

Pharmacy Policy

Skyrizi

Policy Number: 9.140

Version Number: R0

Version Effective Date: 1/1/2021

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:

- Skyrizi (risankizumab-rzaa)

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	Coverage will not be provided for use in combination with other biologics or with targeted synthetic disease-modifying antirheumatic drugs (DMARDs)(includes Otezla, Olumiant, Rinvoq, Xeljanz, Xeljanz XR)
Required Medical Information	<ol style="list-style-type: none"> 1. A diagnosis of Plaque Psoriasis; AND <ol style="list-style-type: none"> a. Trial and failure of 1 or more Preferred products (see Appendix A) required prior to use; AND b. 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):

* 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.

	<ol 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 <p style="margin-left: 40px;">c. A contraindication to all conventional therapies (topical agents, phototherapy, and systemic agents)</p>
Age Restrictions	18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial: 3 months Reauthorization: 1 year
Other criteria	Reauthorization: <ol style="list-style-type: none"> 1. Currently receiving medication via Well Sense benefit or member has previously met initial approval criteria; AND 2. Clinical condition has improved or shown positive response to Skyrizi

Appendix A

Preferred Products
Cosentyx
Enbrel
Humira

Applicable Coding:

None

Clinical Background Information and References

1. Bhosle M, Kulkarni A, Feldman SR et al. Quality of life in patients with psoriasis. Health Qual Life Outcomes. 2006;4:35.
2. Callen JP, Krueger GG, Lebwohl M et al. AAD consensus statement on psoriasis therapies. J Am Acad Dermatol. 2003; 49:897-9.
3. Farahnik B, Beroukhim K, Zhu TH et al. Ixekizumab for the Treatment of Psoriasis: A Review of Phase III Trials. Dermatol Ther. 2016 Mar;6(1):25-37.
4. Food and Drug Administration. Drugs@FDA. URL: accessdata.fda.gov/scripts/cder/drugsatfda. Available from Internet. Accessed 2015 June 12.

^{*} 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.

5. Gisondi P, Fantin F, Del Giglio M et al. Chronic plaque psoriasis is associated with increased arterial stiffness. *Dermatology*. 2009; 218(2):110-3.
6. Gisondi P, Galvan A, Idolazzi L et al. Management of moderate to severe psoriasis in patients with metabolic comorbidities. *Front Med*. 2015 ;2:1.
7. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2015 Dec 7
8. Krueger G, Ellis CN. Psoriasis-recent advances in understanding its pathogenesis and treatment. *J Am Acad Dermatol*. 2005; 53(1 Suppl 1):S94-100.
9. Lebwohl M. Psoriasis. *Lancet*. 2003; 361(9364):1197-204.
10. Lowes MA, Suárez-Fariñas M, Krueger JG. Immunology of psoriasis. *Annu Rev Immunol*. 2014;32:227-55.
11. Mason J, Mason AR, Cork MJ. Topical preparations for the treatment of psoriasis: a systematic review. *Br J Dermatol*. 2002; 146(3):351-64.
12. Menter A, Korman N, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011; 65(1):137-74.
13. National Psoriasis Foundation. About psoriasis. URL: psoriasis.org/about-psoriasis. Available from Internet. Accessed 2016 August 5.
14. Ramiro S, Smolen JS, Landewé R, et al. Pharmacological treatment of psoriatic arthritis: a systematic literature review for the 2015 update of the EULAR recommendations for the management of psoriatic arthritis. *Ann Rheum Dis*. 2015 Dec 11.
15. Skyrizi™ [prescribing information]. Thousand Oaks, CA: Amgen; May 2020
16. Ungprasert P, Thongprayoon C, Davis JM 3rd. Indirect comparisons of the efficacy of biological agents in patients with psoriatic arthritis with an inadequate response to traditional disease-modifying anti-rheumatic drugs or to non-steroidal anti-inflammatory drugs: A meta-analysis. *Semin Arthritis Rheum*. 2015 Oct 3.

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	9.140 Skyrizi Policy created.	1/1/2021	P&T Committee, NH DHHS

* *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.

Next Review Date

2021

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.