

Pharmacy Policy

Simponi subcutaneous (golimumab)

Policy Number: 9.128

Version Number: 2.2

Version Effective Date: 4/1/2022

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input type="checkbox"/> MassHealth - MCO</p> <p><input type="checkbox"/> MassHealth - ACO</p> <p><input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Simponi subcutaneous (golimumab)

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	<p>1. Diagnosis of Rheumatoid Arthritis (RA); AND</p> <p>a. Documentation* is provided showing member has tried TWO of the following: Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR [Note: a trial of either or both Xeljanz products collectively counts as ONE product].</p> <p>2. Diagnosis of Ankylosing Spondylitis(AS); AND</p> <p>a. Documentation* is provided showing member has tried TWO of the following: Enbrel,</p>

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	<p>Humira, Taltz, and Xeljanz/XR [Note: a trial of either or both Xeljanz products collectively counts as ONE product].</p> <p>3. Diagnosis of Psoriatic Arthritis (PsA); AND</p> <p>a. Documentation* is provided showing member has tried TWO of the following: Enbrel, Humira, Otezla, Rinvoq, Skyrizi, Stelara subcutaneous, Taltz, Tremfya, and Xeljanz/XR [Note: a trial of either or both Xeljanz products collectively counts as ONE product].</p> <p>4. Diagnosis of Ulcerative Colitis(UC); AND</p> <p>a. An inadequate response, intolerance, or contraindication to Humira or a clinical rationale for use of the requested agent instead of Humira</p> <p>* Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts</p>
Age Restrictions	18 years of age or older
Prescriber Restriction	AS, RA: Prescribed by or in consultation with a rheumatologist PsA: Prescribed by or in consultation with a rheumatologist or a dermatologist UC: Prescribed by or in consultation with a gastroenterologist
Coverage Duration	Initial: 3 month Reauthorization: 12 months
Other criteria	Reauthorization: 1. Initial criteria are met; AND 2. Member's clinical condition has improved or stabilized

Applicable Coding:

None

Clinical Background Information and References

1. Simponi® injection [prescribing information]. Horsham, PA: Janssen Biotech Inc; September 2019.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/24/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

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Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/24/2021	Policy created	7/1/2021	P&T Committee
8/12/2021	P&T Annual Review. Minor rewording (intent the same). Updated prescriber restrictions	1/1/2022	P&T Committee
1/20/2022	Updated policy to realign with ESI ICCV policy.	3/1/2022	P&T Committee
3/7/2022	Updated policy to realign with ESI ICCV policy designation of Skyrizi PsA preferred status	4/1/2022	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.

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