

**Pharmacy Policy**

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**Skyrizi (risankizumab-rzaa)**

**Policy Number:** 9.140

**Version Number:** 1.3

**Version Effective Date:** 4/1/2022

Product Applicability <input type="checkbox"/> <b>All Plan<sup>+</sup> Products</b>	
<b>Well Sense Health Plan</b>	<b>Boston Medical Center HealthNet Plan</b>
<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**

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**Products Affected:**

- Skyrizi (risankizumab-rzaa)

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

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	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)
<b>Required Medical Information</b>	<ol style="list-style-type: none"> <li>1. A diagnosis of Plaque Psoriasis; <b>AND</b> <ol style="list-style-type: none"> <li>a. One of the following:                             <ol style="list-style-type: none"> <li>i. An inadequate response, or adverse reaction to at least a 3</li> </ol> </li> </ol> </li> </ol>

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	<p>consecutive month trial of one conventional therapy:</p> <ol style="list-style-type: none"> <li>1. One topical agent <b>OR</b></li> <li>2. Phototherapy; <b>OR</b></li> <li>3. One systemic agent <b>OR</b></li> <li>4. A contraindication to methotrexate, as determined by the prescriber; <b>OR</b></li> </ol> <p>ii. An inadequate response or adverse reaction to at least a 3 consecutive month trial of one biologic DMARD that is FDA-approved for plaque psoriasis.</p> <p>2. A diagnosis of Psoriatic Arthritis; <b>AND</b></p> <ol style="list-style-type: none"> <li>i. Prescribed by or in consultation with a dermatologist or rheumatologist</li> </ol>
<b>Age Restrictions</b>	18 years of age or older
<b>Prescriber Restriction</b>	Prescribed by or in consultation with a dermatologist or rheumatologist
<b>Coverage Duration</b>	Initial: 3 months Reauthorization: 1 year
<b>Other criteria</b>	Reauthorization: <ol style="list-style-type: none"> <li>1. Initial criteria; <b>AND</b></li> <li>2. Clinical condition has improved or shown positive response to Skyrizi.</li> </ol>

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

**Applicable Coding:**

None

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## Clinical Background Information and References

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17. 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 diseasemodifying 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

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
8/12/2021	P&T Annual Review: Addition of diagnostic criteria; Addition of 3 consecutive month trial requirement of conventional therapies; change criteria for a contraindication to ALL conventional therapies to a contraindication to methotrexate only to align with ESI ICCV guidelines.	1/1/2022	P&T Committee
3/7/2022	Updated policy to include new indication of Psoriatic Arthritis and to align with ESI ICCV.	4/1/2022	P&T Committee

**Next Review Date**

8/2022

**Other Applicable Policies**

**Reference to Applicable Laws and Regulations, If Any**

**Disclaimer Information**

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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.

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