

Pharmacy Policy

Infliximab Products

Policy Number: 9.123

Revision Number: R0

Version Effective Date: 1/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

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

Prior Authorization Policy

Products Affected:

- Inflectra
- Remicade
- Renflexis

The Plan may authorize coverage of the above products for members meeting the following criteria:

| | |
|-------------------------------------|---|
| Covered Use | All FDA approved indications not otherwise excluded |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following: <ol style="list-style-type: none"> 1. Ankylosing Spondylitis (AS); AND <ol style="list-style-type: none"> a. An inadequate response, intolerance, or contraindication to at least two formulary NSAIDS at maximal doses over 1 month OR incomplete response to at least two different formulary NSAIDS over 2 months; AND b. An inadequate response, intolerance, or contraindication to Enbrel, Humira or |

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

| | |
|-------------------------|---|
| | <p>Cosentyx or a clinical rationale for use of the requested agent instead of Enbrel, Humira or Cosentyx.</p> <ol style="list-style-type: none"> 2. Moderate to severely active Crohn’s Disease (CD) (except fistulizing); AND <ol style="list-style-type: none"> a. An inadequate response, contraindication or intolerance to use of all of the following: <ol style="list-style-type: none"> i. 5-aminosalicylic acid (e.g. mesalamine) ii. 6-mercaptopurine, azathioprine or methotrexate iii. corticosteroids; AND b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira. 3. Fistulizing Crohn’s Disease (CD); <ol style="list-style-type: none"> a. An inadequate response, contraindication or intolerance to use of ONE of the following: <ol style="list-style-type: none"> i. 6-mercaptopurine, azathioprine AND b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira. 4. Plaque Psoriasis (Ps); AND <ol style="list-style-type: none"> a. An inadequate response or adverse reaction to any one of the following combinations (please note: these combinations DO NOT have to be used concurrently): <ol style="list-style-type: none"> i. one topical agent plus one systemic agent; OR ii. one topical agent plus one phototherapy; OR iii. one systemic agent plus one phototherapy; OR iv. two systemic agents; OR b. An inadequate response, intolerance, or contraindication to Enbrel, Humira or Cosentyx or a clinical rationale for use of the requested agent instead of Enbrel, Humira or Cosentyx. 5. Psoriatic Arthritis (PsA); AND <ol style="list-style-type: none"> a. An inadequate response or intolerance to three months of one non-biologic DMARD; AND b. An inadequate response, intolerance, or contraindication to Enbrel, Humira or Cosentyx or a clinical rationale for use of the requested agent instead of Enbrel, Humira or Cosentyx. 6. Rheumatoid arthritis (RA); AND <ol style="list-style-type: none"> a. An inadequate response or intolerance to three months of one formulary non-biologic DMARD, or is currently on methotrexate; AND b. An inadequate response, intolerance, or contraindication to Enbrel or Humira or a clinical rationale for the use of the requested agent instead of Enbrel or Humira 7. Ulcerative Colitis (UC); AND <ol style="list-style-type: none"> a. An inadequate response, contraindication or intolerance to use of ALL of the following: <ol style="list-style-type: none"> i. 5-aminosalicylic acid (e.g. mesalamine) ii. 6-mercaptopurine, azathioprine, and/or methotrexate iii. corticosteroids; AND b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira |
| Age Restrictions | AS, Ps, PsA, RA: 18 year of age or older CD, UC: 6 years of age or older |

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

| | |
|-------------------------------|--|
| Prescriber Restriction | AS, PsA, RA: Prescribed by or in consultation with a rheumatologist CD, UC: Prescribed by or in consultation with a gastroenterologist Ps: Prescribed by or in consultation with a dermatologist |
| Coverage Duration | Initial and reauthorization: 12 months |
| Other criteria | Reauthorization: <ol style="list-style-type: none"> 1. Currently receiving medication via Well Sense benefit or member has previously met initial approval criteria; AND 2. Clinical condition has improved or stabilized |

Applicable Coding:

| Code | Medication |
|--------------|---|
| J1745 | Remicade® (infliximab injection) |
| Q5103 | Inflectra® (infliximab-dyyb injection) - biosimilar |
| Q5104 | Renflexis® (infliximab-abda injection) - biosimilar |

Clinical Background Information and References

1. Aaltonen KJ, Virkki LM, Malmivaara A et al. Systematic review and meta-analysis of the efficacy and safety of existing TNF blocking agents in treatment of rheumatoid arthritis. PLoS One. 2012;7(1):e30275. Epub 2012 Jan 17.
2. Ash Z, Gaujoux-Viala C, Gossec L et al. A systematic literature review of drug therapies for the treatment of psoriatic arthritis: current evidence and meta-analysis informing the EULAR recommendations for the management of psoriatic arthritis. Ann Rheum Dis. 2012 Mar; 71(3):319-26.
3. Bhosle M, Kulkarni A, Feldman SR et al. Quality of life in patients with psoriasis. Health Qual Life Outcomes. 2006;4:35.
4. Callen JP, Krueger GG, Lebwohl M et al. AAD consensus statement on psoriasis therapies. J Am Acad Dermatol. 2003; 49:897-9. 5 Pharmacy Medical Necessity Guidelines: Infliximab Products
5. Chen JS, Makovey J, Lassere M, et al. Comparative effectiveness of anti-tumour necrosis factor (TNF) drugs on health-related quality of life among patients with inflammatory arthritis. Arthritis Care Res (Hoboken). 2013 Sep 10.
6. Enbrel prescribing information. Thousand Oaks, CA: Amgen and Wyeth Pharmaceuticals; 2013 November.
7. Feuerstein, JD, Isaacs KL, Schneider Y, et al. AGA Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;158:1450–1461
8. Flouri I, Markatseli TE, Voulgari PV, et al. Comparative effectiveness and survival of infliximab, adalimumab, and etanercept for rheumatoid arthritis patients in the Hellenic Registry of Biologics: Low rates of remission and 5-year drug survival. Semin Arthritis Rheum. 2013 Sep 5. pii: S0049- 0172(13)00159-5.

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

9. Garnett WR, Yunder N. Treatment of Crohn's Disease with Infliximab. *Am J Health-System Pharmacy* 2001; 58(04): 307-319.
10. Gisondi P, Fantin F, Del Giglio M et al. Chronic plaque psoriasis is associated with increased arterial stiffness. *Dermatology*. 2009; 218(2):110-3.
11. Gisondi P, Galvan A, Idolazzi L et al. Management of moderate to severe psoriasis in patients with metabolic comorbidities. *Front Med*. 2015 ;2:1.
12. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis* .2016;75:499–510.
13. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; June 2016.
14. Inflectra (infliximab-abda) [prescribing information]. Kenilworth, NJ: Merck Sharp & Dohme Corp; April 2017.
15. Kalb RE, Blauvelt A, Sofen HL, et al. Effect of Infliximab on Health-Related Quality of Life and Disease Activity by Body Region in Patients With Moderate-to-Severe Psoriasis and Inadequate Response to Etanercept: Results from the PSUNRISE Trial. *J Drugs Dermatol*. 2013 Aug 1;12(8):874-80.
16. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults. American College of Gastroenterology Practice Parameters Committee. 2004.
17. Krueger G, Ellis CN. Psoriasis-recent advances in understanding its pathogenesis and treatment. *J Am Acad Dermatol*. 2005; 53(1 Suppl 1):S94-100.
18. Langley RGB, Krueger GG, Griffiths CEM. Psoriasis: epidemiology, clinical features, and quality of life. *Ann Rheum Dis*. 2005; 64(Suppl 2): ii18-23.
19. Lebwohl M. Psoriasis. *Lancet*. 2003; 361(9364):1197-204.
20. Lichtenstein G, Loftus E, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2018; 113:481-517.
21. Martínez-Santana V, González-Sarmiento E, Calleja-Hernández M, Sánchez-Sánchez T. Comparison of drug survival rates for tumor necrosis factor antagonists in rheumatoid arthritis. *Patient Prefer Adherence*. 2013 Jul 29;7:719-27.
22. McEvoy GK, ed. AHFS 2013 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2013.
23. Menter A, Korman N, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011; 65(1):137-74.
24. Papoutsaki M, Osório F, Morais P, et al. Infliximab in psoriasis and psoriatic arthritis. *BioDrugs*. 2013 Jan;27 Suppl 1:13-23.
25. Pariser DM, Bagel J, Gelfand JM, Korman NJ, Ritchlin CT, Strober BE, Van Voorhees AS, Young M, Rittenberg S, Lebwohl MG, Horn EJ; National Psoriasis Foundation. National Psoriasis Foundation clinical consensus on disease severity. *Arch Dermatol*. 2007 Feb;143(2):239-42.
26. Present DH, et al. Infliximab for the Treatment of Fistulas in Patients with Crohn's Disease. *N Engl J Med*. 1999; 340:1398-1405, May 6, 1999.
27. Remicade (infliximab) [package insert]. Malvern, PA: Centocor Ortho Biotech, Inc.; January 2015.

* *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

28. Renflexis (infliximab-abda) [package insert]. Kenilworth, NJ: Merck Sharp & Dohme Corp. Inc.; April 2017.
29. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2019;114:384–413.
30. Saag KG, Teng GG, Patkar NM, Anuntiyo J, Finney C, Curtis JR. American College of Rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. *Arthritis Rheum.* Jun 15 2008; 59(6):762-84.
31. Schneider M, Krüger K. Rheumatoid arthritis-early diagnosis and disease management. *Dtsch Arztebl Int.* 2013 Jul;110(27-28):477-84.
32. Singh JA, Furst DE, Bharat A et al. Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in 6 Pharmacy Medical Necessity Guidelines: Infliximab Products the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research.* Vol. 64, No. 5, May 2012, pp 625–639.
33. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol.* 2016 Jan;68(1):1-26
34. Smolen JS, Landewé R, Breedveld FC, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. *Ann Rheum Dis* 2010; 69: 964 – 75.
35. Tugnet N, Pearce F, Tosounidou S, et al. To what extent is NICE guidance on the management of rheumatoid arthritis in adults being implemented in clinical practice? A regional survey. *Clin Med.* 2013 Feb;13(1):42-6.
36. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology.* *Arthritis Rheumatol.* 2019 Oct;71(10):1599-1613.

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|------------------------|-------------------------|-------------------|--|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee, NH DHHS |

| Policy Revisions History | | | |
|--------------------------|--|-------------------------|------------------------|
| Review Date | Summary of Revisions | Revision Effective Date | Approved by |
| 12/1/2020 | 9.186 Infliximab Policy retired, new policy created. Updated AS criteria time requirements to reflect ACR guideline updates, removed abx requirement in CD criteria to reflect ACG guidelines, updated | 1/1/2021 | P&T Committee, NH DHHS |

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Policy Revisions History

| | | | |
|--|---|--|--|
| | PsA criteria time requirements to reflect EULAR guidelines, updated time requirement in RA criteria to reflect ACR guidelines. Removed adherence requirement. Updated policy to match NH PDL trial/fail requirements. | | |
|--|---|--|--|

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

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.

^{*} Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.