Pharmacy Policy

Humira

Policy Number: 9.121
Version Number: 2.0
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☐ 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 other biologic DMARDs
Required Medical Information	Diagnosis of one of the following: 1. Ankylosing Spondylitis (AS); AND a. An inadequate response, or adverse reaction to at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at least 4 weeks unless clinically adverse effects are experienced or NSAIDs are

[+] *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.

contraindicated; ***OR***

b. An inadequate response, or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for ankylosing spondylitis; ***AND***

c. Dose does not exceed 40 mg every other week

2. Moderate to severely active Crohn's Disease (CD); ***AND***
   a. One of the following:
      i. Member has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this member; ***OR***
      ii. Member has tried one other conventional systemic therapy for Crohn's disease (such as azathioprine, 6-mercaptopurine, methotrexate, or a previous trial of a biologic; a trial of mesalamine does not count); ***OR***
      iii. Member has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; ***OR***
      iv. Member had ileocolonic resection (to reduce the chance of Crohn's disease recurrence);***AND***
   b. Dose does not exceed the following: 160 mg on day 1, 80 mg on day 15, then 40 mg every other week starting on day 29

3. Moderate to severe (Hurley Stage II or III) hidradenititis suppurativa (HS); ***AND***
   a. An inadequate response or adverse reaction to at least one other therapy (such as intralesional or oral corticosteroids [such as triamcinolone or prednisone], systemic antibiotics [such as clindamycin, dicloxacillin, or erythromycin] or isotretinoin); AND
   b. Dose does not exceed the following: 160 mg on day 1, 80 mg on day 15, then 40 mg every other week starting on day 29

4. Moderate to severe Plaque Psoriasis (Ps); AND
   a. One of the following:
      i. Involvement of at least 3% of total body surface area; ***OR***
      ii. Hands, feet, scalp, face, or genital area affected; ***AND***
   b. One of the following:
      i. An inadequate response, or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for plaque psoriasis; ***OR***
      ii. An inadequate response or adverse reaction to at least a 3 month trial of 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***

iii. A contraindication to methotrexate, as determined by the prescriber; ***AND***

c. Dose does not exceed 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose

5. Moderate to severe Polyarticular juvenile idiopathic arthritis (pJIA); AND
    a. 5 or more joints with active arthritis; ***AND***
    b. Baseline10-joint clinical juvenile arthritis disease activity score (cJADAS-10) has been documented; ***AND***
    c. One of the following:
        i. An inadequate response, or adverse reaction to at least a 3 month trial of one non-biologic DMARD or contraindication to non-biologic DMARDs; ***OR***
        ii. An inadequate response, or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for pJIA; ***OR***
        iii. Member will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide; ***OR***
        iv. Member has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide [note: examples of contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias]; ***AND***
    d. Dose does not exceed 40 mg every other week
6. Psoriatic Arthritis (PsA); ***AND***
    a. One of the following:
        i. An inadequate response, or adverse reaction to at least a 3 month trial of one non-biologic DMARD or contraindication to non-biologic DMARDs; ***OR***
        ii. An inadequate response, or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for psoriatic arthritis; ***AND***
    b. Dose does not exceed 40 mg every other week
7. Moderate to severe Rheumatoid arthritis (RA); ***AND***
    a. One of the following:
        i. An inadequate response, or adverse reaction to at least a 3 month trial of one non-biologic DMARD or contraindication to non-biologic DMARDs; ***OR***
        ii. An inadequate response, or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for RA; ***AND***
    b. Dose does not exceed 40 mg every other week; ***OR***
    c. If the requested dose is 40 mg every week or 80 mg every other week the following are met:
        i. The member is not taking concomitant methotrexate; ***AND***
        ii. The member tried 40 mg every other week dosing and did not get sufficient benefit
8. Moderate to severe Ulcerative Colitis (UC); ***AND***
    a. One of the following:
        i. Member has tried one systemic therapy (such as 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, a corticosteroid such as prednisone or methylprednisolone, or a previous trial of a biologic); ***OR***

	ii. Member has pouchitis and has tried an antibiotic (such as metronidazole or ciprofloxacin), probiotic, corticosteroid enema, or mesalamine enema; ***AND*** b. Dose does not exceed the following: 160 mg on day 1, 80 mg on day 15, then 40 mg every other week starting on day 29 9. Non-infectious uveitis (UV); ***AND*** a. One of the following: i. An inadequate response, or adverse reaction to one topical or systemic glucocorticoid, or a contraindication to all topical and systemic glucocorticoids; ***OR*** 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); ***AND*** b. Dose does not exceed 80 mg initial dose, followed by 40 mg every other week starting one week after initial dose
Age Restrictions	AS, Ps, PsA, RA: 18 years of age or older CD: 6 years of age or older HS: 12 years of age and older pJIA, UV: 2 years of age and older UC: 5 years of age or older
Prescriber Restriction	CD, UC: Prescribed by or in consultation with a gastroenterologist AS, pJIA, RA: Prescribed by or in consultation with a rheumatologist HS, Ps, PsA: Prescribed by or in consultation with a dermatologist or rheumatologist UV: Prescribed by or in consultation with a uveitis specialist (e.g. ophthalmologist, ocular immunologist)
Coverage Duration	12 months

Appendix

Diagnosis	Non-Biologic DMARD Treatment Options
Plaque Psoriasis	Methotrexate Azathioprine Cyclosporine
Polyarticular-Course Juvenile Idiopathic Arthritis	Methotrexate Leflunomide Sulfasalazine Azathioprine Cyclosporine
Psoriatic Arthritis	Methotrexate Leflunomide Sulfasalazine

	Azathioprine
Rheumatoid Arthritis	Methotrexate Leflunomide Sulfasalazine Azathioprine Hydroxychloroquine

Note: other trials may be considered on a case-by-case basis

Applicable Coding:

Code	Medication
J0135	Humira® (adalimumab injection)

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. 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, Klinkenbijl 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, Taminiau 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.
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
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

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
8/12/2021	P&T Annual Review. Update trial/failure criteria to align with other policies. Add dosing criteria to each indication. Add table of non-biologic DMARDs. Update prescriber and age restrictions. Remove reauthorization criteria.	1/1/2022	P&T Committee

Next Review Date

8/2022

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.