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)
• Inflectra (infliximab-dyyb) • Remicade (infliximab)	• Avsola (infliximab-axxq) • Renflexis (infliximab-adba)

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 with other biologics DMARDs

[+] *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.

Required Medical Information	Diagnosis of one of the following: 1. Ankylosing Spondylitis (AS); ***AND*** a. One of the following: i. 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 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*** An inadequate response, 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, 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-mercaptopurineor 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, 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): 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*** 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, 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 three 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. An inadequate response, 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 three 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, 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, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira; AND 8. Sarcoidosis; ***AND*** 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*** b. The member has severe neurosarcoidosis or cardiac sarcoidosis with life-threatening organ dysfunction <u>In addition to the above criteria, the following needs to be met for requests for **Avsola** and **Renflexis**:</u> 1. Documentation that the member has experienced clinically significant adverse effects from Remicade AND Inflectra; ***OR***

	2. Documentation that member has a contraindication to excipients in Remicade AND Inflectra that are not present in Avsola and Renfelxis
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

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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. Biosimilar products preferred	1/1/2021	P&T Committee
8/12/2021	P&T Annual Review. Add Avsola to coverage. Co-prefer Remicade and Inflectra over Avsola and Renflexis. Add exclusion criteria. Update some requirements to match other policies. Remove reauthorization criteria. Add 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.

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.