BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Stelara

Policy Number: 9.129
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:

- Stelara® (ustekinumab) subcutaneous injection
- Stelara® (ustekinumab) IV (induction of therapy only)

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

Covered Use	All medically accepted indications not otherwise excluded
Exclusion Criteria	Use in combination with other biologics
Required Medical Information	1. Moderate to severely Active Crohn's Disease (CD); ***AND*** a. One of the following: i. Member has tried or is currently taking corticosteroids, or corticosteroids are

[+] *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.

contraindicated in this member; **OR**

ii. Member has tried one conventional systemic therapy for Crohn's disease (such as azathioprine, 6-mercaptopurine, methotrexate, or a previous trial of a biologic; a trial of mesalamine does not count); **OR**

iii. Member has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; **OR**

iv. Member had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); **AND**

b. According to the prescriber, the patient will receive a single induction dose with Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous.

2. 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 one conventional therapy (as defined below) in 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***

iii. Contraindication to methotrexate, as determined by the prescriber.

3. 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 traditional disease modifying antirheumatic drug (DMARD) or contraindication to all traditional DMARDs; **OR**

ii. An inadequate response or adverse reaction to at least a 3 consecutive month trial of one biologic DMARD FDA approved for Psoriatic Arthritis.

4. Moderate to severely active Ulcerative Colitis (UC); ***AND***

	a. One of the following: i. Member has tried one systemic therapy (such as 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, a corticosteroid such as prednisone or methylprednisolone, or a previous trial of a biologic); ***OR*** ii. Member has pouchitis and has tried an antibiotic (such as metronidazole or ciprofloxacin), probiotic, corticosteroid enema, or mesalamine enema; ***AND*** b. According to the prescriber, the patient will receive a single induction dose with Stelara intravenous within 2 months of initiating therapy with Stelara subcutaneous.
Age Restrictions	CD, PsA, UC: 18 years of age or older Ps: 6years of age or older
Prescriber Restriction	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
Other criteria	Reauthorization: 1. Member has previously met initial criteria. **AND** 2. Member's clinical condition has improved or stabilized.

Appendix

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

Applicable Coding:

Code	Medication
J3358	Stelara (ustekinumab IV 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	9.193 Stelara Policy retired, new policy created. Updated age expansion for PS; updated trial and failure requirements for some indications	1/1/2021	P&T Committee
4/23/2021	Removed trial requirement of Humira for diagnosis of Ulcerative Colitis (UC) to align with ESI ICCV	4/23/2021	P&T Committee
8/12/2021	P&T Annual Review: Addition of 3 month requirement for most trials; Addition of criteria to all indications to allow a previous trial of a biologic DMARD to bypass non-biologic DMARD criteria; Criteria updates for CD and UC to align with ESI ICCV policy guidelines and trial requirements; Addition of meeting initial criteria to reauthorization guidelines; Addition of diagnostic criteria for Ps.	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.