Pharmacy Policy

Otezla

Policy Number: 9.127
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:

- Otezla (apremilast)

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	None
Required Medical Information	Diagnosis of one of the following: 1. Active 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 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; ***This includes:***

[+] *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. Patient has documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria). 2. Moderate to severe Plaque Psoriasis; ***AND*** a. An inadequate response, or adverse reaction to **two** conventional therapies in any one of the following combinations (please note: these combinations DO NOT have to be used concurrently) or **a contraindication to all**: I. One topical agent plus one systemic agent; ***OR*** II. One topical agent plus one phototherapy; ***OR*** III. One systemic agent plus one phototherapy; ***OR*** IV. Two systemic agents AND b. An inadequate response, intolerance, or contraindication to Enbrel ,Humira or Cosentyx, OR a clinical rationale for the use of the requested agent instead of Enbrel, Humira or Cosentyx.. ***This includes****:* i. Patient has documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV_TR 300.29 for specific phobia diagnostic criteria) 3. Behçet's Disease; AND a. Documentation of active oral ulcers; ***AND*** b. Documentation of inadequate response, intolerance, or contraindication to **one** topical glucocorticoid (ex: triamcinolone); ***AND*** c. Patient has documentation of inadequate response, intolerance, or contraindication to **one** of the following: i. Azathioprine; ***OR*** ii. Oral colchicine therapy
Age Restrictions	18 years of age or older
Prescriber Restriction	PsA: Prescribed by or in consultation with a rheumatologist Ps: Prescribed by or in consultation with a dermatologist BD: Prescribed by or in consultation with a rheumatologist or dermatologist
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:

None

Clinical Background Information and References

1. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the management of rheumatoid arthritis: 2002 Update. Arthritis Rheum. 2002; 46(2):328-46.
2. Birbara C, Blanco FJ, Crowley JJ et al. Efficacy of apremilast, an oral phosphodiesterase 4 inhibitor, on physical function and pain in patients with psoriatic arthritis, including current skin involvement: results of a phase 3, randomized, controlled trial. Ann Rheum Dis. 2013a; 72(Suppl3):678. Abstract.
3. Birbara C, Blanco FJ, Hu C et al. Apremilast, an oral phosphodiesterase 4 inhibitor, in patients with psoriatic arthritis including current skin involvement: results of a phase 3, randomized, controlled trial. Ann Rheum Dis. 2013b; 72(Suppl3):85. Abstract.
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6. Cutolo M, Myerson GE, Fleischmann RM et al. Long-term (52-week) results of a phase 3, randomized, controlled trial of apremilast, an oral phosphodiesterase 4 inhibitor, in patients with psoriatic arthritis (PALACE 2). Arthritis Rheum. 2013; 65(Suppl10):815. Abstract.
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9. Gladman DD, Antoni C, Mease P et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis. 2005; 64(Suppl2):ii14-ii17.
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12. Hatemi G, Christensen R, Bang D, et al2018 update of the EULAR recommendations for the management of Behçet's syndromeAnnals of the Rheumatic Diseases 2018;77:808-818.
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14. Humira prescribing information. North Chicago, IL: AbbVie Inc.; 2016 June.
15. Kavanaugh A, Mease P, Adebajo AO et al. Long-term (52-week) results of a phase 3, randomized, controlled trial of apremilast, an oral phosphodiesterase 4 inhibitor, in patients with psoriatic arthritis. Ann Rheum Dis. 2013; 72(Suppl3):163. Abstract.

16. Kavanaugh A, Mease P, Gomez-Reino JJ et al. Treatment of psoriatic arthritis in a phase 3 randomised, placebo-controlled trial with apremilast, an oral phosphodiesterase 4 inhibitor. Ann Rheum Dis. In press.
17. Kirkham BW, Kavanaugh A, Reich K. Interleukin-17a: a unique pathway in immune-mediated diseases: psoriasis, psoriatic arthritis and rheumatoid arthritis. Immunology. 2014; 141(2):133- 42.
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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

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.190 Otezla Policy retired; new policy created; updated trial of preferred agents to align with NH PDL requirements	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

9.015 Quantity Limitation 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.