BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Enbrel (etanercept)

Policy Number: 9.119
Version Number: 2.0
Version Effective Date: 11/1/2021

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:

- Enbrel SQ prefilled syringe
- Enbrel Mini SQ cartridge
- Enbrel SQ solution
- Enbrel SureClick SQ Auto-injector

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 Enbrel in combination with other biologic DMARDs
Required Medical Information	1. A diagnosis of 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 clinically adverse effects are experienced or NSAIDs are contraindicated; ***OR*** ii. An inadequate respons, or adverse reaction to at least a 3 month trial of one

[+] *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.

biologic DMARD that is FDA-approved for ankylosing spondylitis; ***AND***

b. Dose does not exceed 50 mg per week

2. A diagnosis of 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. 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. Inadequate response or adverse reaction to at least a 3 month trial of two conventional therapies (as defined below) in any one of the following combinations (please note: these combinations DO NOT have to be used concurrently):
            1. 1 topical agent + 1 systemic agent; ***OR***
            2. 1 topical agent + 1 phototherapy; ***OR***
            3. 1 systemic agent + 1 phototherapy; ***OR***
            4. 2 systemic agents; ***OR***
        iii. Contraindication to methotrexate, as determined by the prescriber; ***AND***
    c. Dose does not exceed one of the following:
        i. Adults: 50 mg twice weekly for 3 months, followed by maintenance dose of 50 mg once weekly
        ii. Pediatrics: 0.8 mg/kg (up to a max dose of 50 mg) once weekly

3. A diagnosis of moderate to severe Polyarticular Juvenile Idiopathic Arthritis (pJIA); ***AND***
    a. 5 or more joints with active arthritis; ***AND***
    b. Baseline 10-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 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 50 mg per week

4. A diagnosis of 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 50 mg per week 5. A diagnosis of 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 50 mg per week
Age Restrictions	Ps: 4 years of age or older pJIA: 2 years of age or older PsA, RA, AS: 18 years of age or older
Prescriber Restriction	RA, pJIA, AS: Prescribed by or in consultation with a rheumatologist 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
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
J1438	Enbrel ® (entanercept injection)

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	9.184 Humira Policy retired, new policy created. Updated age restrictions, added step through Humira for plaque psoriasis, removed adherence requirement.	1/1/2021	P&T Committee
8/12/2021	P&T Annual Review. Removed reauthorization criteria; added 3 month time frame for trial/failure requirements; added some additional criteria to pJIA and Ps; removed Humira requirement from Ps; added table of non-biologic DMARDs.	11/1/2021	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.