

Pharmacy Policy

Humira

Policy Number: 9.121

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:

- Humira (adalimumab)

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 | Use of Humira in combination with another biologic |
| 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"> i. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs; OR ii. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for ankylosing spondylitis 2. Moderate to severely active Crohn's Disease (CD); AND |

* 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.

- i. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for Chron’s disease; OR
 - ii. An inadequate response, contraindication or intolerance to use of two of the following:
 - 1. 5-aminosalicylic acid (e.g. mesalamine)
 - 2. 6-mercaptopurine or azathioprine
 - 3. methotrexate
 - 4. corticosteroids
3. Moderate to severe (Hurley Stage II or III) hidradenitis suppurativa (HS);
4. Plaque Psoriasis (Ps); AND
- a. One of the following:
 - i. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis; **OR**
 - ii. An inadequate response or adverse reaction to any one of the following combinations (please note: these combinations DO NOT have to be used concurrently):
 - 1. one topical agent plus one systemic agent; **OR**
 - 2. one topical agent plus one phototherapy; **OR**
 - 3. one systemic agent plus one phototherapy; **OR**
 - 4. two systemic agents; **OR**
 - b. A contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents); **OR**
5. Polyarticular juvenile idiopathic arthritis (pJIA); AND
- i. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs; OR
 - ii. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for pJIA
6. Psoriatic Arthritis (PsA); AND
- i. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs; OR
 - ii. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for psoriatic arthritis
7. Rheumatoid arthritis (RA); AND
- i. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs; OR
 - ii. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for RA
8. Ulcerative Colitis (UC); AND
- i. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for UC; OR
 - ii. An inadequate response, adverse reaction, or contraindication to ALL of the following:

* 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.

| | |
|-------------------------------|---|
| | <ul style="list-style-type: none"> i. an aminosalicylate; AND ii. a corticosteroid; AND iii. an immunomodulatory (e.g. methotrexate, 6-mercaptopurine, or azathioprine) <p>9. Non-infectious uveitis (UV); AND</p> <ul style="list-style-type: none"> i. An inadequate response, or adverse reaction to one topical or systemic glucocorticoid, or a contraindication to all topical and systemic glucocorticoids; AND ii. An inadequate response, or adverse reaction to one systemic immunosuppressive therapy, or a contraindication to all systemic immunosuppressive therapies (e.g. methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide) |
| Age Restrictions | HS: 18 years of age and older |
| Prescriber Restriction | CD, UC: Prescribed by or in consultation with a gastroenterologist AS, pJIA, PsA, RA: Prescribed by or in consultation with a rheumatologist HS, Ps: Prescribed by or in consultation with a dermatologist UV: Prescribed by or in consultation with a uveitis specialist (e.g. ophthalmologist, ocular immunologist) |
| Coverage Duration | Initial and Reauthorization: 12 months |
| Quantity Limit | RA: 40mg syringe – 4 syringes per 28 days PsA, AS: 40mg syringe – 2 syringes per 28 days pJIA: 40mg syringe – 4 syringes per 28 days; 20mg syringe – 2 syringes per 28 days CD, UC: 40mg syringe – one starter pack containing 6 syringes initially for a 21 day supply, then 2 syringes per 28 days thereafter Ps, UV: 40mg syringe – one starter pack containing 4 syringes initially for a 28 day supply, then 2 syringes per 28 days thereafter HS: 40mg syringe – one starter pack containing 6 syringes initially for a 21 day supply, then 4 syringes per 28 days thereafter |
| Other criteria | Reauthorization: <ul style="list-style-type: none"> 1. Clinical condition has improved or stabilized |

Applicable Coding:

| Code | Medication |
|-------|--------------------------------|
| J0135 | Humira® (adalimumab injection) |

Clinical Background Information and References

* 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.

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. Afif W, Leighton JA, Hanauer SB et al. Open-label study of adalimumab in patients with ulcerative colitis including those with prior loss of response or intolerance to infliximab. Inflamm Bowel Dis. 2009;15(9):1302-7.
3. Agency for Healthcare Research and Quality. Choosing Medications for Rheumatoid Arthritis. Available at effectivehealthcare.ahrq.gov/ehc/products/14/85/RheumArthritisClinicianGuide.pdf. Accessed September 12, 2013.
4. 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.
5. Bhosle M, Kulkarni A, Feldman SR et al. Quality of life in patients with psoriasis. Health Qual Life Outcomes. 2006;4:35.
6. Buimer MG, Wobbes T, Klinkenbijnl JH. Hidradenitis suppurativa. Br J Surg. 2009 Apr. 96(4):350- 60.
7. Callen JP, Krueger GG, Lebwohl M et al. AAD consensus statement on psoriasis therapies. J Am Acad Dermatol. 2003; 49:897-9.
8. 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.
9. Crohn's and Colitis Foundation of America. What is Crohn's disease? Available at ccfa.org/whatare-crohns-and-colitis/what-is-crohns-disease. Accessed 2014 September 25.
10. Escher JC, Taminau JA, Nieuwenhuis EE, et al. Treatment of inflammatory bowel disease in childhood: best available evidence. Inflamm Bowel Dis. 2003; 9(1):34-58.
11. 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: 6 Pharmacy Medical Necessity Guidelines: Humira® (adalimumab) Low rates of remission and 5-year drug survival. Semin Arthritis Rheum. 2013 Sep 5. pii: S0049- 0172(13)00159-5.
12. Gisondi P, Fantin F, Del Giglio M et al. Chronic plaque psoriasis is associated with increased arterial stiffness. Dermatology. 2009; 218(2):110-3.
13. Gisondi P, Galvan A, Idolazzi L et al. Management of moderate to severe psoriasis in patients with metabolic comorbidities. Front Med. 2015;2:1.
14. 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. 2015 Dec 7 15. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; April 2017.
15. Hyams JS, Griffiths A, Markowitz J et al. Safety and efficacy of adalimumab for moderate to severe Crohn's disease in children. Gastroenterology. 2012 Aug; 143(2):36 7 Pharmacy Medical Necessity Guidelines: Humira® (adalimumab)
16. Product Information. Humira®, adalimumab. Abbott Laboratories. North Chicago, Ill. May 2017.
17. Sandborn WJ, van Assche G, Reinisch W et al. Adalimumab induces and maintains clinical remission in patients with moderate-to-severe ulcerative colitis. Gastroenterology. 2012 Feb; 142(2):257-65.

* 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.

18. Santos-Gómez M, Calvo-Río V, Blanco R, et al. The effect of biologic therapy different from infliximab or adalimumab in patients with refractory uveitis due to Behçet's disease: results of a multicentre open-label study. *Clin Exp Rheumatol*. 2016 Apr 7. [Epub ahead of print]
19. Savarino E, Bodini G, Dulbecco P, et al. Adalimumab Is More Effective Than Azathioprine and Mesalamine at Preventing Postoperative Recurrence of Crohn's Disease: A Randomized Controlled Trial. *Am J Gastroenterol*. 2013 Sep 10. doi: 10.1038/ajg.2013.287. [Epub ahead of print] Available from Internet. Accessed 2013 September 12.
20. Schneider M, Krüger K. Rheumatoid arthritis-early diagnosis and disease management. *Dtsch Arztebl Int*. 2013 Jul;110(27-28):477-84.
21. Schreiber S, Reinisch W, Colombel JF, et al. Subgroup analysis of the placebo-controlled CHARM trial: increased remission rates through 3 years for adalimumab-treated patients with early Crohn's disease. *J Crohns Colitis*. 2013 Apr 1;7(3):213-21.
22. Sieper J, van der Heijde D, Dougados M et al. Early response to adalimumab predicts long-term remission through 5 years of treatment in patients with ankylosing spondylitis. *Ann Rheum Dis*. 2012 May;71(5):700-6.
23. 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 the Treatment of Rheumatoid Arthritis. *Arthritis Care & Research*. Vol. 64, No. 5, May 2012, pp 625–639.
24. 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
25. 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.
26. Suhler EB, Lowder CY, Goldstein DA, et al. Adalimumab therapy for refractory uveitis: results of a multicentre, open-label, prospective trial. *Br J Ophthalmol*. 2013 Apr;97(4):481-6.
27. Tanaka C, Shiozawa K, Hashiramoto A, Shiozawa S. A study on the selection of DMARDs for the combination therapy with adalimumab. *Kobe J Med Sci*. 2012 Jun 27;58(2):E41-50.
28. van der Heijde D, Kivitz A, Schiff MH, et al. Efficacy and safety of adalimumab in patients with ankylosing spondylitis: results of a multicenter, randomized, double-blind, placebo-controlled trial. *Arthritis Rheum*. 2006; 54:2136-46.
29. van Vollenhoven RF, Fleischmann R, Cohen S, et al. Tofacitinib or adalimumab versus placebo in rheumatoid arthritis. *N Engl J Med*. 2012 Aug 9; 367(6):508-19.
30. Weinblatt ME, Schiff M, Valente R, et al. Head-to-head comparison of subcutaneous abatacept versus adalimumab for rheumatoid arthritis: findings of a phase IIIb, multinational, prospective, randomized study. *Arthritis Rheum*. 2013 Jan;65(1):28-38.
31. Weinblatt ME, Keystone EC, Furst DE, et al. Adalimumab, a fully human anti-tumor necrosis factor alpha monoclonal antibody, for the treatment of rheumatoid arthritis in patients taking concomitant methotrexate. The ARMADA trial. *Arthritis Rheum*. 2003; 48:35-45.
32. Yamauchi PS, Mau N. Hidradenitis suppurativa managed with adalimumab. *J Drugs Dermatol*. 2009 Feb. 8(2):181-3.

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|------------------------|-------------------------|--------------|-------------|
|------------------------|-------------------------|--------------|-------------|

* 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.

| | | | |
|-----------|----------|-------------------|---|
| 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 | 9.184 Humira Policy retired, new policy created. Removed adherence requirement | 1/1/2021 | P&T Committee, NH DHHS |

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.