Pharmacy Policy

Stelara

Policy Number: 9.129
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:

- Stelara (ustekinumab)

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	Diagnosis of one of the following: 1. Moderate to severely Active Crohn's Disease (CD); ***AND*** a) One of the following i. An inadequate response, contraindication or intolerance to use of **ALL** of the following: 1. 5-aminosalicylic acid (e.g. mesalamine) 2. 6-mercaptopurine, azathioprine, and/or methotrexate

[+] *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.

3. corticosteroids; ***OR***

ii. Patient is considered to have a severe form of the disease. This includes: high risk for surgical intervention (e.g. colectomy), hospitalization, extensive disease, severe endoscopic activity (presence of large and/or deep ulcers), presence of extra-intestinal manifestations, early need for corticosteroids, and elevated inflammatory markers ***AND***

b. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira.

2. Moderate to severe plaque psoriasis (Ps); ***AND***
   a. ONE of the following:
      i. An inadequate response or adverse reaction to any one of the following combinations (please note: these combinations DO NOT have to be used concurrently) **or a contraindication to all**:
         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; ***AND***

   b. An inadequate response, intolerance, or contraindication to Enbrel, Humira, or Cosentyx OR a clinical rationale for use of the requested agent instead of Enbrel, Humira, or Cosentyx.

3. Psoriatic Arthritis (PsA); ***AND***
   a. An inadequate response, or adverse reaction to a 3 month trial of 1 non-biologic DMARD or contraindication to non-biologic DMARDs; ***AND***
   b. An inadequate response, intolerance, or contraindication to Enbrel, Humira, or Cosentyx OR a clinical rationale for use of the requested agent instead of Enbrel, Humira, or Cosentyx

4. Moderate to severely active Ulcerative Colitis (UC); ***AND***
   a. One of the following:
      i. An inadequate response, contraindication or intolerance to ALL of the following:
         i.5-aminosalicylc acid (e.g. mesalamine)
         ii. 6-mercaptopurine, azathioprine, or methotrexate
         iii. A corticosteroid ***OR***
      ii. Patient is considered to have a severe form of the disease. This includes: high risk for surgical intervention (e.g. colectomy), hospitalization, extensive disease, severe endoscopic activity (presence of large and/or deep ulcers), presence of extra-intestinal manifestations, early need for corticosteroids, and elevated inflammatory markers ***AND***
   b. An inadequate response, intolerance, or contraindication to Humira or a clinical

	rationale for use of Stelara instead of Humira
Age Restrictions	CD, PsA, UC: 18 years of age or older Ps: 6 years of age or older
Prescriber Restriction	CD, UC: Prescribed by or in consultation with a gastroenterologist PS: Prescribed by or in consultation with a dermatologist or rheumatologist PsA: Prescribed by or in consultation with a rheumatologist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Currently receiving medication via Well Sense benefit or member has previously met initial approval criteria; **AND** 2. Patient's clinical condition has improved or stabilized

Applicable Coding:

Code	Medication
J3358	Stelara (ustekinumab injection)

Clinical Background Information and References

1. Ash Z, Gaujoux-Viala C, Gossec L et al. A systematic literature review of drug therapies for the treatment of psoriatic arthritis: current evidence and meta-analysis informing the EULAR recommendations for the management of psoriatic arthritis. Ann Rheum Dis. 2012 Mar; 71(3):319-26.
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15. Langley RGB, Krueger GG, Griffiths CEM. Psoriasis: epidemiology, clinical features, and quality of life. Ann Rheum Dis. 2005; 64(Suppl 2): ii18-23.
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17. Lebwohl M. Psoriasis. Lancet. 2003; 361(9364):1197-204.
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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**
12/1/2020	9.193 Stelara Policy retired, new policy created. Updated age expansion for PS; updated policy for trial and failure to align with NH state PDL requirements	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.