Pharmacy Policy

Taltz

Policy Number: 9.130
Version Number: 2.0
Version Effective Date: 1/1/2022

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:

- 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: 1. Active psoriatic arthritis (PsA); ***AND*** a. One of the following: i. An inadequate response or adverse reaction to at least a 3 consecutive month trial of one traditional DMARD or contraindication to ALL traditional

[+] *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.

	DMARDs; ***OR*** ii. An inadequate response or adverse reaction to at least a 3 consecutive month trial of one biologic DMARD that is FDA-approved for psoriatic arthritis. 2. Moderate to severe Plaque Psoriasis (Ps); ***AND*** a. One of the following: i. Involvement of at least 3% of total body surface area; **OR** ii. Hands, feet, scalp, face, or genital area affected; **AND** b. One of the following i. An inadequate response or adverse reaction to any one of the following combinations for at least 3 consecutive months (please note: these combinations DO NOT have to be used concurrently): 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*** 5. A contraindication to methotrexate, as determined by the prescriber; **OR** ii. An inadequate response or adverse reaction to one biologic DMARD that is FDA-approved for plaque psoriasis***.*** 3. Ankylosing Spondylitis (AS); ***AND*** a. One of the following: i. An inadequate response or adverse reaction to at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at least 4 weeks unless clinically adverse effects are experienced or ALL NSAIDs are contraindicated; **OR** ii. An inadequate response or adverse reaction to at least a 3 consecutive month trial of one biologic DMARD that is FDA-approved for ankylosing spondylitis. 4. Non-Radiographic axial spondyloarthritis (nr-axSpA); **AND** a. Both of the following: i. Provider attestation that there is active inflammation of the sacroiliac joints; **AND** ii. An inadequate response or adverse reaction to at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at least 4 weeks unless clinically adverse effects are experienced or NSAIDs are contraindicated.
Age	PsA, AS, nr-azSpA: 18 years of age or older

Restrictions	PS: 6 years and older
Prescriber Restriction	PsA, AS, nr-azSpA: Prescribed by or in consultation with a rheumatologist Ps: Prescribed by or in consultation with a dermatologist
Coverage Duration	12 months
Other criteria	Reauthorization: 1. Initial criteria are met; ***AND*** 2. Member's clinical condition has improved or stabilized

Appendix

Diagnosis	Non-Biologic DMARD Treatment Options (systemic agents)
Plaque Psoriasis	Methotrexate Azathioprine Cyclosporine
Psoriatic Arthritis	Methotrexate Leflunomide Sulfasalazine Azathioprine

Note: other trials may be considered on a case-by-case basis

Applicable Coding:

None

Clinical Background Information and References

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16. Ogdie A, et al. 2021 American College of Rheumatology Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2021 Jan;71(1):5-32.
17. Taltz (ixekizumab) [prescribing information]. Indianapolis, Indiana: Eli Lilly and Company; Accessed July 2021.
18. Ward M, Deodhar A, Gensler L et. al. 2019 Update of the American College of Rheumatology/ Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis and Rheumatology. 2019; 71 (10): 1599-1613.

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**

Policy Revisions History			
12/1/2020	9.194 Taltz Policy retired, new policy created; removed adherence criteria from reauthorization; updated trial and failure requirements; updated age expansion for PS	1/1/2021	P&T Committee
5/24/2021	Update criteria to align with ESI criteria.	7/1/2021	P&T Committee
8/12/2021	Annual P&T Review: Addition of trial time requirement to PsA and AS; Addition of diagnostic criteria, contraindication to MTX only for non-biologic DMARD trials, change criteria for AS from trial of one to two NSAIDS; addition of minor language to nr-axSpA criteria in regards to dosing of trial meds and addition of trial time requirement of 4 weeks.	1/1/2022	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.