BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Infliximab Products

Policy Number: 9.123
Version Number: 2.0
Version Effective Date: 1/1/2022

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:

Preferred	**Non-Preferred** (additional criteria apply)
• Avsola (infliximab-axxq) • Inflectra (infliximab-dyyb) • Renflexis (infliximab-adba)	• Remicade (infliximab)

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

Covered Use	All FDA approved indications not otherwise excluded

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Exclusion Criteria	Use with other biologics DMARDs
Required Medical Information	Diagnosis of one of the following: 1. Ankylosing Spondylitis (AS); ***AND*** a. One of the following: i. An inadequate responseor 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 NSAIDs are contraindicated; ***OR*** ii. 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*** b. An inadequate response (to at least a 3 month trial), intolerance, or contraindication to Enbrel AND Humira or a clinical rationale for use of the requested agent instead of Enbrel AND Humira. 2. Moderate to severely active Crohn's Disease (CD) (except fistulizing); ***AND*** a. One of the following: i. An inadequate response or adverse reaction to at least a 3 consecutive month trial of at least one immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate) or a contraindication to them all; ***OR*** ii. An inadequate response or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for Crohn's disease; ***AND*** b. An inadequate response (to at least a 3 month trial), intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira. 3. Fistulizing Crohn's Disease (CD); a. One of the following: i. An inadequate response or adverse reaction to at least a 3 consecutive month trial of azathioprine or 6-mercaptopurine or a contraindication to them both; ***OR*** ii. An inadequate response or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for Crohn's disease; ***AND*** b. An inadequate response (to at least a 3 month trial), intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira. 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 any one of the following combinations (please note: these combinations DO NOT have to be used concurrently): a. one topical agent plus one systemic agent; ***OR*** b. one topical agent plus one phototherapy; ***OR*** c. one systemic agent plus one phototherapy; ***OR*** d. two systemic agents; ***OR*** ii. A contraindication to all conventional therapies (topical agents,

phototherapy, and systemic agents); ***OR***

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

c. An inadequate response(to at least a 3 month trial), intolerance, or contraindication to Enbrel AND Humira or a clinical rationale for use of the requested agent instead of Enbrel AND Humira

5. Psoriatic Arthritis (PsA); ***AND***
   a. One of the following:
      i. An inadequate response or intolerance to at least a 3month 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. An inadequate response (to at least a 3 month trial), intolerance, or contraindication to Enbrel AND Humira or a clinical rationale for use of the requested agent instead of Enbrel AND Humira.
6. Moderate to severe Rheumatoid arthritis (RA); ***AND***
   a. One of the following:
      i. An inadequate response or intolerance 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. An inadequate response(to at least a 3 month trial), intolerance, or contraindication to Enbrel AND Humira or a clinical rationale for the use of the requested agent instead of Enbrel AND Humira
7. Moderate to severe Ulcerative Colitis (UC); ***AND***
   a. One of the following:
      i. An inadequate response or adverse reaction to at least a 3 consecutive month trial of azathioprine, 6-mercaptopurine, or an aminosalicylate (e.g. sulfasalazine) or a contraindication to all three; ***OR***
      ii. An inadequate response or adverse reaction to at least a 3 month trial of one biologic DMARD that is FDA-approved for UC; ***AND***
   b. An inadequate response(to at least a 3 month trial), intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira

<u>8. Sarcoidosis; ***AND***</u>

<u>a. The member has had an inadequate response or intolerance to a trial of corticosteroids or immunosuppressants (such as methotrexate, azathioprine, leflunomide, mycophenolate mofetil, etc.) or a contraindication to both corticosteroids and immunosuppressants; ***OR***</u>

<u>b. The member has severe neurosarcoidosis or cardiac sarcoidosis with life-threatening organ dysfunction</u>

<u>In addition to the above criteria, the following needs to be met for requests for **Remicade**:</u>

1. Documentation that the member has experienced clinically significant adverse effects from all formulary infliximab biosimilars; ***OR***
2. Documentation that member has a contraindication to excipients in all formulary infliximab

	biosimilars that are not present in Remicade
Age Restrictions	AS, Ps, PsA, RA: 18 year of age or older CD, UC: 6 years of age or older
Prescriber Restriction	AS, RA: Prescribed by or in consultation with a rheumatologist CD, UC: Prescribed by or in consultation with a gastroenterologist Ps. PsA: Prescribed by or in consultation with a dermatologist or rheumatologist
Coverage Duration	12 months

Appendix

Diagnosis	Non-Biologic DMARD Treatment Options
Plaque Psoriasis	Methotrexate 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
J1745	Remicade® (infliximab injection)
Q5103	Inflectra® (infliximab-dyyb injection) - biosimilar
Q5104	Renflexis® (infliximab-abda injection) - biosimilar
Q5121	Avsola™ (infliximab-axxq 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. Avsola (infliximab-axxq) [package insert]. Thousand Oaks, CA: Amgen, Inc.; April 2021.
4. Bhosle M, Kulkarni A, Feldman SR et al. Quality of life in patients with psoriasis. Health Qual Life Outcomes. 2006;4:35.
5. 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
6. 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.
7. Enbrel prescribing information. Thousand Oaks, CA: Amgen and Wyeth Pharmaceuticals; 2013 November.
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.
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. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; June 2016.
13. Inflectra (infliximab-abda) [prescribing information]. Kenilworth, NJ: Merck Sharp & Dohme Corp; April 2017.
14. 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.
15. Kornbluth A, Sachar DB. Ulcerative Colitis Practice Guidelines in Adults. American College of Gastroenterology Practice Parameters Committee. 2004.
16. Krueger G, Ellis CN. Psoriasis-recent advances in understanding its pathogenesis and treatment. J Am Acad Dermatol. 2005; 53(1 Suppl 1):S94-100.
17. Langley RGB, Krueger GG, Griffiths CEM. Psoriasis: epidemiology, clinical features, and quality of life. Ann Rheum Dis. 2005; 64(Suppl 2): ii18-23.
18. Lebwohl M. Psoriasis. Lancet. 2003; 361(9364):1197-204.

19. Lichtenstein G, Loftus E, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol 2018; 113:481-517.
20. 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.
21. McEvoy GK, ed. AHFS 2013 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2013.
22. 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.
23. Papoutsaki M, Osório F, Morais P, et al. Infliximab in psoriasis and psoriatic arthritis. BioDrugs. 2013 Jan;27 Suppl 1:13-23.
24. 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.
25. 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.
26. Remicade (infliximab) [package insert]. Malvern, PA: Centocor Ortho Biotech, Inc.; January 2015.
27. Renflexis (inflisimab-abda) [package insert]. Kenilworth, NJ: Merck Sharp & Dohme Corp. Inc.; April 2017.
28. 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.
29. Schneider M, Krüger K. Rheumatoid arthritis-early diagnosis and disease management. Dtsch Arztebl Int. 2013 Jul;110(27-28):477-84.
30. 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.
31. 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
32. 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.
33. 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.

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	9.186 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 PsA criteria time requirements to reflect EULAR guidelines, updated time requirement in RA criteria to reflect ACR guidelines. Removed adherence requirement.	1/1/2021	P&T Committee
8/12/2021	P&T Annual Review. Added Avsola to coverage and made Remicade non-preferred. Added exclusion criteria. Updated some requirements to match other policies. Added table of non-biologic DMARDs.	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.

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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.