

Pharmacy Policy

Tremfya

Policy Number: 9.150

Version Number: 2.0

Version Effective Date: 1/1/2022

Product Applicability <input type="checkbox"/> All Plan+ Products	
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input type="checkbox"/> New Hampshire Medicaid	<input type="checkbox"/> MassHealth - MCO
	<input type="checkbox"/> MassHealth - ACO
	<input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Tremfya (guselkumab)

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 in combination with another biologic
Required Medical Information	Diagnosis of one of the following: 1. 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

* 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.

	<p>b. One of the following:</p> <ul style="list-style-type: none"> i. An inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis; OR ii. An inadequate response or adverse reaction to at least a 3 month consecutive trial of any one of the following combinations (please note: these combinations DO NOT have to be used concurrently) <ul style="list-style-type: none"> 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. <p>2. Psoriatic Arthritis (PsA); AND</p> <ul style="list-style-type: none"> a. One of the following: <ul style="list-style-type: none"> i. An inadequate response or adverse reaction to at least a 3 consecutive month trial of one traditional disease modifying antirheumatic drug (DMARD) or contraindication to all traditional DMARDs; OR ii. An inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for psoriatic arthritis.
Age Restrictions	18 years of age or older
Prescriber Restriction	Ps: Prescribed by or in consultation with a dermatologist PsA: Prescribed by or in consultation with a rheumatologist
Coverage Duration	12 months
Other criteria	Reauthorization: <ul style="list-style-type: none"> 1. Initial criteria are met; AND 2. Members clinical condition has improved or stabilized

Appendix

Diagnosis	Non-Biologic DMARD Treatment Options
Plaque Psoriasis	Methotrexate Azathioprine Cyclosporine
Psoriatic Arthritis	Methotrexate Leflunomide

* 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.

	Sulfasalazine Azathioprine
--	-------------------------------

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

Applicable Coding:

None

Clinical Background Information and References

1. American Academy of Dermatology Association. Psoriasis Clinical Guideline. <https://www.aad.org/member/clinical-quality/guidelines/psoriasis>. Accessed July 2021
2. Ogdie A, et al. 2021 American College of Rheumatology Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology*. 2021 Jan;71(1):5-32.
3. Tremfya (guselkumab) [package insert]. Horsham, PA. Accessed July 21, 2020.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/24/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/24/2021	New policy created.	7/1/2021	P&T Committee
8/12/2021	P&T Annual Review: Addition of 3 month trial time requirement; Addition of diagnostic criteria and change to non-biologic DMARD contraindication from all to MTX only for Ps to align with ESI ICCV guidelines.	1/1/2022	P&T Committee

Next Review Date

8/2022

* 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.

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.

^{*} *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.