

Pharmacy Policy

Taltz

Policy Number: 9.130

Revision 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:

- Taltz (ixekizumab)

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	Use in combination with another biologic
Required Medical Information	Diagnosis of one of the following: <ol style="list-style-type: none"> 1. Active psoriatic arthritis (PsA); AND <ol style="list-style-type: none"> a. Inadequate response, intolerance, or contraindication to a non-biologic DMARD or current use of a non-biologic DMARD; 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.

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	<p>2. Moderate to severe Plaque Psoriasis (Ps); AND</p> <p>a. ONE of the following:</p> <p>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):</p> <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>b. A contraindication to ALL conventional therapies (topical agents, phototherapy, and systemic agents); AND</p> <p>c. 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.</p>
Age Restrictions	<p>PsA: 18 years of age or older</p> <p>Ps: 6 years and older</p>
Prescriber Restriction	<p>PsA: Prescribed by or in consultation with a rheumatologist</p> <p>Ps: Prescribed by or in consultation with a dermatologist</p>
Coverage Duration	12 months
Other criteria	<p>Reauthorization:</p> <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 stabilized

Applicable Coding:

None

Clinical Background Information and References

1. Armstrong AW, Lynde CW, McBride SR et al. Effect of Ixekizumab Treatment on Work Productivity for Patients With Moderate-to-Severe Plaque Psoriasis: Analysis of Results From 3 Randomized Phase 3 Clinical Trials. JAMA Dermatol. 2016 Mar 7.
2. Bhosle M, Kulkarni A, Feldman SR et al. Quality of life in patients with psoriasis. Health Qual Life Outcomes. 2006;4:35.
3. Callen JP, Krueger GG, Lebwohl M et al. AAD consensus statement on psoriasis therapies. J Am Acad Dermatol. 2003; 49:897-9.

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4. Enbrel prescribing information. Thousand Oaks, CA: Amgen Inc. and Pfizer Inc.; 2015 March.
5. 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.
6. Gisondi P, Fantin F, Del Giglio M et al. Chronic plaque psoriasis is associated with increased arterial stiffness. *Dermatology.* 2009; 218(2):110-3.
7. Gisondi P, Galvan A, Idolazzi L et al. Management of moderate to severe psoriasis in patients with metabolic comorbidities. *Front Med.* 2015 ;2:1.
8. Gordon KB. Ixekizumab for treatment of moderate-to-severe plaque psoriasis: 60-week results from a double-blind phase 3 induction and randomized withdrawal study (UNCOVER-1). Presented at: 73rd Annual Meeting of the American Academy of Dermatology; San Francisco; 2015.
9. Griffiths CE, Reich K, Lebwohl M et al. Comparison of ixekizumab with etanercept or placebo in moderate-to-severe psoriasis (UNCOVER-2 and UNCOVER-3): results from two phase 3 randomised trials. *Lancet.* 2015 Aug 8;386(9993):541-51.
10. Humira prescribing information. North Chicago, IL: AbbVie Inc.; 2016 June.
11. Krueger G, Ellis CN. Psoriasis-recent advances in understanding its pathogenesis and treatment. *J Am Acad Dermatol.* 2005; 53(1 Suppl 1):S94-100.
12. Lebwohl M. Psoriasis. *Lancet.* 2003; 361(9364):1197-204
13. Lowes MA, Suárez-Fariñas M, Krueger JG. Immunology of psoriasis. *Annu Rev Immunol.* 2014;32:227-55.
14. Mason J, Mason AR, Cork MJ. Topical preparations for the treatment of psoriasis: a systematic review. *Br J Dermatol.* 2002; 146(3):351-64.
15. 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.
16. Taltz (ixekizumab) [prescribing information]. Indianapolis, Indiana: Eli Lilly and Company; May 2018.

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	9.194 Taltz Policy retired, new policy created; removed adherence criteria from reauthorization; aligned trial and failure to align with NH State PDL	1/1/2021	P&T Committee, NH DHHS

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Policy Revisions History

	requirements; updated age expansion of PS		
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Next Review Date

2021

Other Applicable Policies

9.002 Mandatory Generic Substitution 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.

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