Pharmacy Policy

Enbrel (etanercept)

Policy Number: 9.119
Revision Number: R0
Version Effective Date: 1/1/2021

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:

- Enbrel (etanercept)

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 another biologic
Required Medical Information	Diagnosis of one of the following: 1. A diagnosis of Ankylosing Spondylitis (AS); ***AND*** a. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs; ***OR*** b. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for ankylosing spondylitis 2. A diagnosis of Plaque Psoriasis (Ps); ***AND*** a. ONE 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.

	i. Inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis; ***OR*** ii. Inadequate response, or adverse reaction to 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 ALL conventional therapies (topical agents, phototherapy, and systemic agents) 3. A diagnosis of Polyarticular Juvenile Idiopathic Arthritis (pJIA); ***AND*** a. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs; ***OR*** b. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for pJIA 4. A diagnosis of Psoriatic Arthritis (PsA); ***AND*** a. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDs; ***OR*** b. An inadequate response, or adverse reaction to one biologic DMARD that is FDA-approved for psoriatic arthritis 5. A diagnosis of Rheumatoid Arthritis (RA); ***AND*** a. An inadequate response, or adverse reaction to one traditional DMARD or contraindication to traditional DMARDS; ***OR*** b. An inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for RA.
Age Restrictions	Ps: 4 years of age or older pJIA: 2 years of age or older AS, PsA, RA: 18 years of age or older
Prescriber Restriction	RA, pJIA, PsA, RA, AS: Prescribed by or in consultation with a rheumatologist Ps: Prescribed by or in consultation with a dermatologist
Coverage Duration	12 months
Quantity Limit	RA, pJIA, AS, PsA: 25mg syringe – 8 syringes per 28 days; 50mg syringe – 4 syringes per 28 days Ps: 25mg syringe: 16 syringes per 28 days for initial 12 weeks, then 8 syringes per 28 days thereafter; 50mg syringe – 8 syringes per 28 days for initial 12 weeks, then 4 syringes per 28 days thereafter
Other criteria	Reauthorization: 1. Clinical condition has improved or stabilized

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, NH DHHS

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
6/12/2018	Moved from Policy 9.126 Systemic Immunomodulators	11/01/2018	P&T Committee
05/09/2019	P&T Annual review. No criteria changes	09/02/2019	P&T Committee and NH DHHS
6/11/2020	P&T Annual Review, No changes required	10/1/2020	P&T Committee
12/1/2020	9.184 Humira Policy retired, new policy created. Updated age restrictions, removed adherence requirement.	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

9.015 Quantity Limitation Policy
9.080 Non Preferred Policy

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.