01/01/22.  Administrative changes made to the Policy Summary, Clinical Criteria, Applicable Coding, and References sections. Removed the Limitations section.	11/01/21 Version 23	10/20/21: MPCTAC
08/01/22	Review for effective date 09/01/22. Administrative changes made to the Clinical Criteria and References sections.	09/01/22 Version 24	08/26/22: MPCTAC (electronic vote)
08/01/22	Review for policy retired date 11/01/22. Administrative changes made to the Policy Summary and Applicable Coding sections. Medical policy criteria revised in the Clinical Criteria and Limitations and Exclusions sections. Service will be managed by AIM Specialty Health as of 11/01/22 with AIM prior authorization required.	11/01/22 Version 25	08/26/22: MPCTAC (electronic vote)



Medical Policy - Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 11/01/22

# Physical Therapy in the Outpatient Setting

<b>Policy Number:</b>	OCA 3.544
Version Number	<b>r</b> : 25

Policy Retired Date: 11/01/22

## **Impacted Products**

	All Products
X	NH Medicaid
$\boxtimes$	NH Medicare Advantage
	MA MassHealth ACO
	MA MassHealth MCO
	MA Qualified Health Plans/Employer Choice Direct
	MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers outpatient physical therapy (PT) medically necessary, including habilitative services and/or rehabilitative services, when AIM clinical appropriateness guidelines are met for an adult or pediatric member or are required EPSDT services for a member age 20 or younger on the date of service. Prior authorization from AIM Specialty Health is required for outpatient PT after the initial evaluation. PT must be provided within the scope of practice of the treating professional and/or paraprofessional and follow all applicable state licensing and supervisory requirements.

#### Clinical Criteria

No medical policy criteria.

## **Limitations and Exclusions**

None.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for NH Medicare Advantage members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's

most recent policy review, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO or NH Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

# **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for physical therapy, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

<b>CPT Codes</b>	Code Descriptions
97010	Application of a modality to 1 or more areas; hot or cold packs
97012	Application of a modality to 1 or more areas; traction, mechanical
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
97016	Application of a modality to 1 or more areas; vasopneumatic devices
97018	Application of a modality to 1 or more areas; paraffin bath
97022	Application of a modality to 1 or more areas; whirlpool
97024	Application of a modality to 1 or more areas; diathermy (e.g., microwave)
97026	Application of a modality to 1 or more areas; infrared
97028	Application of a modality to 1 or more areas; ultraviolet
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes
97034	Application of a modality to 1 or more areas; contrast baths, each 15 minutes
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes
97036	Application of a modality to 1 or more areas; Hubbard tank, each 15 minutes
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97113	Therapeutic procedure, 1 or more areas, each 15 minutes; aquatic therapy with therapeutic exercises
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)

97124	Therapoutic precedure 1 or more areas, each 15 minutes; massage, including effective as
9/124	Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage,
07120	petrissage and/or tapotement (stroking, compression, percussion)
97129	Therapeutic interventions that focus on cognitive function (e.g., attention, memory,
	reasoning, executive function, problem solving, and/or pragmatic functioning) and
	compensatory strategies to manage the performance of an activity (e.g., managing time or
	schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient
	contact; initial 15 minutes
97130	Therapeutic interventions that focus on cognitive function (e.g., attention, memory,
	reasoning, executive function, problem solving, and/or pragmatic functioning) and
	compensatory strategies to manage the performance of an activity (e.g., managing time or
	schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient
	contact; each additional 15 minutes (List separately in addition to code for primary
	procedure)
97140	Manual therapy techniques (e.g., mobilization/manipulation, manual lymphatic drainage,
	manual traction), 1 or more regions, each 15 minutes
97150	Therapeutic procedure(s), group (2 or more individuals)
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An
	examination including a review of history and use of standardized tests and measures is
	required; and revised plan of care using a standardized patient assessment instrument
	and/or measurable assessment of functional outcome. Typically, 20 minutes are spent
	face-to-face with the patient and/or family.
97530	Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic
	activities to improve functional performance), each 15 minutes
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive
	responses to environmental demands, direct (one-on-one) patient contact, each 15
	minutes
97535	Self-care/home management training (e.g., activities of daily living (ADL) and
	compensatory training, meal preparation, safety procedures, and instructions in use of
	assistive technology devices/adaptive equipment) direct one-on-one contact, each 15
	minutes
97537	Community/work reintegration training (e.g., shopping, transportation, money
	management, avocational activities and/or work environment/modification analysis, work
	task analysis, use of assistive technology device/adaptive equipment), direct one-on-one
	contact, each 15 minutes
97545	Work hardening/conditioning; initial 2 hours
97546	Work hardening/conditioning; each additional hour (List separately in addition to code for
	primary procedure)
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with
	written report, each 15 minutes
97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing
-	function, optimize functional tasks and/or maximize environmental accessibility), direct
	one-on-one contact, with written report, each 15 minutes
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise
<del></del>	reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s)
	encounter, each 15 minutes
	and anter, each to minutes

97761	Prosthetic training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each
	15 minutes
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower
	extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15
	minutes

### References

American Association of Acupuncture and Oriental Medicine (AAAOM). AAAOM Position Statement on Trigger Point Dry Needling (TPDN) and Intramuscular Manual Therapy (IMT).

American College of Physicians (ACP), American Pain Society (APS). Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK; Clinical Efficacy Assessment Subcommittee of the ACP; ACP; APS Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the ACP and the APS. Ann Intern Med. 2007 Oct 2;147(7):478-91. Erratum in: Ann Intern Med. 2008 Feb 5;148(3):247-8. PMID: 17909209.

American College of Physicians (ACP). Qaseem A, Wilt TJ, McLean RM, Forciea MA; Clinical Guidelines Committee of the ACP. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the ACP. Ann Intern Med. 2017 Apr 4;166(7):514-30. doi: 10.7326/M16-2367. Epub 2017 Feb 14. PMID: 28192789.

American Heart Association/American Stroke Association. Winstein CJ, Stein J, Arena R, Bates B, Cherney LR, Cramer SC, Deruyter F, Eng JJ, Fisher B, Harvey RL, Lang CE, MacKay-Lyons M, Ottenbacher KJ, Pugh S, Reeves MJ, Richards LG, Stiers W, Zorowitz RD; American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke. 2016 Jun;47(6):e98-e169. doi: 10.1161/STR.0000000000000098. Epub 2016 May 4. Review. Erratum in: Stroke. 2017 Feb;48(2):e78. Stroke. 2017 Dec;48(12):e369. PMID: 27145936.

American Pain Society (APS). Guideline Summaries.

American Physical Therapy Association (APTA). APTA Clinical Practice Guidelines Development Manual.

American Physical Therapy Association (APTA). Balance and Falls.

American Physical Therapy Association (APTA). Clinical Practice Guidelines (CPGs) Developed by APTA.

American Physical Therapy Association (APTA). Coding and Billing.

American Physical Therapy Association (APTA). Direction and Supervision of the Physical Therapist Assistant.

American Physical Therapy Association (APTA). Dry Needling.

American Physical Therapy Association (APTA). Ethics and Professionalism. Code of Ethics for the Physical Therapist, Standards of Ethical Conduct for the PTA, Value-Based Behaviors for the PTA, Core Values for the PT and PTA, Standards of Practice for Physical Therapy.

American Physical Therapy Association (APTA). Guide to Physical Therapist Practice. Guide 3.0. 2016.

American Physical Therapy Association (APTA). Physical Therapy Documentation of Patient/Client Management.

American Physical Therapy Association (APTA). Supervision and Teamwork.

American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA). Rosenquist RW, Benzon HT, Connis RT, De Leon-Casasola OA, Glass D, Korevaar WC, Cynwyd B, Mekhail NA, Merrill DG, NIckinovich DG, Rathnmell JP, Nai-Mei Sang C, Simon DL; ASA Task Force on Chronic Pain Management. Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA. Anesthesiology. 2010 Apr;112(4):810-33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.

Centers for Medicare & Medicaid Services (CMS). Early and Periodic Screening, Diagnostic and Treatment (EPSDT). Medicaid.gov.

Centers for Medicare & Medicaid Services (CMS). EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents. 2014 Jun.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare and Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) Neuromuscular Electrical Stimulation (NMES) 160.12. Version 2. 2006 Oct 1.

Cruickshank TM, Reyes AR, Ziman MR. A systematic review and meta-analysis of strength training in individuals with multiple sclerosis or Parkinson disease. Medicine (Baltimore). 2015 Jan;94(4):e411. doi: 10.1097/MD.000000000000011. PMID: 25634170.

Hayes. Health Technology Assessment. Cognitive Rehabilitation Therapy for Traumatic Brain Injury (TBI). Dallas, TX: Hayes; 2017 Sep 26. Annual Review 2021 Feb 8.

Madsen M, Larsen K, Madsen IK, Søe H, Hansen TB. Late group-based rehabilitation has no advantages compared with supervised home-exercises after total knee arthroplasty. Dan Med J. 2013 Apr;60(4):A4607. PMID: 23651717.

Monticone M, Ferrante S, Rocca B, Baiardi P, Farra FD, Foti C. Effect of a long-lasting multidisciplinary program on disability and fear-avoidance behaviors in patients with chronic low back pain: results of a randomized controlled trial. Clin J Pain. 2013 Nov;29(11):929–38. doi: 10.1097/AJP.0b013e31827fef7e. PMID: 23328343.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. NH Medicaid Program.

New Hampshire Department of Health and Human Services. Provider Notices.

New Hampshire Medicaid. Therapies. Physical, Occupational, Speech. Provider Manual. Volume II. 2017 Dec 1.

New Hampshire Office of Professional Licensure and Certification. Office of Licensed Allied Health Professionals. Laws and Administrative Rules Governing Licensed Allied Health Professionals.

Parikh SS, Baxi N, Padavan SA. Musculoskeletal medicine. In: Sackheim KA, editor. Rehab Clinical Pocket Guide. New York, NY: Springer; 2013:357-426.

Reid MC, Eccleston C, Pillemer K. Management of chronic pain in older adults. BMJ. 2015 Feb 13;350:h532. doi: 10.1136/bmj.h532. PMID: 25680884.

Schaufele MK, Tate JL. Lumbar degenerative disease. In: Frontera WR, Silver JK, Rizzo TD Jr, editors. Essentials of Physical Medicine and Rehabilitation: Musculoskeletal Disorders, Pain, and Rehabilitation. 3rd ed. Philadelphia, PA: Elsevier Saunders; 2015:225–32.

Stanos SP, Tybursky MD, Harden RN. Chronic pain. In: Cifu DX, et al., editors. Braddom's Physical Medicine and Rehabilitation. 5th ed. Elsevier; 2016:809–33.

#### **Next Review Date**

Not applicable

#### **Retired Date**

11/01/22

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	09/16/05	Director of Medical Policy as	Quality and Clinical
	Version 1	Chair of Medical Policy,	Management
Internal Approval:		Criteria, and Technology	Committee
09/16/05		Assessment Committee	(Q&CMC)
		(MPCTAC)	

<sup>\*</sup>Effective Date for NH Medicaid Product: 01/01/13

Physical Therapy policy renumbered OCA 3.544 for physical therapy provided to NH Medicaid members age 21 or older in the outpatient setting as of 01/11/15. (Policy formerly numbered OCA 3.54 for physical therapy in the outpatient setting for all adult and pediatric NH Medicaid members from 01/01/13 to 01/10/15.) Policy title changed to *Physical Therapy in the Outpatient Setting* as of 12/01/21.

Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
02/07/06	Added definitions for modality and visit. Defined coverage for visits, evaluations and units billed.	Version 2	02/07/06: Q&CMC
07/06/06	Removed verbiage regarding reimbursement for evaluation and modality services.	Version 3	07/06/06: Q&CMC
03/27/07	Policy archived.	Not applicable	Not specified
10/14/08	Reviewed policy and updated clinical criteria, effective date of the revised policy is 12/16/08.	12/16/08 Version 4	11/10/08: MPTAC 12/16/08: Quality Improvement Committee (QIC)
09/22/09	No changes.	Version 5	09/22/09: MPCTAC 10/28/09: QIC
10/01/10	Updated template and references.	Version 6	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Added Commercial benefit limitations, updated coding and references.	Version 7	10/19/11: MPCTAC 11/29/11: QIC
08/01/12	Off cycle review for WellSense New Hampshire Medicaid product, revised Summary statement, reformatted Medical Policy Statement, revised	Version 8	08/13/12: MPCTAC 09/06/12: QIC

<sup>\*</sup>Effective Date for NH Medicare Advantage HMO Product: 01/01/22

	Applicable Coding introductory paragraph,		
	updated code list, revised Limitations section,		
	and revised references.		
11/01/12	Review for effective date 03/01/13. Updated	03/01/13	11/21/12: MPCTAC
11/01/12	references. Revised Summary section. Clarified	Version 9	12/20/12: QIC
	text in Medical Policy Statement section.	VCISION 5	12/20/12. Q1C
	Revised language in introductory paragraph in		
	Applicable Coding section and updated		
	applicable code list. Clinical criteria moved from		
	Clinical Background and Summary sections to		
	Medical Policy Statement section. Moved		
	services not considered medically necessary		
	from the Medical Policy Statement section to		
	the Limitations section. Removed duplicate text		
	from Clinical Background Information section.		
	Referenced Plan reimbursement policy 4.609		
	for physical therapy reimbursement guidelines.		
	Removed "Guideline" from title.		
08/14/13 and	Off cycle review for the NH Medicaid product	Version 10	08/14/13: MPCTAC
08/15/13:	and merged policy format. Incorporate policy	version to	(electronic vote)
00/13/13.	revisions dated 11/01/12 (as specified above) for		08/15/13: QIC
	the NH Medicaid product; these policy revisions		00/13/13. QIC
	were approved by MPCTAC on 11/21/12 and QIC		
	on 12/20/12 for applicable Plan products.		
11/01/13,	Review for effective date 05/01/14. Updated	05/01/14	02/11/14: MPCTAC
12/01/13,	code definitions, introductory paragraph in	Version 11	02/18/14: QIC
		V CI SIOII II	02/10/14. QIC
02/01/11			
	·		
	·		
	·		
	•		
	, , , , , , , , , , , , , , , , , , , ,		
	1		
09/08/14	,	10/01/14	09/17/14: MPCTAC
03/00/11	· · · · · · · · · · · · · · · · · · ·		, , ,
	- , ,		03/00/11. Q10
		/ taderidam / t	
11/04/14 and		01/11/15	11/06/14: MPCTAC
11/19/14		, ,	' '
	1. Talifar Siley Statement Sections aparted With	. 5.5.5.1.12	`
.,, 13, 17	quidelines specified in version 11 addendum A		1 11/11/14· (31C)
n/ 12/ 1 <del>1</del>	guidelines specified in version 11, addendum A. Policy renumbered OCA 3.544 to include		11/11/14: QIC (electronic vote)
01/01/14, and 02/01/14  09/08/14  11/04/14 and	Applicable Coding section, and the applicable code lists for the MA products and the NH Medicaid product. Updated references. Removed prior authorization waiver for the first 32 units of PT for the NH Medicaid product. Add criterion in the Medical Policy Statement sections for the MA products and NH Medicaid product requiring an updated physician prescription and supporting clinical documentation after 20 OT visits per treatment episode. Revised Limitations sections.  For NH Medicaid product only, waived prior authorization of first eight (8) 15-minute treatment units per member per servicing provider per calendar year.  Review for effective date 01/11/15. Summary and Medical Policy Statement sections updated with	10/01/14 Version 11 Addendum A 01/11/15 Version 12	09/17/14: MPCTAC 09/30/14: QIC 11/06/14: MPCTAC (electronic vote)

	Modicaid members ago 21 or older on the data of		12/10/14: 010
	Medicaid members age 21 or older on the date of service. Revised Limitations section. (PT		12/10/14: QIC
	services formerly included in policy number OCA		
	3.54 for all adult and pediatric members.)		
	Revised review calendar.		
11/01/15	Review for effective date 01/01/16. Updated	01/01/16	12/03/15: MPCTAC
, , ,	template, Summary section, and References	Version 13	(electronic vote)
	section. Administrative changes made to the		12/09/15: QIC
	Medical Policy Statement and Limitations		, ,
	section without changing criteria. Revised		
	language in the Applicable Coding section.		
	Added definitions.		
12/01/16	Review for effective date 02/01/17. Industry-	02/01/17	12/21/16: MPCTAC
	wide revisions of applicable codes. Clarified	Version 14	01/11/17: QIC
	existing criteria in the Medical Policy Statement		
	section.		
12/01/17	Review for effective 01/01/18. Industry-wide	01/01/18	12/20/17: MPCTAC
	updates to codes included in the Applicable	Version 15	
	Coding section. Annual review of policy with		
	administrative changes made to the Definitions		
	and Reference sections.		
02/01/18	Review for effective date 03/01/18.	03/01/18	02/21/18: MPCTAC
	Administrative changes made to the Policy	Version 16	
44 (04 (40	Summary and Limitations sections.	40 /04 //0	44 (04 (40 140 07 10
11/01/18	Review for effective date 12/01/18.	12/01/18	11/21/18: MPCTAC
	Administrative changes made to the Policy	Version 17	
	Summary, Medical Policy Statement, Limitations,		
	Definitions, References, Other Applicable		
	Policies, and Reference to Applicable Laws and Regulations sections.		
03/01/19	Review for effective date 07/01/19.	07/01/19	03/20/19: MPCTAC
03/01/13	Administrative changes made to the Limitations	Version 18	03/20/13. WIT CTAC
	and Reference to Applicable Laws and	Version to	
	Regulations sections. Criteria revised in the		
	Medical Policy Statement section.		
12/01/19	Review for effective date 01/01/20. Industry-	01/01/20	Not applicable
, ,	wide updates to codes included in the Applicable	Version 19	because industry-
	Coding section.		wide code changes
11/01/19	Review for effective date 02/01/20.	02/01/20	11/20/19: MPCTAC
	Administrative changes made to the References	Version 20	
	and Reference to Applicable Laws and		
	Regulations sections. Revised criteria in the	Renumbered to	
	Medical Policy Statement and Limitations	version 20 to	
	sections.	implement	
		industry-wide code	
		updates effective	

		01/01/20 included	
		in version 19	
12/01/19	Review for effective 02/01/20. Industry-wide	02/01/20	12/18/19: MPCTAC
	updates to codes effective 01/01/20 included in	Version 21	
	the Applicable Coding section of the policy		
	version 20 effective 02/01/20.		
12/01/19	Review for effective date 03/01/20. Revised in	03/01/20	12/18/19: MPCTAC
	the Medical Policy Statement section the	Version 22	
	definition of a servicing PT provider for the prior		
	authorization waiver.	12 / 2 / 2 2	
11/01/20	Review for effective date 12/01/20. Updated the	12/01/20	11/18/20: MPCTAC
	References section. Administrative change	Version 23	
	made to the Applicable Coding section.	10.101.101	
11/01/21	Review for effective date 12/01/21. Adopted new	12/01/21	11/17/21: MPCTAC
	medical policy template; removed administrative	Version 24	
	sections, Medical Policy Statement section		
	renamed Clinical Criteria section, and Limitations		
	section renamed Limitations and Exclusions		
	section. Administrative changes made to the		
	Policy Summary, Applicable Coding, and		
	References sections. Medical policy criteria		
	retired and InterQual criteria will continue to be		
	used to determine the medical necessity of		
	services. Revised policy title because policy		
	applies to adult and pediatric members as of 12/01/21.		
08/01/22	Review for policy retired date 11/01/22.	11/01/22	08/26/22: MPCTAC
	Administrative changes made to the Policy	Version 25	(electronic vote)
	Summary and Applicable Coding sections.		
	InterQual medical necessity criteria and medical		
	policy guidelines in the Clinical Criteria and		
	Limitations and Exclusions sections retired on		
	11/01/22. AIM criteria adopted for outpatient PT		
	on 11/01/22. Plan prior authorization waivers		
	removed after 10/31/22. AIM prior authorization		
	is required for outpatient PT after the initial		
	evaluation as of 11/01/22, even when applicable		
	codes are not listed in this Plan policy.		



#### **Medical Policy**

# Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous)

Policy Number: OCA 3.562

Version Number: 21

**Version Effective Date**: 11/01/22

## Impacted Products

- ⋈ NH Medicaid
- ⋈ NH Medicare Advantage
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

Posterior tibial nerve stimulation may include percutaneous tibial nerve stimulation (PTNS) and/or transcutaneous posterior tibial nerve stimulation (TPTNS, also known as transcutaneous electrical nerve stimulation/TENS). The Plan considers PTNS medically necessary for the treatment of non-neurogenic overactive bladder syndrome in adult members when Plan criteria are met. Plan prior authorization is required.

AIM clinical appropriateness criteria will be used to determine the medical necessity of therapeutic electrical stimulation (TENS) as part of a therapy plan of care. Prior authorization from AIM Specialty Health is required.

## **Clinical Criteria**

The Plan will NOT approve more than 6 sessions of PTNS per prior authorization request. Criteria must be met in either item A (medical necessity criteria) or item B (Medical Director review required):

A. ALL criteria in items 1 through 8 must be met for PTNS:

- 1. Member is age 18 or older on the date of service; AND
- Member is diagnosed with non-neurogenic overactive bladder (OAB) syndrome and the member has NOT received a course of treatment with PTNS sessions in the past for the treatment of OAB symptoms; AND
- 3. Member has consistently attempted for at least 8 to 12 weeks ALL behavioral therapies listed in items a through d but these conservative treatments have failed to manage member's symptoms of OAB:
  - a. Bladder training; AND
  - b. Bladder control strategies; AND
  - c. Pelvic floor muscle training; AND
  - d. Fluid management; AND
- 4. Member has failed second-line therapy with a trial of at least 2 anticholinergic agents (antimuscarinics) and Myrbetrig® (mirabegron), with each administered for a minimum of 4 weeks to treat the member's symptoms of OAB syndrome, unless this pharmacotherapy is NOT tolerated or is contraindicated for the member; AND
- 5. Device requested is FDA approved for the intended use; AND
- 6. Member does NOT have an implanted or planned implantation of a sacral nerve neurostimulator; AND
- 7. Each PTNS session will be 30 minutes in duration; AND
- 8. Member's first course of treatment is defined as first-time use of PTNS to treat one (1) or more urological symptoms per member regardless of treating provider and date of service. The Plan will authorize PTNS sessions ONLY when it is the member's first course of treatment with PTNS and ONE (1) of the applicable treatment frequency criteria in items a through c must be met:
  - a. 6 Initial PTNS Sessions for First Course of Treatment:

BOTH criteria must be met in items (1) and item (2):

(1) Treating provider will be objectively documenting the degree of improvement (e.g., member voiding diaries) of the member's symptoms after each PTNS session; AND

(2) Each of the 6 initial PTNS sessions will occur once a week for 6 consecutive weeks; OR

#### b. PTNS Sessions Number 7 Through 12 for First Course of Treatment:

BOTH criteria must be met in item (1) and item (2):

- (1) Treating provider has objectively documented the degree of improvement (e.g., member voiding diaries) of the member's symptoms after each of the initial sessions 1 through 6 and will continue to objectively document improvement after each of the PTNS sessions number 7 through 12; AND
- (2) Each of PTNS sessions number 7 through 12 will occur once a week for ALL consecutive weeks; OR

#### c. PTNS After 12 Sessions for First Course of Treatment

ALL criteria must be met in items (1) through (3):  $\infty$ 

- (1) Additional PTNS sessions will occur no more frequently than monthly for the first 6 months of treatment (with the first 6 months of treatment defined as 6 consecutive calendar months from the date of the initial PTNS session for the member regardless of treating provider); AND
- (2) Treating provider has objectively documented (e.g., member voiding diaries) that the member has consistently experienced 50% or greater improvement in voiding symptoms for at least 48 hours after each PTNS session if this improvement threshold is not met or not documented, the PTNS treatment will be immediately discontinued (even if additional PTNS sessions are authorized by the Plan); AND
- (3) PTNS sessions do not exceed 6 consecutive calendar months from the initial PTNS session for the member (regardless of treating provider).  $\infty$
- B. Plan Medical Director review is required for ANY condition listed in items 1 through 3:
  - Request for PTNS after 12 sessions when that the member has NOT experienced 50% or greater improvement in voiding symptoms for at least 48 hours; the efficacy of continued treatment with PTNS has NOT been established if the initial 12-week course of PTNS has failed to adequately manage the member's urological symptoms; OR
  - 2. Request for PTNS for a member whose sessions will exceed 6 consecutive calendar months from the member's initial PTNS session (regardless of treating provider and dates of service) to determine if PTNS remains the most effective treatment option for the member (rather than

first-line therapy or a long-term treatment option such as implantable sacral nerve stimulation which has greater accuracy because the sacral nerve is directly stimulated); OR

3. Request for PTNS sessions more frequently than once a week.

#### **Limitations and Exclusions**

Contraindications for PTNS include ANY of the following conditions listed in items 1 through 7:

- 1. Neurogenic overactive bladder syndrome/neurogenic lower urinary tract dysfunction; OR
- 2. Pacemaker or implantable defibrillator; OR
- 3. Prone to excessive bleeding; OR
- 4. Nerve damage that could impact either percutaneous tibial nerve or pelvic floor function; OR
- 5. Pregnant or planning to become pregnant during the duration of the treatment; OR
- 6. Active infection in the area of the percutaneous puncture; OR
- 7. Unable to tolerate needle stick (e.g., phobia to needles).

## **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and NH Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, no NCD was found. LCD L33396 includes medical necessity criteria for posterior tibial nerve stimulation for voiding dysfunction. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

# **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan

billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Code	Description: Code Considered Medically Necessary for PTNS for Non- Neurogenic Overactive Bladder Syndrome	
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming	

#### References

Abrams P, Andersson KE, Birder L, Brubaker L, Cardozo L, Chapple C, Cottenden A, Davila W, de Ridder D, Dmochowski R, Drake M, Dubeau C, Fry C, Hanno P, Smith JH, Herschorn S, Hosker G, Kelleher C, Koelbl H, Khoury S, Madoff R, Milsom I, Moore K, Newman D, Nitti V, Norton C, Nygaard I, Payne C, Smith A, Staskin D, Tekgul S, Thuroff J, Tubaro A, Vodusek D, Wein A, Wyndaele JJ; Members of Committees; Fourth International Consultation on Incontinence. Fourth international consultation on incontinence recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. Neurourol Urodyn. 2010;29(1):213-40. doi: 10.1002/nau.20870. PMID: 20025020.

American College of Gastroenterology (ACG). Guidelines.

American College of Gastroenterology (ACG). Rao SS, ACG Practice Parameters Committee. Diagnosis and management of fecal incontinence. Am J Gastroenterol. 2004 Aug;99(8):1585-604. doi: 10.1111/j.1572-0241.2004.40105.x. PMID: 15307881.

The American College of Obstetricians and Gynecologists (ACOG). Clinical Guidance.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 155. Urinary Incontinence in Women. 2015. Reaffirmed 2018. Obstet Gynecol. 2015 Nov;126(5):e66-81. doi: 10.1097/AOG.000000000001148. PMID: 26488524.

The American College of Obstetricians and Gynecologists (ACOG). ACOG Practice Bulletin No. 210. Fecal Incontinence. Obstet Gynecol. 2019 Apr;133(4):837-39. doi: 10.1097/AOG.00000000003188. PMID: 30913191.

The American College of Obstetricians and Gynecologists (ACOG), American Urogynecologic Society (AUGS). ACOG Committee on Gynecologic Practice. Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment. Committee Opinion Number 603. 2014 Jun. Reaffirmed 2017.

The American College of Obstetricians and Gynecologists (ACOG). Urinary Incontinence. Patient Resources.

American College of Physicians (ACP). Clinical Guidelines & Recommendations.

American College of Physicians (ACP). Qaseem A, Dallas P, Forciea MA, Starkey M, Denberg TD, Shekelle P. Clinical Guidelines Committee of the ACP. Nonsurgical management of urinary incontinence in women: a clinical practice guideline from the ACP. Ann Intern Med. 2014 Sep 16;161(6):429-40. doi: 10.7326/M13-2410. PMID: 25222388.

American Gastroenterological Association (AGA). Bharucha AE, Pemberton JH, Locke GR. American Gastroenterological Association technical review on constipation. Gastroenterology. 2013 Jan;144(1):218-38. doi: 10.1053/j.gastro.2012.10.028. PMID: 23261065.

American Gastroenterological Association (AGA). Clinical Guidelines.

The American Society of Colon and Rectal Surgeons (ASCRS). Clinical Practice Guidelines.

The American Society of Colon and Rectal Surgeons (ASCRS). Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. Dis Colon Rectum. 2015 Jul;58(7):623-36. doi: 10.1097/DCR.000000000000397. PMID: 26200676.

American Urogynecologic Society (AUGS). Clinical Guidance Documents.

American Urological Association (AUA). Guidelines & Policies.

American Urological Association (AUA) and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU). Lightner DJ, Gomelsky A, Souter L, Vasavada SP. Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline Amendment 2019. J Urol. 2019 Sep;202(3):558-63. doi: 10.1097/JU.00000000000000309. Epub 2019 Aug 8. PMID: 31039103.

Ammi M, Chautard D, Brassart E, Culty T, Azzouzi AR, Bigot P. Transcutaneous posterior tibial nerve stimulation: evaluation of a therapeutic option in the management of anticholinergic refractory overactive bladder. Int Urogynecol J. 2014 Aug;25(8):1065-9. doi: 10.1007/s00192-014-2359-0. Epub 2014 Mar 6. PMID: 24599180.

Anderson CA, Omar MI, Campbell SE, Hunter KF, Cody JD, Glazener CM. Conservative management for postprostatectomy urinary incontinence. Cochrane Database Syst Rev. 2015 Jan 20;1:CD001843. doi: 10.1002/14651858.CD001843.pub5. PMID: 25602133.

Barker A, Hurley J. Novel treatment options for fecal incontinence. Clin Colon Rectal Surg. 2014 Sep;27(3):116–20. doi: 10.1055/s-0034-1387800. PMID: 25320572.

Barnett G, Ockrim J. Re: Cost of neuromodulation therapies for overactive bladder: percutaneous tibial nerve stimulation versus sacral nerve stimulation: M. Martinson, S. MacDiarmid and E. Black J Urol 2013; 189: 210-16. J Urol. 2013 Oct;190(4):1444-5. doi: 10.1016/j.juro.2013.04.131. Epub 2013 Jul 22. PMID: 23886880.

Barroso U Jr, Viterbo W, Bittencourt J, Farias T, Lordêlo P. Posterior tibial nerve stimulation vs parasacral transcutaneous neuromodulation for overactive bladder in children. J Urol. 2013 Aug;190(2):673-7. doi: 10.1016/j.juro.2013.02.034. Epub 2013 Feb 16. PMID: 23422257.

Canadian Urological Association. Bettez M, Tu LM, Carlson K, Corcos J, Gajewski J, Jolivet M, Bailly G. 2012 Update: Guidelines for Adult Urinary Incontinence Collaborative Consensus Document for the Canadian Urological Association. Can Urol Assoc J. 2012 Oct;6(5):354–63. doi: 10.5489/cuaj.12248. PMID: 23093627.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) Posterior Tibial Nerve Stimulation for Voiding Dysfunction L33396. National Government Services, Inc. 2015 Oct 1. Revision Effective Date 2019 Oct 24.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Biofeedback Therapy for the Treatment of Urinary Incontinence 30.1.1. Effective 2001 Jul 1.

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Bladder Stimulators (Pacemakers) 230.16. 1996 Oct 7.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Incontinence Control Devices 230.10. 1996 Oct 7.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Non-Implantable Pelvic Floor Electrical Stimulator 230.8. Effective 2006 Jun 19.

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence 230.18. Effective 2002 Jan 1.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

de Sèze M, Raibaut P, Gallien P, Even-Schneider A, Denys P, Bonniaud V, Gamé X, Amarenco G. Transcutaneous posterior tibial nerve stimulation for treatment of the overactive bladder syndrome in multiple sclerosis: results of a multicenter prospective study. Neurourol Urodyn. 2011 Mar;30(3):306-11. doi: 10.1002/nau.20958. Epub 2011 Feb 8. PMID: 21305588.

de Wall LL, Heesakkers JP. Effectiveness of percutaneous tibial nerve stimulation in the treatment of overactive bladder syndrome. Res Rep Urol. 2017 Aug 14;9:145-57. doi: 10.2147/RRU.S124981. eCollection 2017. PMID: 28861404.

Dedemadi G, Takano S. Efficacy of Bilateral Transcutaneous Posterior Tibial Nerve Stimulation for Fecal Incontinence. Perm J. 2018 Jul 31;22. doi: 10.7812/TPP/17-231. PMID: 30028671.

Edenfield AL, Amundsen CL, Wu JM, Levin PJ, Siddiqui NY. Posterior tibial nerve stimulation for the treatment of fecal incontinence: a systematic evidence review. Obstet Gynecol Surv. 2015 May;70(5):329-41. doi: 10.1097/OGX.00000000000171. PMID: 25974730.

European Association of Urology (EAU). Blok B, Castro-Diaz D, Del Popolo G, Groen J, Hamid R, Karsenty G, Kessler TM, Pannek J, Ecclestone H, Musco S, Padilla-Fernández B, Sartori A, 't Hoen LA. Guidelines. Neuro-Urology. 2020.

European Association of Urology (EAU). Burkland FC, Bosch JLHR, Cruz F, Lemack GE, Nambiar AK, Thiruchelvam N, Tubaro A, Ambühl D, Bedretdinova DA, Farag F, Lombardo R, Schneider MP. Guidelines. Urinary Incontinence.

European Association of Urology (EAU). Burkhard FC, Lucas MG, Berghmans LC, Bosch JLHR, Cruz F, Lemack GE, Nambiar AK, Nilsson CG, Pickard R, Tubaro A. EAU Guidelines on Urinary Incontinence in Adults. 2016.

European Association of Urology (EAU). Nambiar AK, Bosch R, Cruz F, Lemack GE, Thiruchelvam N, Tubaro A, Bedretdinova DA, Ambühl D, Farag F, Lombardo R, Schneider MP, Burkhard FC. EAU Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence. Eur Urol. 2018 Apr;73(4):596-609. doi: 10.1016/j.eururo.2017.12.031. Epub 2018 Feb 3. PMID: 29398262.

Fritel X, Fauconnier A, Bader G, Cosson M, Debodinance P, Deffieux X, Denys P, Dompeyre P, Faltin D, Fatton B, Haab F, Hermieux JF, Kerdraon J, Mares P, Mellier G, Michel-Laaengh N, Nadeau C, Robain G, de Tayrac R, Jacquetin B; French College of Gynecologists and Obstetricians. Diagnosis and management of adult female stress urinary incontinence: guidelines for clinical practice from the French College of Gynecologists and Obstetricians. Eur J Obstet Gynecol Reprod Biol. 2010 Jul;151(1):14-9. doi: 10.1016/j.ejogrb.2010.02.041. Epub 2010 Mar 16. PMID: 20236751.

Gaziev G, Topazio L, Iacovelli V, Asimakopoulos A, Di Santo A, De Nunzio C, Finazzi-Agro. Percutaneous tibial nerve stimulation (PTNS) efficacy in the treatment of lower urinary tract dysfunctions: a systematic review. BMC Urol. 2013 Nov 25;13:61. doi: 10.1186/1471-2490-13-61. PMID: 24274173.

George AT, Kalmar K, Sala S, Kopanakis K, Panarese A, Dudding TC, Hollingshead JR, Nicholls RJ, Vaizey CJ. Randomized controlled trial of percutaneous versus transcutaneous posterior tibial nerve stimulation in faecal incontinence. Br J Surg. 2013 Feb;100(3):330–8. doi: 10.1002/bjs.9000. PMID: 23300071.

George AT, Maitra RK, Maxwell-Armstrong C. Posterior tibial nerve stimulation for fecal incontinence: Where are we? World J Gastroenterol. 2013 Dec 28;19(48):9139–45. Published online 2013 Dec 28. doi: 10.3748/wjg.v19.i48.9139. PMID: 24409042.

Gungor Ugurlucan F, Onal M, Aslan E, Ayyildiz Erkan H, Kizilkaya Beji N, Yalcin O. Comparison of the effects of electrical stimulation and posterior tibial nerve stimulation in the treatment of overactive bladder syndrome. Gynecol Obstet Invest. 2013;75(1):46-52. doi: 10.1159/000343756. Epub 2012 Nov 16. PMID: 23171636.

Hayes. Comparative Effectiveness Review. Comparative Effectiveness Review of Percutaneous Tibial Nerve Stimulation for the Treatment of Symptomatic Non-Neurogenic Overactive Bladder. Dallas, TX: Hayes; 2018 Oct 31. Annual Review 2021 May 11.

Hayes. Health Technology Assessment. Percutaneous Tibial Nerve Stimulation for the Treatment Of Symptomatic Neurogenic Lower Urinary Tract Dysfunction. Dallas, TX: Hayes; 2019 Apr 15. Annual Review 2021 Jun 4.

Horrocks EJ, Thin N, Thaha MA, Taylor SJ, Norton C, Knowles CH. Systematic review of tibial nerve stimulation to treat fecal incontinence. Br J Surg. 2014 Apr;101(5):457-68. doi: 10.1002/bjs.9391. Epub 2014 Jan 20. PMID: 24446127.

Hotouras A, Murphy J, Allison M, Curry A, Williams NS, Knowles CH, Chan CL. Prospective clinical audit of two neuromodulatory treatments for fecal incontinence: sacral nerve stimulation (SNS) and percutaneous tibial nerve stimulation (PTNS). Surg Today. 2014 Nov;44(11):2124-30. doi: 10.1007/s00595-014-0898-0. Epub 2014 May 5. PMID: 24792064.

Martinson M, MacDiarmid S, Black E. Cost of neuromodulation therapies for overactive bladder: percutaneous tibial nerve stimulation versus sacral nerve stimulation. J Urol. 2013 Jan;189(1):210-6. doi: 10.1016/j.juro.2012.08.085. Epub 2012 Nov 20. Erratum in: J Urol. 2013 Sep;190(3):1142. PMID: 23174264.

Maternik M, Krzeminska K, Zurowska A. The management of childhood urinary incontinence. Pediatr Nephrol. 2015 Jan;30(1):41-50. doi: 10.1007/s00467-014-2791-x. Epub 2014 Mar 11. PMID: 24615564.

Monga AK, Tracey MR, Subbaroyan J. A systematic review of clinical studies of electrical stimulation for treatment of lower urinary tract dysfunction. Int Urogynecol J. 2012 Aug;23(8):993-1005. doi: 10.1007/s00192-012-1691-5. Epub 2012 Mar 17. PMID: 22426872.

Moossdorff-Steinhauser HF, Berghmans B. Effects of percutaneous tibial nerve stimulation on adult patients with overactive bladder syndrome: a systematic review. Neurourol Urodyn. 2013 Mar;32(3):206-14. doi: 10.1002/nau.22296. Epub 2012 Aug 20. PMID: 22907807.

National Institute for Health and Care Excellence (NICE). Lower urinary tract symptoms in men: management. Clinical Guideline CG97. 2010 May 23. Last Updated 2015 Jun 3.

National Institute for Health and Care Excellence (NICE). Urinary incontinence in neurological disease: assessment and management. Clinical Guideline CG148. 2012 Aug 8.

National Institute for Health and Care Excellence (NICE). Urinary incontinence and pelvic organ prolapse in women: management. NICE Guideline NG123. 2019 Apr 2. Last Updated 2019 Jun 24.

Nepple KG, Cooper CS. Management of bladder dysfunction in children. UpToDate. 2021 Jun 22.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Peters KM, Carrico DJ, Wooldridge LS, Miller CJ, MacDiarmid SA. Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. J Urol. 2013 Jun; 189(6):2194-201. doi: 10.1016/j.juro.2012.11.175. Epub 2012 Dec 3. PMID: 23219541.

Rostaminia G, Chang C, Pincus JB, Sand PK, Goldberg RP. Predictors of successful percutaneous tibial nerve stimulation (PTNS) in the treatment of overactive bladder syndrome. Int Urogynecol J. 2018 Nov 29. doi: 10.1007/s00192-018-3834-9. [Epub ahead of print] PMID: 30498931.

Sanford MT, Suskind AM. Neuromodulation in neurogenic bladder. Transl Androl Urol. 2016 Feb;5(1):117–26. doi: 10.3978/j.issn.2223-4683.2015.12.01. PMID: 26904417.

Santos JD, Lopes RI, Koyle MA. Bladder and bowel dysfunction in children: An update on the diagnosis and treatment of a common, but underdiagnosed pediatric problem. Can Urol Assoc J. 2017 Jan-Feb;11(1-2Suppl1):S64-S72. doi: 10.5489/cuaj.4411. PMID: 28265323.

Schreiner L, Santos TG, Souza AB, Nygaard CC, Silva Filho IG. Electrical stimulation for urinary incontinence in women: a systematic review. Int Braz J Urol. 2013 Jul-Aug;39(4):454-64. doi: 10.1590/S1677-5538.IBJU.2013.04.02. PMID: 24054395.

Sharan E, Hunter K, Hassouna M, Yoo PB. Characterizing the transcutaneous electrical recruitment of lower leg afferents in healthy adults: implications for non-invasive treatment of overactive bladder. BMC Urol. 2018 Feb 13;18(1):10. doi: 10.1186/s12894-018-0322-y. PMID: 29439703.

Staskin DR, Peters KM, MacDiarmid S, Shore N, de Groat WC. Percutaneous tibial nerve stimulation: a clinically and cost effective addition to the overactive bladder algorithm of care. Curr Urol Rep. 2012 Oct;13(5):327-34. doi: 10.1007/s11934-012-0274-9. PMID: 22893501.

Thomas GP, Dudding TC, Rahbour G, Nicholls RJ, Vaizey CJ. A review of posterior tibial nerve stimulation for faecal incontinence. Colorectal Dis. 2013 May;15(5):519-26. doi: 10.1111/codi.12093. PMID: 23216902.

Tudor KI, Seth JH, Liechti MD, Ochulor J, Gonzales G, Haslam C, Fox Z, Pakzad M, Panicker JN. Outcomes following percutaneous tibial nerve stimulation (PTNS) treatment for neurogenic and idiopathic overactive bladder. Clin Auton Res. 2018 Aug 3. doi: 10.1007/s10286-018-0553-8. [Epub ahead of print] PMID: 30074101.

Tutolo M, Ammirati E, Heesakkers J, Kessler TM, Peters KM, Rashid T, Sievert KD, Spinelli M, Novara G, Van der Aa F, De Ridder D. Efficacy and Safety of Sacral and Percutaneous Tibial Neuromodulation in Non-neurogenic Lower Urinary Tract Dysfunction and Chronic Pelvic Pain: A Systematic Review of the Literature. Eur Urol. 2018 Jan 11. pii: S0302-2838(17)30978-8. doi: 10.1016/j.eururo.2017.11.002. [Epub ahead of print.] PMID: 29336927.

U.S. Food and Drug Administration (FDA). Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence – Guidance for Industry and FDA Staff. 2011 Mar 8.

U. S. Food and Drug Administration (FDA). Medical Devices. 510(k) Clearances.

U. S. Food and Drug Administration (FDA). Medical Devices. Device Registration and Listing.

Wald A. Update on the Management of Fecal Incontinence for the Gastroenterologist. Gastroenterol Hepatol (NY). 2016 Mar;12(3):155–64. PMID: 27231444.

#### **Next Review Date**

09/01/22

# **Authorizing Entity**

**MPCTAC** 

# **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# Appendix: Policy History

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	12/03/06	Director of Medical Policy as	Quality and Clinical
	Version 1	Chair of Medical Policy,	Management
Internal Approval:		Criteria, and Technology	Committee
10/03/06		Assessment Committee	(Q&CMC)
		(MPCTAC)	

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

Notes: Effective 05/01/13, this policy replaced the Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence policy, policy number OCA: 3.56, for a service-specific policy for posterior tibial nerve stimulation. Policy title was Posterior Tibial Nerve Stimulation from 05/01/13 to 12/31/18. Effective 01/01/19, policy title changed to Posterior Tibial Nerve Stimulation (Percutaneous or Transcutaneous).

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
09/11/07	Updated template and added coding.	Version 2	09/11/07: MPCTAC 09/25/07: Utilization Management Committee (UMC) 10/15/07: Quality Improvement Committee (QIC)
09/09/08	No changes.	Version 3	09/09/08: MPCTAC 09/30/08: UMC 10/22/08: QIC
09/22/09	Updated references, no changes to criteria.	Version 4	09/22/09: MPCTAC 10/28/09: QIC
09/01/10	Updated template and references. No changes to criteria.	Version 5	10/20/10: MPCTAC 11/22/10: QIC
10/01/11	Updated limitations to include that sacral nerve stimulation for the treatment of fecal incontinence and posterior tibial nerve	Version 6	10/19/11: MPCTAC 11/29/11: QIC

<sup>\*</sup>Effective Date for New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for NH Medicare Advantage HMO Product: 01/01/22

	stimulation for the treatment of symptoms associated with overactive bladder are considered experimental and investigational. Updated references and coding.		
07/20/12	Off cycle review for Well Sense Health Plan: Updated title, revised Summary statement, added posterior tibial stimulation to Description of Item or Service, reformatted Medical Policy Statement, updated Definitions, revised language in Applicable Coding section, updated code list.	Version 7	08/13/12: MPCTAC 09/13/12: QIC
12/01/12	Review for effective date 05/01/13. Separated pelvic floor electrical stimulation, sacral nerve stimulation, and posterior tibial nerve stimulation into three separate policies; policy formerly titled Pelvic Floor/Sacral Nerve Stimulation for Urinary Incontinence (formerly policy number OCA: 3.65). Revised title and renumbered policy. Updated language in Summary, Description of Item or Service, Medical Policy Statement, Definitions, Applicable Coding, and Clinical Background Information sections. Updated references and revised limitations. Revised applicable code list. Referenced the following policies: Experimental and Investigational Treatment, Non-Implantable Pelvic Floor Electrical Stimulation for Urinary Incontinence, Sacral Nerve Stimulation (Including Peripheral Nerve Stimulation Test and Two-Stage Tined Lead Procedure) for Incontinence and Urinary Incontinence.	05/01/13 Version 8	12/19/12: MPCTAC 01/31/13: QIC
12/01/13	Review for effective date 02/01/14. Updated references.	02/01/14 Version 9	12/18/13: MPCTAC 01/21/14: QIC
12/01/14	Review for effective date 02/01/15. Updated references.	02/01/15 Version 10	12/17/14: MPCTAC 01/14/15: QIC
10/01/15	Review for effective date 12/01/15. Updated list of applicable products and corresponding notes. Updated Clinical Background Information and References sections.	12/01/15 Version 11	10/21/15: MPCTAC 11/11/15: QIC
11/25/15	Review for effective date 01/01/16. Revised language in the Applicable Coding section.	01/01/16 Version 12	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
10/01/16	Review for effective date 12/01/16.  Administrative changes made to the Summary, Medical Policy Statement, Definitions, Clinical	12/01/16 Version 13	10/19/16: MPCTAC 11/09/16: QIC

		1	
	Background Information, References, and References to Applicable Laws and Regulations sections. No change to criteria or the applicable code list.		
10/01/17	Review for effective date 11/01/17.  Administrative changes made to the Policy Summary, Description of Item or Service, Limitations, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Percutaneous tibial nerve stimulation (PTNS) remains an experimental and investigational treatment.	11/01/17 Version 14	10/18/17: MPCTAC
10/01/18	Review for effective date 01/01/19. Revised policy title. Administrative changes made to the Policy Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections (designating PTNS as medically necessary when applicable criteria are met and listing TPTNS as an experimental and investigational service). Revised code list in the Applicable Coding section.	01/01/19 Version 15	10/17/18: MPCTAC
12/01/18	Review for effective date 03/01/19. Revised the code list (including industry-wide code update) and Plan notes in the Applicable Coding section.	03/01/19 Version 16	12/19/18: MPCTAC
09/01/19	Review for effective date 12/01/19. Administrative changes made to the Other Applicable Policies, References, and Reference to Applicable Laws and Regulations sections. Administrative change made to the Plan notes in the Applicable Coding section. Revised criteria in the Limitations section.	12/01/19 Version 17	09/18/19: MPCTAC
09/01/20	Review for effective date 10/01/20. Administrative changes made to the References and Other Applicable Policies sections.	10/01/20 Version 18	09/16/20: MPCTAC
05/01/21	Review for effective date 06/01/21. Administrative changes made to the Applicable Coding and References sections.	06/01/21 Version 19	05/19/21: MPCTAC
10/01/21	Review for effective date 11/01/21. Adopted new medical policy template; removed administrative sections and the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed	11/01/21 Version 20	10/20/21: MPCTAC

	Limitations and Exclusions section. Added NH		
	Medicare Advantage HMO as an applicable		
	product effective 01/01/22. Administrative		
	changes made to the Policy Summary, Clinical		
	Criteria, Limitations and Exclusions, Applicable		
	Coding, and References sections.		
08/01/22	Review for effective date 11/01/22. Removed	11/01/22	08/26/22: MPCTAC
	codes considered experimental and	Version 21	(electronic vote)
	investigational for PTNS and made		
	administrative changes to the language in the		
	Applicable Coding section. Administrative		
	changes made to the Policy Summary, Clinical		
	Criteria, and Limitations and Exclusions		
	sections.		



Medical Policy - Policy Retired and AIM Criteria Adopted as of 11/01/22

# Sacroiliac Joint Injections

Policy Number: OCA 3.9642

**Version Number**: 22

Policy Retired Date: 11/01/22

## **Impacted Products**

#### 

- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers diagnostic or therapeutic sacroiliac joint (SIJ) injections to be medically necessary when AIM clinical appropriateness guidelines are met. Prior authorization from AIM Specialty Health is required.

#### Clinical Criteria

No medical policy criteria.

#### **Limitations and Exclusions**

None.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and NH Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, no guidelines were found for sacroiliac joint injections. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a SCO or NH Medicare Advantage HMO member. When there is no

Sacroiliac Joint Injections

guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for this service, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

CPT Code	Code Description
27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance
	(fluoroscopy or CT) including arthrography when performed
	Plan notes: This code should only be used for the professional component of the service.
	Code 27096 is a unilateral procedure; for bilateral procedure, use modifier 50.
<b>HCPCS Code</b>	Code Description
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other
	therapeutic agent, with or without arthrography
	Plan notes: This code should only be used for the technical component of the service. Code
	is NOT payable for the MassHealth or Qualified Health Plan products.

## References

Allegri M, Montella S, Salici F, Valente A, Marchesini M, Compagnone C, Baciarello M, Manferdini ME, Fanelli G. Mechanisms of low back pain: a guide for diagnosis and therapy. Version 2. F1000Res. 2016 Jun 28 [revised 2016 Jan 1];5. pii: F1000 Faculty Rev-1530. eCollection 2016. doi: 10.12688/f1000research.8105.2. PMID: 27408698.

American Academy of Orthopedic Surgeons (AAOS). Ortholnfo. Spinal Injections.

American Association of Neurological Surgeons (AANS). AANS Position Statements.

American College of Occupational and Environmental Medicine (ACOEM). Occupational Medicine Practice Guidelines.

American College of Physicians (ACP), American Pain Society (APS). Chou R, Qaseem A, Snow V, Casey D, Cross JT Jr, Shekelle P, Owens DK; Clinical Efficacy Assessment Committee of the ACP; ACP; APS Low Back Pain Guidelines Panel. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the ACP and the APS. Ann Intern Med. 2007 Oct 2;147(7):478-91. Erratum in: Ann Intern Med. 2008 Feb 5;148(3):247-8. PMID: 17909209.

American College of Physicians (ACP). Clinical Guidelines & Recommendations.

American College of Radiology (ACR). ACR Appropriateness Criteria.

American College of Radiology (ACR). ACR Appropriateness Criteria. Cervical Neck Pain or Cervical Radiculopathy. 2018.

American College of Radiology (ACR). ACR Appropriateness Criteria. Chronic Back Pain: Suspected Sarcoilitis/Spondyloarthropasty. 2016.

American College of Radiology (ACR). ACR Appropriateness Criteria. Low Back Pain. 2015. Revised 2021.

American Pain Society (APS). Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical Interventional Therapies for Low Back Pain: a Review of the Evidence for an American Pain Society Clinical Practice Guideline. Spine. 2009 May 1;34(10):1078-93. doi: 10.1097/BRS.0b013e3181a103b1. PMID: 19363456.

American Pain Society (APS). Chou R, Loeser JD, Owens DK, Rosenquist RW, Atlas SJ, Baisden J, Carragee EJ, Grabois M, Murphy DR, Resnick DK, Stanos SP, Shaffer WO, Wall EM; APS Low Back Pain Guideline Panel. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the APS. Spine (Phila Pa 1976). 2009 May 1;34(10):1066-77. doi: 10.1097/BRS.0b013e3181a1390d. PMID: 19363457.

American Society of Anesthesiologists (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA). Rosenquist RW, Benzon HT, Connis RT, De Leon-Casasola OA, Glass D, Korevaar WC, Cynwyd B, Mekhail NA, Merrill DG, NIckinovich DG, Rathnmell JP, Nai-Mei Sang C, Simon DL; ASA Task Force on Chronic Pain Management. Practice guidelines for chronic pain management: an updated report by the ASA Task Force on Chronic Pain Management and the ASRA. Anesthesiology. 2010 Apr;112(4):810-33. doi: 10.1097/ALN.0b013e3181c43103. PMID: 20124882.

American Society of Interventional Pain Physicians (ASIPP). Boswell MV, Trescot AM, Datta S, Schultz DM, Hansen HC, Abdi S, Sehgal N, Shah RV, Singh V, Benyamin RM, Patel VB, Buenaventura RM, Colson JD, Cordner HJ, Epter RS, Jasper JF, Dunbar EE, Atluri SL, Bowman RC, Deer TR, Swicegood JR, Staats PS, Smith HS, Burton AW, Kloth DS, Giordano J, Manchikanti L; ASIPP. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. Pain Physician. 2007 Jan;10(1):7-111. PMID: 17256025.

American Society of Interventional Pain Physicians (ASIPP). Interventional Pain Management (IPM) Practice Guidelines.

American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks TA, Caraway DL, Calodney AK, Cash KA, Christo PJ, Cohen SP, Colson J, Conn A, Cordner HJ, Coubarous S, Datta S, Deer TR, Diwan SA, Falco FJE, Fellows B, Geffert SC, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm II S, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel V, Racz GB, Sehgal N, Sharma M, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood J, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. Interventional Pain Management (IPM) Practice Guideline. An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part 2: Guidance and Recommendations. Pain Physician. 2013;16:S49-283. PMID: 23615883.

American Society of Interventional Pain Physicians (ASIPP). Manchikanti L, Falco FJE, Singh V, Benyamin RM, Racz GB, Helm II S, Caraway DL, Calodney AK, Snook LT, Smith HS, Gupta S, Ward SP, Grider JS, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part I: introduction and general considerations. Pain Physician 2013 Apr;16(2 Suppl):S1-48. PMID: 23615882.

American Society of Regional Anesthesia and Pain Medicine (ASRA). The specialty of chronic pain management.

Assessment of SpondyloArthritis international Society (ASAS), European League Against Rheumatism (EULAR). van der Heijde D, Ramiro S, Landewé R, Baraliakos X, Van den Bosch F, Sepriano A, Regel A, Ciurea A, Dagfinrud H, Dougados M, van Gaalen F, Géher P, van der Horst-Bruinsma I, Inman RD, Jongkees M, Kiltz U, Kvien TK, Machado PM, Marzo-Ortega H, Molto A, Navarro-Compàn V, Ozgocmen S, Pimentel-Santos FM, Reveille , Rudwaleit M, Sieper J, Sampaio-Barros P, Wiek D, Braun J. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis. 2017 Jun;76(6):978-91. doi: 10.1136/annrheumdis-2016-210770. Epub 2017 Jan 13. PMID: 28087505.

Baber Z, Erdek MA. Failed back surgery syndrome: current perspectives. J Pain Res. 2016 Nov 7;9:979–87. eCollection 2016. doi: 10.2147/JPR.S92776. PMID: 27853391.

Beinart NA, Goodchild CE, Weinman JA, Ayis S, Godfrey EL. Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: a systematic review. Spine J. 2013 Dec;13(12):1940-50. doi: 10.1016/j.spinee.2013.08.027. Epub 2013 Oct 26. PMID: 24169445.

Büker N, Akkaya S, Gökalp O, Kıtış A, Savkın R, Kıter AE. Middle-term therapeutic effect of the sacroiliac joint blockade in patients with lumbosacral fusion-related sacroiliac pain. Acta Orthop Traumatol Turc. 2014;48(1):61-6. doi: 10.3944/AOTT.2014.3190. PMID: 24643102.

Burgos-Vargas R. The assessment of the spondyloarthritis international society concept and criteria for the classification of axial spondyloarthritis and peripheral spondyloarthritis: A critical appraisal for the pediatric rheumatologist. Pediatr Rheumatol Online J. 2012 May 31;10:14. doi: 10.1186/1546-0096-10-14. PMID: 22650358.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L35936). National Government Services, Inc.

Change Healthcare. InterQual® Criteria. Sacroiliac Joint Injections.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Cimolin V, Vismara L, Galli M, Zaina F, Negrini S, Capodaglio P. Effects of obesity and chronic low back pain on gait. J Neuroeng Rehabil. 2011 Sep 26;8:55. doi: 10.1186/1743-0003-8-55. PMID: 21943156.

Cohen SP, Chen Y, Neufeld NJ. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment. Expert Rev Neurother. 2013 Jan;13(1):99-116. doi: 10.1586/ern.12.148. PMID: 23253394.

Cook KM, Heiderscheit B. Conservative management of a young adult with hip arthrosis. J Orthop Sports Phys Ther. 2009 Dec;39(12):858-66. doi: 10.2519/jospt.2009.3207. PMID: 20026881.

Cousins MJ, Bridenbaugh PO, Horlocker TT, Carr DB. Cousins and Bridenbaugh's Neural Blockade in Clinical Anesthesia and Pain Medicine. 4th edition. 2012.

Datta S, Manchikanti L, Falco FJ, Calodney AK, Atluri S, Benyamin RM, Buenaventura RM, Cohen SP. Diagnostic utility of selective nerve root blocks in the diagnosis of lumbosacral radicular pain: systematic review and update of current evidence. Pain Physician 2013 Apr;16(2 Suppl):SE97-124. PMID: 23615888.

Dreyfuss P, Snyder BD, Park K, Willard F, Carreiro J, Bogduk N. The ability of single site, single depth sacral lateral branch blocks to anesthetize the sacroiliac joint complex. Pain Med. 2008 Oct;9(7):844-50. doi: 10.1111/j.1526-4637.2008.00517.x. PMID: 18950439.

Forst SL, Wheeler MT, Fortin JD, Vilensky JA. The sacroiliac joint: anatomy, physiology and clinical significance. Pain Physician. 2006 Jan;9(1):61-7. PMID: 16700283.

Fritz J, Sequeiros RB, Carrino JA. Magnetic resonance imaging-guided spine injections. Top Magn Reson Imaging. 2011 Aug;22(4):143-51. doi: 10.1097/RMR.0b013e31827e5de1. PMID: 23514922. Hansen H, Manchikanti L, Simopoulos TT, Christo PJ, Gupta S, Smith HS, Hameed H, Cohen SP. A systematic evaluation of the therapeutic effectiveness of sacroiliac joint interventions. Pain Physician. 2012 May-Jun;15(3):E247-78. PMID: 22622913.

Hartung W, Ross CJ, Straub R, Feuerbach S, Schölmerich J, Fleck M, Herold T. Ultrasound-guided sacroiliac joint injection in patients with established sacroilitis: precise IA injection verified by MRI scanning does not predict clinical outcome. Rheumatology (Oxford). 2010 Aug;49(8):1479–82. doi: 10.1093/rheumatology/kep424. Epub 2009 Dec 17. PMID: 20019067.

Jee H, Lee JH, Park KD, Ahn J, ark Y. Ultrasound-guided versus fluoroscopy-guided sacroiliac joint intra-articular injections in the noninflammatory sacroiliac joint dysfunction: A prospective, randomized, single-blinded study. Arch Phys Med Rehabil. 2014 Feb;95(2):330-7. doi: 10.1016/j.apmr.2013.09.021. Epub 2013 Oct 9. PMID: 24121083.

Kennedy DJ, Shokat M, Visco CJ. Sacroiliac joint and lumbar zygapophysial joint corticosteroid injections. Phys Med Rehabil Clin N Am. 2010 Nov;21(4):835-42. doi: 10.1016/j.pmr.2010.06.009. PMID: 20977966.

Kim WM, Lee HG, Jeong CW, Kim CM, Yoon MH. A randomized controlled trial of intra-articular prolotherapy versus steroid injection for sacroiliac joint pain. J Altern Complement Med. 2010;16:1285-90. 2010 Dec;16(12):1285-90. doi: 10.1089/acm.2010.0031. PMID: 21138388.

Kotsenas AL. Imaging of posterior element axial pain generators: facet joints, pedicles, spinous processes, sacroiliac joints, and transitional segments. Radiol Clin North Am 2012 Jul;50(4):705-30. doi: 10.1016/j.rcl.2012.04.008. PMID: 22643392.

Krawczyk-Wasielewska A, Skorupska E, Samborski W. Sacroiliac joint pain as an important element of psoriatic arthritis diagnosis. Postepy Dermatol Alergol. 2013 Apr;30(2):108-12. doi: 10.5114/pdia.2013.34161. Epub 2013 Apr 12. PMID: 24278057.

Manchikanti L, Falco FJ, Benyamin RM, Caraway DL, Kaye AD, Helm S 2nd, Wargo BW, Hansen H, Parr AT, Singh V, Swicegood JR, Smith HS, Schultz DM, Malla Y, Hirsch JA. Assessment of bleeding risk of interventional techniques: a best evidence synthesis of practice patterns and perioperative management of anticoagulant and antithrombotic therapy. Pain Physician. 2013 Apr;16(2 Suppl):SE261-318. PMID: 23615893.

Manchikanti L, Hirsch JA, Pampati V, Boswell MV. Utilization of Facet Joint and Sacroiliac Joint Interventions in Medicare Population from 2000 to 2014: Explosive Growth Continues! Curr Pain Headache Rep. 2016 Oct;20(10):58. doi: 10.1007/s11916-016-0588-2. PMID: 27646014.

Manchikanti L, Pampati V, Falco FJ, Hirsch JA. Growth of spinal interventional pain management techniques: analysis of utilization trends and Medicare expenditures 2000 to 2008. Spine (Phila Pa 1976). 2013 Jan 15;38(2):157-68. doi: 10.1097/BRS.0b013e318267f463. PMID: 22781007.

Masala S, Fiori R, Bartolucci DA, Mammucari M, Angelopoulos G, Massari F, Simonetti G. Diagnostic and therapeutic joint injections. Semin Intervent Radiol. 2010 Jun;27(2):160-71. doi: 10.1055/s-0030-1253514. PMID: 21629405.

Meucci RD, Fassa AG, Faria NM. Prevalence of chronic low back pain: systemic review. Rev Saude Publica. 2015;49:1. Published online 2015;49. pii: S0034-89102015000100408. doi: 10.1590/S0034-8910.2015049005874. Epub 2015 Oct 20. PMID: 26487293.

National Institute for Health and Clinical Excellence (NICE). Low back pain and sciatica in over 16s: assessment and management. NICE guideline NG59. 2016 Nov.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

North American Spine Society (NASS). Clinical Guidelines.

North American Spine Society (NASS). Current Coverage Policy Recommendations. Sacroiliac Joint Injections.

North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care. Diagnosis and Treatment of Low Back Pain. 2020. Endorsed by the American Academy of Physical Medicine and Rehabilitation (AAPM&R) and American Association of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS).

Official Disability Guidelines (ODG). Treatment Guidelines.

Patel DR, Kinsella E. Evaluation and management of lower back pain in young athletes. Transl Pediatr. 2017 Jul;6(3):225–35. doi: 10.21037/tp.2017.06.01. PMID: 28795014.

Rashbaum RF, Ohnmeiss DD, Lindley EM, Kitchel SH, Patel VV. Sacroiliac Joint Pain and Its Treatment. Clin Spine Surg. 2016 Mar;29(2):42-8. doi: 10.1097/BSD.000000000000359. PMID: 26889985.

Savran Sahin B, Aktas E, Haberal B, Harman A, Canan Yazici A, Kaygusuz H, Aribas BK. Sacroiliac pain and CT-guided steroid injection treatment: high-grade arthritis has an adverse effect on outcomes in long-term follow-up. Eur Rev Med Pharmacol Sci. 2015 Aug;19(15):2804-11. PMID: 26241533.

Scholten PM, Patel SI, Christos PJ, Singh JR. Short-term efficacy of sacroiliac joint corticosteroid injection based on arthrographic contrast patterns. PM R. 2015 Apr;7(4):385–91. doi: 10.1016/j.pmrj.2014.10.007. PMID: 25452127.

Simopoulos TT, Manchikanti L, Gupta S, Aydin SM, Kim CH, Solanki D, Nampiaparampil DE, Singh V, Staats PS, Hirsch JA. Systematic Review of the Diagnostic Accuracy and Therapeutic Effectiveness of Sacroiliac Joint Interventions. Pain Physician. 2015 Sep-Oct;18(5):E713-56. PMID: 26431129.

Simopoulos TT, Manchikanti L, Singh V, Gupta S, Hameed H, Diwan S, Cohen SP. A systematic evaluation of prevalence and diagnostic accuracy of sacroiliac joint interventions. Pain Physician. 2012 May-Jun;15(3):E305-44. PMID: 22622915.

Soto Quijano DA, Otero Loperena E. Sacroiliac Joint Interventions. Phys Med Rehabil Clin N Am. 2018 Feb;29(1):171-183. doi: 10.1016/j.pmr.2017.09.004. PMID: 29173661.

Spine Intervention Society (SIS). Bogduk N, ed. ISIS Practice Guidelines. Practice Guidelines for the Spinal Diagnostic and Treatment Procedures. (Formerly known as International Spine Intervention Society/ISIS.) Second Edition. San Francisco. 2013.

Staal JB, de Bie RA, de Vet HC, Hildebrandt J, Nelemans P. Injection therapy for subacute and chronic low back pain: an updated Cochrane review. Spine (Phila Pa 1976). 2009 Jan 1;34(1):49-59. doi: 10.1097/BRS.0b013e3181909558. PMID: 19127161.

Sudol-Szopinska I, Urbanik A. Diagnostic imaging of sacroiliac joints and the spine in the course of spondyloarthropathies. Pol J Radiol. 2013 Apr-Jun;78(2):43–9. doi: 10.12659/PJR.889039. PMID: 23807884.

Vanaclocha V, Herrera JM, Sáiz-Sapena N, Rivera-Paz M, Verdú-López F. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. Neurosurgery. 2018 Jan 1;82(1):48-55. doi: 10.1093/neuros/nyx185. PMID: 28431026.

Visser LH, Woudenberg NP, de Bont J, van Eijs F, Verwer K, Jenniskens H, Den Oudsten BL. Treatment of the sacroiliac joint in patients with leg pain: a randomized-controlled trial. Eur Spine J. 2013 Oct;22(10):2310-7. doi: 10.1007/s00586-013-2833-2. Epub 2013 May 30. PMID: 23720124.

#### **Next Review Date**

Not applicable

#### **Retired Date**

11/01/22

### **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date*	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	11/01/08	Medical Policy	MPCTAC , UMC, and
	Version 1	Manager as Chair	QIC
Internal Approval:		of MPCTAC	
06/10/08: Medical Policy, Criteria,			
and Technology Assessment			
Committee (MPCTAC)			
06/24/08: Utilization Management			
Committee (UMC)			
08/13/08: Quality Improvement			
Committee (QIC)			

<sup>\*</sup>Effective Date for the QHP Commercial Product: 01/01/12

Effective 06/01/13, this policy replaced the Facet Joint Nerve Injections and Sacroiliac Joint Injections for Chronic Neck Pain and Chronic Back Pain policy (policy number OCA 3.964) which was effective from 11/01/08 to 05/31/13. Also, see Plan policy, Facet Joint Nerve Injections for Chronic Back Pain and Chronic Neck Pain (policy number OCA 3.9641) effective 06/01/13. Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
06/23/09	Changed name of the policy, added additional criteria for SIJ injections and replaced the criteria for radiological findings negative for disc herniation and nerve root compression with: negative physical signs of radiculopathy or radicular pain, including negative straight leg raising or root tension signs, normal neurological examination, absence of signs of radiculopathy on any electrodiagnostic examinations. Updated the diagnostic clinical criteria to allow no more than 2 joint levels bilaterally or 3 joint levels unilaterally in a 7 to 14 day period to determine the origin of the patient's pain. For SIJ injections, no more than 2 procedures may be allowed in a 7 to 14 day period to determine	10/01/09 Version 2	06/23/09: MPCTAC 06/23/09: UMC 07/22/09: QIC

<sup>\*</sup>Effective Date for the New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for the Senior Care Options Product: 01/01/16

<sup>\*</sup>Effective Date for the New Hampshire Medicare Advantage HMO Product: 01/01/22

Policy Revision	ons History		
	the origin of the patient's pain. Updated references and coding sections. Effective date of changes is 10/01/09.		
06/01/10	No changes to criteria. Updated references and coding.	Version 3	06/30/10: MPCTAC 07/28/10: QIC
06/01/11	Updated clinical criteria to clarify that the absence of prior spinal fusion must be at the clinically suspect levels. Updated references.	Version 4	06/29/11: MPCTAC 07/27/11: QIC
07/01/12	Updated references and revised the introductory paragraph in Applicable Coding section. Code descriptions updated but no change to list of applicable codes. Revised policy title and text to specify the policy relates to chronic neck pain and chronic back pain. Added the following additional contraindication for procedures: 'Patient with a malignancy at the injection site.' Clinical criteria updated for facet joint nerve injections and sacroiliac joint injections. Definitions added for radiculopathy and straight leg raise test. For facet joint injections, added symptoms of axial pain and signs of facet disease. For sacroiliac joint injections, added types of tests used for a sacroiliac exam. Added definition of a comprehensive pain management program and referenced the Plan's Medically Necessary policy.	Version 5	06/20/12: MPCTAC 07/18/12: MPCTAC 08/22/12: QIC
08/01/12	Off cycle review for NH Medicaid product. No changes.	Version 6	08/13/12: MPCTAC 09/06/12: QIC
12/01/12	Revised sacroiliac joint injection frequency guidelines in Medical Policy Statement section.	Version 7	12/19/12: MPCTAC 12/20/12: QIC
02/01/13	Review for effective date 06/01/13. Separated facet joint nerve injections and sacroiliac joint injections into two separate policies; policy formerly titled Facet Joint Nerve Injections and Sacroiliac Joint Injections for Chronic Neck Pain and Chronic Back Pain (formerly policy number OCA 3.964). Revised title and re-numbered policy. Updated language in Summary, Description of Item or Service, and Clinical Background Information sections. Revised applicable code list, and updated references. Deleted definitions for radiculopathy and straight leg raise test in Definition section because not referenced in policy. Added the following definitions: Compression test, Fortin finger test, Gaenslen test, Gillet's test, Patrick test (or Faber maneuver), Piedallu seated flexion test,	06/01/13 Version 8	02/20/13: MPCTAC 03/21/13: QIC

Policy Revis	ions History		
	and Van Durson standing flexion test. Revised medical criteria in the Medical Policy Statement section (formerly named the Clinical Guideline Statement section).		
08/14/13	Off cycle review for NH Medicaid and merged policy format. Incorporate policy revisions dated 12/01/12 and 02/01/13 (as specified above) for the NH Medicaid product; these policy revisions were approved by MPCTAC (on 12/19/12 and 02/20/13) and QIC (on 12/20/12 and 03/21/13) for applicable Plan products.	Version 9	08/14/13: MPCTAC (electronic vote) 08/15/13: QIC
03/01/14	Review for effective date 07/01/14. Changed policy title from Sacroiliac Joint Injections for Chronic Low Back Pain to Sacroiliac Joint Injections. Revised Summary and References sections. Revised criteria in the Medical Policy Statement section and the Limitations section. Removed HCPCS code G0259 as an applicable code.	07/01/14 Version 10	03/19/14: MPCTAC 04/16/14: QIC
09/01/14	Review for effective date 11/01/14. Clarified in the Medical Policy Statement section that bilateral injections may be medically necessary for both the diagnostic phase and therapeutic phase when all Plan applicable criteria are met. Updated references.	11/01/14 Version 11	09/17/14: MPCTAC 10/08/14: QIC
02/01/15	Review for effective 06/01/15. Updated Definitions and References sections. Revised criteria in the Medical Policy Statement and Limitations sections. Removed Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available.	06/01/15 Version 12	02/27/15: MPCTAC (electronic vote) 03/11/15: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.	01/01/16 Version 13	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
02/01/16	Review for effective date 06/01/16. Updated criteria in the Medical Policy Statement section.  Administrative changes made to the Applicable Coding section without changing the list of codes. Revised the Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections.	06/01/16 Version 14	02/17/16: MPCTAC 03/09/16: QIC
01/01/17	Review for effective date 05/01/17. Updated criteria in the Medical Policy Statement and Limitations sections. Updated Summary, Clinical	05/01/17 Version 15	01/18/17: MPCTAC 02/08/17: QIC

Policy Revis	ions History		
	Background Information, and References sections. Plan note added to Applicable Coding section (with no change to the applicable code list).		
02/01/18	Review for effective date 05/01/18. Administrative changes made to the Policy Summary, Limitations References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement section.	05/01/18 Version 16	02/21/18: MPCTAC
02/01/19	Review for effective date 03/01/19. Administrative changes made to the Policy Summary, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	03/01/19 Version 17	02/20/19: MPCTAC
02/01/20	Review for effective date 03/01/20. Administrative changes made to the Limitations, Applicable Coding, References, and Reference to Applicable Laws and Regulations sections.	03/01/20 Version 18	02/19/20: MPCTAC
02/01/21	Review for effective date 03/01/21. Administrative changes made to the References section.	03/01/21 Version 19	02/17/21: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitation and Exclusions section. Added NH Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 20	11/17/21: MPCTAC
02/01/22	Review for effective date 05/01/22. Administrate changes made to the References section. Updated criteria in the Clinical Criteria section (i.e., added neurological testing as criterion).	05/01/22 Version 21	02/16/22: MPCTAC
08/01/22	Review for policy retired date 11/01/22.  Administrative changes made to the Policy  Summary and Applicable Coding sections. Criteria revised in the Clinical Criteria and Limitations and Exclusions sections. AIM medical necessity criteria adopted for this service and AIM prior authorization is required as of 11/01/22, even when applicable codes are not listed in this Plan policy.	09/01/22 Version 22	08/26/22: MPCTAC (electronic vote)



Medical Policy – Policy with InterQual Criteria Retired and AIM Criteria Adopted as of 11/01/22

# Speech Therapy, Language Therapy, Voice Therapy, or Auditory Rehabilitation in the Outpatient Setting

Policy Number: OCA 3.542 Version Number: 32 Policy Retired Date: 11/01/22 Impacted Products
<ul> <li>□ All Products</li> <li>□ NH Medicaid</li> <li>□ NH Medicare Advantage</li> <li>□ MA MassHealth ACO</li> <li>□ MA MassHealth MCO</li> <li>□ MA Qualified Health Plans/Employer Choice Direct</li> <li>□ MA Senior Care Options</li> </ul>
Note: Disclaimer and audit information is located at the end of this document.  Policy Summary
The Plan considers outpatient speech therapy (i.e., speech and language therapy, swallowing therapy, feeding therapy, aural or auditory rehabilitation, and/or voice therapy) medically necessary, including habilitative services and/or rehabilitative services, when AIM clinical appropriateness guidelines are met for an adult or pediatric member or are required EPSDT services for a member age 20 or younger on the date of service. Prior authorization from AIM Specialty Health is required for outpatient speech therapy (ST) after the initial evaluation. ST must be provided within the scope of practice of the treating professional and/or paraprofessional and follow all applicable state licensing and supervisory requirements.
Clinical Criteria
No medical policy criteria.
Limitations and Exclusions
None.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Plan's New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, no applicable clinical guidelines were found from CMS. Verify CMS criteria in effect for the requested service on the date of the prior authorization request for a NH Medicare Advantage HMO member. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

# **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. The list of applicable codes included in this policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization from AIM for speech therapy, even if an applicable code appropriately describing the service is not included in this policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

<b>CPT Codes</b>	Code Descriptions
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, two or more individuals
92526	Treatment of swallowing dysfunction and/or oral function for feeding
92606	Therapeutic services for use of non-speech-generating device with programming
92609	Therapeutic services for use of speech-generating device with programming
97129	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; initial 15 minutes
97130	Therapeutic interventions that focus on cognitive function (e.g., attention, memory, reasoning, executive function, problem solving, and/or pragmatic functioning) and compensatory strategies to manage the performance of an activity (e.g., managing time or schedules, initiating, organizing, and sequencing tasks), direct (one-on-one) patient contact; each additional 15 minutes (List separately in addition to code for primary procedure)

Speech Therapy, Language Therapy, Voice Therapy, or Auditory Rehabilitation in the Outpatient Setting (NH Products)

#### References

American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF). Clinical Practice Guidelines.

American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF). Schwartz S, Cohen S, Dailey S, Rosenfeld R, Deutsch E, Gillespie B, Granieri E, Hapner E, Kimball E, Krouse H, McMurray S, Medina S, O'Brien K, Ouellette D, Messinger-Rapport B, Stachler R, Strode S, Thompson D, Stemple J, Willging P, Cowley T, McCoy, Bernad P, Patel M. Clinical practice guideline: hoarseness (dysphonia). Otolaryngol Head Neck Surg. 2009 Sep;141(3S2):S1-31. doi: 10.1016/j.otohns.2009.06.744. PMID: 19729111.

American Academy of Otolaryngology - Head and Neck Surgery Foundation (AAO-HNSF). Stachler RJ, Francis DO, Schwartz SR, Damask CC, Digoy GP, Krouse HJ, McCoy SJ, Ouellette DR, Patel RR, Reavis CCW, Smith LJ, Smith M, Strode SW, Woo P, Nnacheta LC. Clinical Practice Guideline: Hoarseness (Dysphonia) (Update). Otolaryngol Head Neck Surg. 2018 Mar;158(1\_suppl):S1-S42. doi: 10.1177/0194599817751030. PMID: 29494321.

American Speech-Language-Hearing Association (ASHA). Adult Speech and Language.

American Speech-Language-Hearing Association (ASHA). Cognitive-Communication. ASHA Policy Documents.

American Speech-Language-Hearing Association (ASHA). Scope of Practice in Speech-Language Pathology.

American Speech-Language-Hearing Association (ASHA). Speech-Language Pathology Medical Review Guidelines.

American Speech-Language-Hearing Association (ASHA). Stuttering.

American Speech-Language-Hearing Association (ASHA). Swallowing and Feeding Disorders.

Bahar-Fuchs A, Clare L, Woods B. Cognitive training and cognitive rehabilitation for persons with mild to moderate dementia of the Alzheimer's or vascular type: a review. Alzheimers Res Ther. 2013;5(4):35. doi: 10.1186/alzrt189. PMID: 23924584.

Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) L33580. Speech-Language Pathology. 2015 Oct 1. National Governmental Services, Inc. 2015 Dec 19. Revision Effective Date 2019 Dec 19.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) 170.3. Speech-Language Pathology Services for the Treatment of Dysphagia. 2006 Oct 1.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Hauser RA. What is the Lee Silverman Voice Treatment (LSVT) program for Parkinson disease (PD)? Medscape. 2019 Aug 29.

Hayes. Health Technology Assessment. Cognitive Rehabilitation Therapy for Traumatic Brain Injury (TBI). Dallas, TX: Hayes; 2017 Sep 26. Annual Review 2021 Feb 8.

Hayes. Health Technology Assessment. Lee Silverman Voice Treatment (LSVT) LOUD for Speech and Voice Problems in Parkinson Disease. Dallas, TX: Hayes; 2020 Nov 9.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. NH Medicaid Program.

New Hampshire Department of Health and Human Services. Provider Notices.

New Hampshire Medicaid. Therapies. Physical, Occupational, Speech. Provider Manual. Volume II. 2017 Dec 1.

New Hampshire Office of Professional Licensure and Certification. Office of Licensed Allied Health Professionals. Laws and Administrative Rules Governing Licensed Allied Health Professionals.

#### **Next Review Date**

Not applicable

#### **Retired Date**

11/01/22

### **Authorizing Entity**

MPCTAC

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	07/01/11 Version 1	Director of Medical Policy as Chair of	MPCTAC and QIC
Internal Approval: 03/16/11: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 04/27/11: Quality Improvement Committee (QIC)		Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC)	

<sup>\*</sup> Effective Date for NH Medicaid Product: 01/01/13

Policy retired and service managed by AIM Specialty Health as of 11/01/22.

Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
03/19/12	Updated references.	Version 2	03/21/12: MPCTAC 04/25/12: QIC
08/01/12	Off cycle review. Revised Summary statement, reformatted Medical Policy Statement, revised Applicable Coding introductory paragraph, updated code list, revised Limitations, and updated references.	Version 3	08/13/12: MPCTAC 09/06/12: QIC
11/01/12	Review for effective date 03/01/13. Updated references. Revised title so policy applies to members age 22 or older (rather than members over the age of 21). Added language in Summary section to clarify text. Referenced Plan reimbursement policy 4.609 for therapy reimbursement guidelines. Reorganized clinical criteria in Medical Policy Statement section and referenced InterQual® criteria. Revised applicable code list.	03/01/13 Version 4	11/21/12: MPCTAC 12/20/12: QIC
08/14/13 and 08/15/13	Off cycle review. Incorporate policy revisions dated 11/01/12 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on		08/14/13: MPCTAC (via electronic vote) 08/15/13: QIC

 $Speech\ Therapy,\ Language\ Therapy,\ Voice\ Therapy,\ or\ Auditory\ Rehabilitation\ in\ the\ Outpatient\ Setting\ (NH\ Products)$ 

<sup>\*</sup> Effective Date for NH Medicare Advantage HMO Product: 01/01/22

11/01/13, 12/01/13, 01/01/14, and 02/01/14	11/21/12 and QIC on 12/20/12 for applicable Plan products. Additional review of policy conducted.  Review for effective date 05/01/14. Revised Applicable Coding section by updating code definitions and Plan notes, introductory paragraph, and applicable codes for the Massachusetts and New Hampshire products.	05/01/14 Version 5	02/11/14: MPCTAC 02/18/14: QIC
09/08/14	Reformatted Limitations section without changing criteria. Updated references.  For New Hampshire products only, waive prior authorization of first 2 treatment sessions per member per servicing provider per calendar year.	10/01/14 Version 11 Addendum A	09/17/14: MPCTAC 09/30/14: QIC
11/04/14 and 11/19/14	Review for effective date 01/11/15. Summary and Medical Policy Statement sections updated with guidelines specified in version 11, addendum A. Policy renumbered OCA 3.542 to include speech therapy (and associated therapies) for members age 21 or older in the outpatient setting for Well Sense Health Plan members. Revised language in the Applicable Coding section without changing the applicable code list. Age range changed from age 22 or older to age 21 or older for adult Well Sense members; ST services for adult members formerly in policy number OCA 3.551. Revised review calendar.	01/11/15 Version 12	11/06/14: MPCTAC (electronic vote) 11/11/14: QIC (electronic vote) 11/19/14: MPCTAC 12/10/14: QIC
12/03/15	Review for effective date 01/01/16. Updated template and Summary section. Administrative changes made to the Medical Policy Statement and Limitations sections without changing criteria. Revised language in the Applicable Coding section. Added definitions.	01/01/16 Version 13	12/03/15: MPCTAC (electronic vote) 12/09/15: QIC
12/01/16	Review for effective date 02/01/17. Clarified existing criteria in the Medical Policy Statement section. Updated references.	02/01/17 Version 14	12/21/16: MPCTAC 01/11/17: QIC
05/01/17	Review for effective date 08/01/17. Removed CPT code 92524 from the applicable code list because it is an initial evaluation code for voice and resonance.	08/01/17 Version 15	05/17/17: MPCTAC
12/01/17	Review for effective date 01/01/17. Updated Policy Summary section.  Review for effective date 01/01/18. Industry-	01/01/17 Version 16 01/01/18	12/20/17: MPCTAC 12/20/17: MPCTAC
, ., .,	wide updates to codes included in the Applicable Coding section. Annual review of	Version 17	,,

	policy with administrative changes made to the Medical Policy Statement, Definitions, and Reference sections.		
02/01/18	Review for effective date 03/01/18. Administrative changes made to the Policy Summary and Limitations sections.	03/01/18 Version 18	02/21/18: MPCTAC
11/01/18	Review for effective date 12/01/18. Administrative changes made to the Limitations, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/18 Version 19	11/21/18: MPCTAC
03/01/19	Review for effective date 07/01/19. Administrative changes made to the Limitations and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement section.	07/01/19 Version 20	03/20/19: MPCTAC
05/01/19	Review for effective date 08/01/19. Revised criteria in the Medical Policy Statement section. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections.	05/15/19 Version 21	05/15/19: MPCTAC
12/01/19	Review for effective date 01/01/20. Industry-wide code deletion required revision to coding in the Applicable Coding section.	01/01/20 Version 22	Not applicable because industry-wide code changes.
11/01/19	Review for effective date 02/01/20. Administrative changes made to the Policy Summary, References and Reference to Applicable Laws and Regulations sections. Criteria revised in the Medical Policy Statement and Limitations sections.	02/01/20 Version 23  Renumbered to version 23 to implement industry-wide code updates effective 01/01/20 in version 22.	11/20/19: MPCTAC
12/01/19	Review for effective 02/01/20. Industry-wide code deletion required revision to coding in the Applicable Coding section of the policy version 23 effective 02/01/20.	02/01/20 Version 24	Not applicable because industry-wide code changes.
12/01/19	Review for effective date 03/01/20. Revised in the Medical Policy Statement section the definition of a servicing ST provider for the prior authorization waiver.	03/01/20 Version 25	12/18/19: MPCTAC
11/01/20	Review for effective date 02/01/21. Administrative changes made to the Definitions, Applicable Coding, and References sections.	02/01/21 Version 26	11/18/20: MPCTAC

	Revised criteria in the Medical Policy Statement section.		
05/01/21	Review for effective date 08/01/21.  Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, Definitions, and References sections. Codes added to the Applicable Coding section.	08/01/21 Version 27	05/19/21: MPCTAC
10/01/21	Review for effective date 01/01/22 Adopted new medical policy template; removed administrative sections, Medical Policy Statement section renamed Clinical Criteria section, and Limitations section renamed Limitations and Exclusions section.  Administrative changes made to the Policy Summary, Limitations and Exclusions, Applicable Coding, and References sections.  Added New Hampshire Medicare Advantage HMO as an applicable product effective 01/01/22. Added gender dysphoria as a medically necessary indication for voice therapy in the Criteria section.	01/01/22 Version 28	10/20/21: MPCTAC
02/01/22	Review for effective date 02/01/22.  Administrative changes made to the Policy Summary. Revised policy title because policy will apply to adult and pediatric members.  Adopted InterQual criteria to determine medical necessity and retired medical policy criteria. Gender dysphoria specified as a medically necessary indication for voice therapy in the Gender Affirmation Services medical policy, OCA 3.11, as of 01/01/22.	02/01/22 Version 29	11/17/21: MPCTAC
05/01/22	Review for effective date 06/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, and Applicable Coding sections.	06/01/22 Version 30	05/11/22: MPCTAC (electronic vote)
05/01/22	Review for effective date 08/01/22. Revised code list in the Applicable Coding section.	08/01/22 Version 31	05/11/22: MPCTAC
08/01/22	Review for policy retired date 11/01/22.  Administrative changes made to the Policy Summary and Applicable Coding sections.  InterQual medical necessity criteria and medical policy guidelines in the Clinical Criteria and Limitations and Exclusions sections retired on 11/01/22. AIM criteria adopted for outpatient ST on 11/01/22. Plan prior authorization waivers	11/01/22 Version 32	08/26/22: MPCTAC (electronic vote)

removed after 10/31/22. AIM prior	
authorization is required for outpatient ST after	
the initial evaluation as of 11/01/22, even when	
applicable codes are not listed in this Plan	
policy.	



#### **Medical Policy**

# **Temporomandibular Joint Disorder Treatment**

**Policy Number**: OCA 3.968

**Version Number**: 22

**Version Effective Date**: 11/01/22

### Impacted Products

- ⋈ NH Medicaid
- ⋈ MA MassHealth ACO
- ⋈ MA MassHealth MCO
- ☑ MA Qualified Health Plans/Employer Choice Direct
- ☑ MA Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

# **Policy Summary**

The Plan considers medical and/or surgical (non-dental) treatment of a temporomandibular joint (TMJ) disorders to be medically necessary ONLY when the disorders are caused by, or results from a specific medical condition. Examples of specific medical conditions include jaw fractures and/or dislocations and degenerative arthritis. Plan prior authorization is required. Separate coverage is outlined in the member's benefit documents for dental services (if dental services are covered for the Plan member). This medical policy ONLY includes guidelines for TMJ disorders related to a medical condition for medical and/or surgical (non-dental) treatment.

Effective 11/01/22, the Plan uses AIM clinical appropriateness guidelines to determine the medical necessity of radiology services, musculoskeletal services (i.e., spine surgeries, joint surgeries, and interventional pain management treatments), genetic testing, and outpatient rehabilitation services (i.e., physical therapy, occupational therapy, and speech therapy). Prior authorization from AIM Specialty Health is required for these services.

#### Clinical Criteria

Criteria must be met in item A (medical necessity criteria) or item B (services that require Plan Medical Director review):

A. Criteria must be met in either item 1 or item 2:

- 1. Initial Medical Evaluation: Prior authorization is REQUIRED for the initial medical evaluation for a TMJ disorder ONLY when conducted by a provider who is NOT a participating oral and maxillofacial surgeon or participating otolaryngologist; OR
- 2. Treatment after the Initial Evaluation: All medical and/or surgical treatments for TMJ disorders REQUIRE prior authorization after the initial medical evaluation. ALL criteria must be met in items a through c:
  - a. Medical condition eligible for treatment includes ANY of the following:
    - (1) Jaw fracture or jaw dislocation (i.e., current fracture or acute dislocation); OR
    - (2) Degenerative arthritis; AND
  - b. Medical condition is confirmed by diagnostic x-rays or other generally accepted diagnostic procedures used to diagnose a jaw fracture, jaw dislocation, and/or degenerative arthritis, including but not limited to a CT scan, MRI, tomogram, or arthrogram; AND
  - c. Based on the treatment plan determined by the treating provider, the member requires ANY treatment specified in item (1) or item (2):
    - (1) Criteria for Non-Surgical Treatment: Covered first-line, conservative treatment may include diet and behavior modification and ANY combination of treatment listed below in items (a) through (e):
      - (a) Pharmacologic therapy such as anti-inflammatory, muscle relaxants, and/or analgesics (according to guidelines included in the Plan's pharmacy policies and fomulary applicable for the member's benefit coverage); OR
      - (b) Occupational therapy, speech therapy, and/or physical therapy (according to Plan-adopted medical necessity criteria); OR
      - (c) Use of mandibular orthopedic repositioning appliances (MORA); OR
      - (d) Therapeutic injections (e.g. local anesthetic or corticosteroids); OR
      - (e) Manipulation for reduction of fracture or dislocation; OR
    - (2) Criteria for Surgical Treatment: ANY criteria must be met in items (a) through (e):
      - (a) Arthrocentesis (e.g., for acute closed lock); OR
      - (b) Arthroscopic surgery (e.g., for arthritis); OR

Temporomandibular Joint Disorder Treatment

- (c) Intraoral vertical ramus osteotomy (IVRO) to correct internal derangements; OR
- (d) Open surgical procedure such as open reduction, arthroplasty, condylectomy, meniscus or disc plication, or disc removal; OR
- (e) TMJ arthroplasty will be performed with an FDA-approved prosthetic implant (only) according to the FDA-approved indication for the implantation.
- B. Medical Director review is required for individual consideration when medical necessity criteria are NOT met and/or the disorder may be caused by a medical condition other than a jaw fracture, jaw dislocation, and/or degenerative arthritis.

#### **Limitations and Exclusions**

- A. The treatment of TMJ disorders or TMJ syndrome that is NOT related to a medical condition would be considered a dental service rather than a medical benefit.
- B. ANY of the following services is considered NOT medically necessary for the assessment and/or treatment of TMJ disorders or other TMJ-related indications:
  - Treatment of a TMJ disorder that is NOT proven to be caused by or to result in a specific medical condition; OR
  - 2. Acupuncture (unless a covered benefit for the member for the specified indication); OR
  - 3. Arthroscopy of the TMJ for diagnostic purposes only; OR
  - 4. Biofeedback; OR
  - 5. Dental or orthodontic services (including restorations, prostheses procedures, radiographic images, oral/facial photographic images, supplies) for TMJ-related indications and/or to adjust the height of teeth or other way restore occlusion, such as crowns, bridges, braces; OR
  - 6. Devices/appliances such as mechanical stretching devices or devices to maintain range of motion, gain increased range of motion, and/or improve functioning of the TMJ, including but not limited to continuous passive motion (CPM) devices, passive rehabilitation therapy devices, mandibular orthopedic repositioning appliances (MORA); OR
  - 7. Dry needling alone or in combination with a stretching regimen used to reduce pain and increase range of motion in patients with TMJ pain; OR
  - 8. Electrical stimulation techniques such as:

- a. Electrogalvanic stimulation; OR
- b. Microcurrent electrical therapy (MET); OR
- c. Percutaneous electrical stimulation (PENS); OR
- d. Percutaneous neuromodulation therapy (e.g., the Percutaneous Neuromodulation Therapy™ by Vertis Neurosciences system or the Deepwave® Percutaneous Neuromodulation Pain Therapy System by Biowave Corp.); OR
- e. Transcutaneous electrical nerve stimulation (TENS); OR
- 9. Electromyography (EMG); OR
- 10. Intra-articular injection of hyaluronic acid (viscosupplementation); OR
- 11. Iontophoresis using electricity to enhance the percutaneous absorption of a drug or chemical ions (e.g., lidocaine hydrochloride, dexamethasone sodium phosphate); OR
- 12. Jaw tracking devices, computerized jaw tracking technologies, and associated jaw tracking services using one or more technologies/services (e.g., TENS, 3D imaging/computerized mandibular scans, kinesiography, magnetic recording devices, electronic motion recording methods, and/or range of motion measurements); OR
- 13. Kinesiography; OR
- 14. Laser therapy; OR
- 15. Neuromuscular junction studies, range of motion measurements, and/or muscle testing; OR
- 16. Phonophoresis using ultrasound to enhance the delivery of topically applied drugs; OR
- Somatosensory testing (also known as somatosensory evoked potentials test, SEPs, or SSEPs);
   OR
- 18. Thermography (including digital infrared thermal imaging, magnetic resonance thermography and temperature gradient studies); OR
- 19. Transcranial or lateral skull x-rays; OR
- 20. Ultrasonic Doppler auscultation/ultrasound imaging/sonogram for diagnosing disorders of the temporomandibular joint; OR

21. Use of a TMJ arthroplasty implant or device not FDA approved or not used according to FDA approved indications.

#### **Variations**

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for the Plan's Senior Care Options (SCO) members and New Hampshire Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, no applicable clinical guidelines were found from CMS specifically for temporomandibular joint disorder, but CMS guidelines do exist for services that may be used for the diagnosis or treatment of TMJ. Verify CMS criteria in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service for the specified indication on the date of the prior authorization request, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

## **Applicable Coding**

The Plan utilizes up-to-date, industry-standard Current Procedural Terminology (CPT) codes, Health Care Common Procedure Coding System (HCPCS) codes, and International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes in the Plan's medical policies. Since these codes may be updated at different intervals than the medical policy review cycle, the list of applicable codes included in a policy is informational only and may not be all inclusive. Applicable codes are subject to change without prior notification and do not guarantee member coverage or provider reimbursement. Review the Plan's reimbursement policies for Plan billing guidelines. Providers are responsible for obtaining prior authorization for the services specified in the Clinical Criteria section and Limitations and Exclusions section of a medical policy, even if an applicable code appropriately describing the service is not included in the policy's Applicable Coding section. Providers are expected to report all services using the most up-to-date, industry-standard procedures and diagnosis codes at the time of the service.

ICD-10	Description: Diagnoses Requiring Prior Authorization for Any Treatment		
Diagnosis			
Codes	Plan note: The initial medical evaluation does NOT require prior authorization when it is a component of a new patient office visit and conducted by a participating oral and maxillofacial surgeon or participating otolaryngologist and bills with one of the following diagnosis codes.		
M26.601	Right temporomandibular joint disorder		
M26.602	Left temporomandibular joint disorder		
M26.603	Bilateral temporomandibular joint disorder		
M26.609	Unspecified temporomandibular joint disorder		
M26.611	Adhesions and ankylosis of right temporomandibular joint		
M26.612	Adhesions and ankylosis of left temporomandibular joint		
M26.613	Adhesions and ankylosis of bilateral temporomandibular joint		
M26.619	Adhesions and ankylosis of temporomandibular joint, unspecified side		

Temporomandibular Joint Disorder Treatment

1406 601	A de la Calaca de
M26.621	Arthralgia of right temporomandibular joint
M26.622	Arthralgia of left temporomandibular joint
M26.623	Arthralgia of bilateral temporomandibular joint
M26.629	Arthralgia of temporomandibular joint
M26.631	Articular disc disorder of right temporomandibular joint
M26.632	Articular disc disorder of left temporomandibular joint
M26.633	Articular disc disorder of bilateral temporomandibular joint
M26.639	Articular disc disorder of temporomandibular joint, unspecified side
M26.641	Arthritis of right temporomandibular joint
M26.642	Arthritis of left temporomandibular joint
M26.643	Arthritis of bilateral temporomandibular joint
M26.649	Arthritis of unspecified temporomandibular joint
M26.651	Arthropathy of right temporomandibular joint
M26.652	Arthropathy of left temporomandibular joint
M26.653	Arthropathy of bilateral temporomandibular joint
M26.659	Arthropathy of unspecified temporomandibular joint
M26.69	Other specified disorders of temporomandibular joint

#### References

Abboud WA, Givol N, Yahalom R. Arthroscopic lysis and lavage for internal derangement of the temporomandibular joint. Ann Maxillofac Surg. 2015 Jul-Dec;5(2):158-62. doi: 10.4103/2231-0746.175754. PMID: 26981463.

Abboud WA, Yarom N, Yahalom R, Joachim M, Reiter S, Koren O, Elishoov H. Comparison of two physiotherapy programs for rehabilitation after temporomandibular joint arthroscopy. Int J Oral Maxillofac Surg. 2018 Jun;47(6):755-61. doi: 10.1016/j.ijom.2017.10.019. Epub 2017 Nov 15. PMID: 29150380.

Abboud W, Nadel S, Yarom N, Yahalom R. Arthroscopy of the Temporomandibular Joint for the Treatment of Chronic Closed Lock. Isr Med Assoc J. 2016 Jul;18(7):397-400. PMID: 28471560.

Abboud W, Yahalom R, Leiba M, Greenberg G, Yarom N. Temporomandibular joint involvement in patients with multiple myeloma-a retrospective study. Int J Oral Maxillofac Surg. 2016 Dec;45(12):1545-50. doi: 10.1016/j.ijom.2016.06.014. Epub 2016 Jul 1. PMID: 27377681.

Al-Baghdadi M, Durham J, Steele J. Timing interventions in relation to temporomandibular joint closed lock duration: a systematic review of 'locking duration.' J Oral Rehabil. 2014 Jan;41(1):24-58. doi: 10.1111/joor.12126. Epub 2014 Jan 7. PMID: 24393132.

Al-Morass EA. Open versus arthroscopic surgery for the management of internal derangement of the temporomandibular joint: a meta-analysis of the literature. Int J Oral Maxillofac Surg. 2015 Jun;44(6):763-70. doi: 10.1016/j.ijom.2015.01.024. Epub 2015 Feb 18. PMID: 25701306.

The American Academy of Orofacial Pain (AAOP). Orofacial Pain: Guidelines for Assessment, Diagnosis and Management. Fifth Edition. 2013.

American Association of Oral and Maxillofacial Surgeons (AAOMS). Parameters of Care Version 6: Clinical Practice Guidelines for Oral and Maxillofacial Surgery. 2017.

American Dental Association, Clinical Practice Guidelines.

American Society of Temporomandibular Joint Surgeons (ASTMJS). Guidelines.

American Society of Temporomandibular Joint Surgeons (ASTMJS). Guidelines for diagnosis and management of disorders involving the temporomandibular joint and related musculoskeletal structures. Cranio. 2003 Jan;21(1):68-76. PMID: 12555934.

Blasco-Bonora PM, Martín-Pintado-Zugasti A. Effects of myofascial trigger point dry needling in patients with sleep bruxism and temporomandibular disorders: a prospective case series. Acupunct Med. 2017 Mar;35(1):69-74. doi: 10.1136/acupmed-2016-011102. Epub 2016 Oct 3. PMID: 27697769.

Butts R, Dunning J, Pavkovich R, Mettille J, Mourad F. Conservative management of temporomandibular dysfunction: A literature review with implications for clinical practice guidelines (Narrative review part 2). J Bodyw Mov Ther. 2017 Jul; 21(3):541–548. doi: 10.1016/j.jbmt.2017.05.021. Epub 2017 Jun 1. PMID: 28750962.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Service (CMS). National Coverage Determination (NCD) for Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy 160.7.1. Version 2. 2006 Jun 19.

Centers for Medicare & Medicaid Service (CMS). National Coverage Determination (NCD) for Manipulation 150.1. Effective date not posted.

Centers for Medicare & Medicaid Service (CMS). National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) 280.13. Version 2. 2012 Jun 8.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Chebbi R, Khalifa HB, Dhidah M. Temporomandibular joint disorder in systemic sclerosis: a case report. Pan Afr Med J. 2016 Nov 16;25:164. doi: 10.11604/pamj.2016.25.164.10432. eCollection 2016.

Temporomandibular Joint Disorder Treatment

PMID: 28292126.

Chen YW, Chiu YW, Chen CY, Chuang SK. Botulinum toxin therapy for temporomandibular joint disorders: a systematic review of randomized controlled trials. Int J Oral Maxillofac Surg. 2015 Aug;44(8):1018-26. doi: 10.1016/j.ijom.2015.04.003. Epub 2015 Apr 25. PMID: 25920597.

Cömert Kiliç S, Güngörmüs M. Is dextrose prolotherapy superior to placebo for the treatment of temporomandibular joint hypermobility? A randomized clinical trial. Int J Oral Maxillofac Surg. 2016 Jul;45(7):813-9. doi: 10.1016/j.ijom.2016.01.006. Epub 2016 Feb 2. PMID: 2684679.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts, MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

de Freitas RF, Ferreira MÂ, Barbosa GA, Calderon PS. Counselling and self-management therapies for temporomandibular disorders: a systematic review. J Oral Rehabil. 2013 Nov;40(11):864-74. doi: 10.1111/joor.12098. Epub 2013 Sep 18. PMID: 24102692.

de Leeuw R, Klasser GD. Orofacial Pain: Guidelines for Assessment, Diagnosis, and Management, Fifth Edition. 2013.

Gauer RL, Semidey MJ. Diagnosis and Treatment of Temporomandibular Disorders. Am Fam Physician. 2015 Mar 15; 91(6):378-86. PMID: 25822556.

Gurung T, Singh RK, Mohammad S, Pal US, Mahdi AA, Kumar M. Efficacy of arthrocentesis versus arthrocentesis with sodium hyaluronic acid in temporomandibular joint osteoarthritis: A comparison. Natl J Maxillofac Surg. 2017 Jan-Jun;8(1):41–9. doi: 10.4103/njms.NJMS\_84\_16. PMID: 28761275.

Hayes. Comparative Effectiveness Review. Comparative Effectiveness Review of Dry Needling for Indications Other than Neck or Trapezius Muscle Pain in Adults. Dallas, TX: Hayes; 2017 Jun 22. Annual Review 2021 Jun 30.

Huang IY, Chen CM, Kao YH, Chen CM, Wu CW. Management of long-standing mandibular dislocation. Int J Oral Maxillofac Surg. 2011 Aug;40(8):810-4. doi: 10.1016/j.ijom.2011.02.031. Epub 2011 Apr 6. PMID: 21474286.

Huang IY. A simple method to expand the joint space for TMJ surgery. Int J Oral Maxillofac Surg. 2011 Sep;40(9):983-4. doi: 10.1016/j.ijom.2011.04.011. Epub 2011 May 23. PMID: 21602029.

Ivorra-Carbonell L, Montiel-Company JM, Almerich-Silla JM, Paredes-Gallardo V, Bellot-Arcis C. Impact of functional mandibular advancement appliances on the temporomandibular joint - a systematic review. Med Oral Patol Oral Cir Buccal. 2016 Sep; 21(5):e565-72. doi: 10.4317/medoral.21180. PMID: 27475694.

Korkmaz YT, Altıntas NY, Korkmaz FM, Candırlı C, Coskun U, Durmuslar MC. Is Hyaluronic Acid Injection Effective for the Treatment of Temporomandibular Joint Disc Displacement With Reduction? J Oral Maxillofac Surg. 2016 Sep;74(9):1728-40. doi: 10.1016/j.joms.2016.03.005. Epub 2016 Mar 15. PMID: 27058964.

Liu F, Steinkeler A. Epidemiology, diagnosis, and treatment of temporomandibular disorders. Dent Clin North Am. 2013 Jul;57(3):465-79. doi: 10.1016/j.cden.2013.04.006. PMID: 23809304.

MacIntosh RB, Shivapuja PK, Naqvi R. Scleroderma and the temporomandibular joint: reconstruction in 2 variants. J Oral Maxillofac Surg. 2015 Jun;73(6):1199–210. doi: 10.1016/j.joms.2014.12.012. Epub 2014 Dec 17. PMID: 25795177.

Majumdar SK, Krishna S, Chatterjee A, Chakraborty R, Ansari N. Single Injection Technique Prolotherapy for Hypermobility Disorders of TMJ Using 25% Dextrose: A Clinical Study. J Maxillofac Oral Surg. 2017 Jun;16(2):226-30. doi: 10.1007/s12663-016-0944-0. Epub 2016 Jul 25. PMID: 28439165.

Manfredini D. Current Concepts on Temporomandibular Disorders. Quintessence Publishers 2010. Manfredini D, Favero L, Michieli M, Salmaso L, Cocilovo F, Guarda-Nardini L. An assessment of the usefulness of jaw kinesiography in monitoring temporomandibular disorders: correlation of treatment-related kinesiographic and pain changes in patients receiving temporomandibular joint injections. J Am Dent Assoc. 2013 Apr;144(4):397-405. PMID: 23543694.

Martins WD, Ribas Mde O, Bisinelli J, França BH, Martins G. Recurrent dislocation of the temporomandibular joint: a literature review and two case reports treated with eminectomy. Cranio. 2014 Apr; 32(2):110-7. doi: 10.1179/0886963413Z.00000000017. PMID: 24839722.

Mina R, Melson P, Powell S, Rao M, Hinze C, Passo M, Graham TB, Brunner HI. Effectiveness of dexamethasone iontophoresis for temporomandibular joint involvement in juvenile idiopathic arthritis. Arthritis Care Res (Hoboken). 2011 Nov;63(11):1511-6. doi: 10.1002/acr.20600. PMID: 22034112.

Monje-Gil F, Nitzan D, González-Garcia R. Temporomandibular joint arthrocentesis. Review of the literature. Med Oral Patol Oral Cir Buccal. 2012 July;17(4): e575–81. PMID: 22322493.

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.

Niibo P, Pruunsild C, Voog-Oras Ü, Nikopensius T, Jagomägi T, Saag M. Contemporary management of TMJ involvement in JIA patients and its orofacial consequences. EPMA J. 2016 Jun 2;7:12. doi: 10.1186/s13167-016-0061-7. eCollection 2016. PMID: 27257443.

O'Connor RC, Fawthrop F, Salha R, Sidebottom AJ. Management of the temporomandibular joint in inflammatory arthritis: Involvement of surgical procedures. Eur J Rheumatol. 2017 Jun;4(2):151–6. doi: 10.5152/eurjrheum.2016.035. Epub 2017 Feb 23. PMID: 28638693.

Politi M, Sembronio S, Robiony M, Costa F, Toro C, Undt G. High condylectomy and disc repositioning compared to arthroscopic lysis, lavage, and capsular stretch for the treatment of chronic closed lock of the temporomandibular joint. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. 2007 Jan;103(1):27-33. Epub 2006 Jul 27. PMID: 17178490.

Prechel U, Ottl P, Ahlers OM, Neff A. The Treatment of Temporomandibular Joint Dislocation. Dtsch Arztebl Int. 2018 Feb 2; 115(5):59-64. doi: 10.3238/arztebl.2018.0059. PMID: 29439762.

Rigon M, Pereira LM, Bortoluzzi MC, Loguercio AD, Ramos AL, Cardoso JR. Arthroscopy for Temporomandibular Disorders. Cochrane Database Syst Rev. 2011 May 11;(5):CD006385. doi: 10.1002/14651858.CD006385.pub2. PMID: 21563153.

Rodrigues-Bigaton D, Dibai Filho AV, Costa AC, Packer AC, de Castro EM. Accuracy and reliability of infrared thermography in the diagnosis of arthralgia in women with temporomandibular disorder. J Manipulative Physiol Ther. 2013 May;36(4):253-8. doi: 10.1016/j.jmpt.2013.04.006. Epub 2013 May 27. PMID: 23719519.

Rodrigues PC, da Mota AS, Pereira JR, Stuginski-Barbosa J. Management of painful temporomandibular joint clicking with different intraoral devices and counseling: a controlled study. J Appl Oral Sci. 2015 Sep-Oct;23(5):529–35. doi: 10.1590/1678-775720140438. PMCID: PMC4621948.

Schiffman EL, Velly AM, Look JO, Hodges JS, Swift JQ, Decker KL, Anderson QN, Templeton RB, Lenton PA, Kang W, Fricton JR. Effects of four treatment strategies for temporomandibular joint closed lock. Int J Oral Maxillofac Surg. 2014 Feb;43(2):217-26. doi: 10.1016/j.ijom.2013.07.744. Epub 2013 Sep 14. PMID: 24042068.

Schiffman E, Ohrbach R. Executive summary of the Diagnostic Criteria for Temporomandibular Disorders for clinical and research applications. J Am Dent Assoc. 2016 Jun;147(6):438-45. doi: 10.1016/j.adaj.2016.01.007. PMID: 26922248.

Scrivani SJ, Khawaja SN, Bavia PF. Nonsurgical Management of Pediatric Temporomandibular Joint Dysfunction. Oral Maxillofac Surg Clin North Am. 2018 Feb;30(1):35-45. doi: 10.1016/j.coms.2017.08.001. PMID: 29153236.

Shukla D, Muthusekhar MR. Efficacy of low-level laser therapy in temporomandibular disorders: A systematic review. Natl J Maxillofac Surg. 2016 Jan-Jun;7(1):62–6. doi: 10.4103/0975-5950.196127.

PMID: 28163481.

U. S. Food & Drug Administration (FDA). Medical Devices. 510(k) Clearances.

U.S. Food & Drug Administration (FDA). 510(k) Summary for the Biowave Deepwave Percutaneous Neuromodulation Pain Therapy System. 2006 Jul 19.

U.S. Food & Drug Administration (FDA). 510(k) Summary of Safety and Effectiveness. Vertis Neuroscience, Inc. Percutaneous Neuromodulation Therapy (PNT) ™ Control Unit and Accessories. 2002.

U. S. Food & Drug Administration (FDA). Medical Devices. Device Registration and Listing.

Wieckiewicz M, Boening K, Wiland P, Shiau YY, Paradowska-Stolarz A. Reported concepts for the treatment modalities and pain management of temporomandibular disorders. J Headache Pain. 2015;16:106. doi: 10.1186/s10194-015-0586-5. Epub 2015 Dec 7. PMID: 26644030.

Xu GZ, Jia J, Jin L, Li JH, Wang ZY, Cao DY. Low-Level Laser Therapy for Temporomandibular Disorders: A Systematic Review with Meta-Analysis. Pain Res Manag. 2018 May 10;2018:4230583. doi: 10.1155/2018/4230583. eCollection 2018. PMID: 29861802.

Zhang C, Wu JY, Deng DL, He BY, Tao Y, Niu YM, Deng MH. Efficacy of splint therapy for the management of temporomandibular disorders: a meta-analysis. Oncotarget. 2016 Dec 20;7(51):84043-53. doi: 10.18632/oncotarget.13059. PMID: 27823980.

#### **Next Review Date**

07/01/23

# **Authorizing Entity**

**MPCTAC** 

## **Appendix**

Appendix: Policy History

#### **Disclaimer Information:**

Plan refers to Boston Medical Center Health Plan, Inc. which operates under the trade name WellSense Health Plan. Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity

definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

# **Appendix: Policy History**

Original Approval Date	Original Effective Date* and Version	Policy Owner	Original Policy Approved by
Regulatory Approval: N/A	01/01/09 Version 1	Director of Medical Policy as Chair of	MPCTAC, QIC, and UMC
Internal Approval:		MPCTAC	
09/09/08: Medical Policy, Criteria, and			
Technology Assessment Committee			
(MPCTAC)			
09/30/08: Utilization Management			
Committee (UMC)			
10/22/08: Quality Improvement			
Committee (QIC)			

<sup>\*</sup>Effective Date for QHP Commercial Product: 01/01/12

<sup>\*</sup>Effective Date for New Hampshire Medicare Advantage HMO Product: 01/01/22

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
09/22/09	No criteria changes. Updated references.	Version 2	09/22/09: MPCTAC 10/28/09: QIC
09/01/10	No changes to criteria. Updated references and coding.	Version 3	09/15/10: MPCTAC 11/22/10: QIC
09/01/11	Updated limitations and references.	Version 4	09/21/11: MPCTAC 10/26/11: QIC
07/01/12	References updated, revised language in the Applicable Coding section, and deleted four-digit diagnosis code 524.6.	Version 5	07/18/12: MPCTAC 08/22/12: QIC
07/01/13	Review for effective date 11/01/13. Updated references. Added criteria for medical evaluation of TMJ disorders. Reformatted, revised, and added examples in the Medical Policy Statement section. Added definition for temporomandibular joint syndrome. Deleted duplicate text in Clinical Background Information section.	11/01/13 Version 6	07/17/13: MPCTAC 08/15/13: QIC
07/29/12	Off cycle review for WellSense New Hampshire Medicaid product, revised Description of Item or Service section, reformatted the Medical Policy	Version 7	08/03/12: MPCTAC 09/05/12: QIC

<sup>\*</sup>Effective Date for New Hampshire Medicaid Product: 01/01/13

<sup>\*</sup>Effective Date for Senior Care Options Product: 01/01/16

	Statement section, and updated the References		
	section.		
01/30/14	Off cycle review for effective date 04/01/14. Added ICD10 diagnosis code equivalents of	Version 8	01/27/14: MPCTAC 01/30/14: QIC
00/01/14	existing ICD9 diagnosis codes.	01/01/15	00 /17 /14: NADCTAC
09/01/14	Review for effective date 01/01/15. Revised language in the Limitations section related to benefit coverage. Revised medical criteria in the Medical Policy Statement and Limitations sections. Updated references.	01/01/15 Version 9	09/17/14: MPCTAC 10/08/14: QIC
09/01/15	Annual review for effective date 01/01/16. Revised the list of applicable products, including removing Commonwealth Care, Commonwealth Choice, and Employer Choice from the list of applicable products because the products are no longer available. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Clinical Background Information and References sections.	01/01/16 Version 10	09/16/15: MPCTAC 10/14/15: QIC
11/25/15	Review for effective date 01/14/16. Revised language in the Applicable Coding section.	01/14/16 Version 11	11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
09/01/16	Review for effective date 01/01/17. Removed	01/01/17	09/21/16: MPCTAC
and 09/28/16	ICD9 diagnosis codes. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Medical Policy Statement and Limitations sections. Administrative changes made to clarify language related to gender.	Version 12	09/30/16: MPCTAC (electronic vote) 10/12/16: QIC
12/05/16	Industry-wide changes to applicable ICD-10 diagnosis codes for temporo-mandibular joint disorder effective 01/01/17.	01/01/17 Version 13	Not applicable because industry-wide revisions to ICD-10 diagnosis codes.
09/01/17	Review for effective date 12/01/17. Revised criteria in the Medical Policy Statement and Limitations sections. Updated the Policy Summary, Definitions, References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	12/01/17 Version 14	09/20/17: MPCTAC
09/01/18	Review for effective date 12/01/18. Updated the Clinical Background Information, References, and Other Applicable Policies sections. Criteria revised in the Medical Policy Statement and Limitations sections.	12/01/18 Version 15	09/19/18: MPCTAC
12/01/18	Review for effective date 01/01/19. Administrative change made to the Limitations	01/01/19 Version 16	12/19/18: MPCTAC

	section (removing the reference to the NH Health Protection Program).		
09/01/19	Review for effective date 12/01/19. Administrative changes made to the Policy Summary, Definitions, References, and Reference to Applicable Laws and Regulations sections. Revised criteria in the Limitations section.	12/01/19 Version 17	09/18/19: MPCTAC
07/01/20	Review for effective date 10/01/20 to be consistent with implementation date of industry-wide diagnosis code updates made to the Applicable Coding section. Administrative changes made to the Medical Policy Statement, References, and Other Applicable Policies sections.	10/01/20 Version 18	07/15/20: MPCTAC
08/01/21	Review for effective date 09/01/21. Administrative changes made to the Policy Summary, Medical Policy Statement, Limitations, and References sections.	09/01/21 Version 19	08/27/21: MPCTAC (electronic vote)
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 20	11/17/21: MPCTAC
07/01/22	Review for effective date 08/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	08/01/22 Version 21	07/25/22: MPCTAC (electronic vote)
08/01/22	Review for effective date 11/01/22. Administrative changes made to the Policy Summary section.	11/01/22 Version 22	08/26/22: MPCTAC (electronic vote)