CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Taltz (ixekizumab)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Taltz is an anti-interleukin 17A monoclonal antibody initially approved by the FDA in 2016. It currently has FDA labeled indications for ankylosing spondylitis, a rare inflammatory disease that causes some vertebrae bones to fuse, in adult patients; active non- radiographic axial spondyloarthritis, arthritis of the spine that could potentially lead to ankylosing spondylitis, with objective signs of inflammation in adult patients; moderate to severe plaque psoriasis, which is dry, raised, red patches covered with silvery scales on the skin, in adult and pediatric patients ≥ 6 years of age who are candidates for systemic therapy or phototherapy; and active psoriatic arthritis, a disease affecting points where tendons and ligaments attach to bones- causing painful, sausage-like swelling of the fingers and toes.

Taltz (ixekizumab) will be considered for coverage when the following criteria are met:

Ankylosing Spondylitis (AS) or Non-radiographic axial spondyloarthritis (nr-axSpA)

Note: Diagnosis of axial spondyloarthritis (axSpA) is also accepted. SpA comprises of 2 subtypes – ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Member has a documented diagnosis of active AS, nr-axSpA or axSpA; AND
3. Medication must be prescribed by or in consultation with a rheumatologist; AND
4. Member shows ONE of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacrolitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** Quantity Limit: 1 injection per 28 days (after loading doses).
   a) AS/axSpA: 160 mg subcutaneously (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks
   b) nr-axSpA: 80 mg subcutaneously every 4 weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has clinical documentation of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member has tried and failed to respond to treatment with **ONE** of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
5. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
6. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each (if member is < 18 years of age, member must try Enbrel only); AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** Quantity limit: 1 injection per 28 days (after loading doses).
   a) Adults: 160 mg (two 80 mg injections) at week 0, followed by 80 mg at week 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.
   b) Pediatrics:
      i) Weight > 50 kg: 160 mg (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks.
      ii) Weight 25-50 kg: 80 mg at week 0, followed by 40 mg every 4 weeks.
      iii) Weight < 25 kg: 40 mg at week 0, followed by 20 mg every 4 weeks.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing the member has shown improvement of signs and symptoms of disease such as documented member's BSA improvement, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Psoriatic Arthritis (PsA)

For initial authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or dermatologist; AND
3. Member has a documented diagnosis of active PsA; AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses AND a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Non-biologic DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are **NOT** required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has tried and failed **TWO** preferred biologic DMARDs for 3 months each; AND
6. Must have had a negative TB test within the last 12 months.
7. **Dosage allowed:** 160 mg (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks. For PsA patients with coexistent moderate-to-severe PsO, use the dosing regimen for adult PsO. Quantity limit: 1 injection per 28 days (after loading doses).

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease such as decreased joint swelling and pain, improved skin appearance, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Taltz (ixekizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/19/2017	New policy for Taltz created.
02/05/2018	New indication for Psoriatic Arthritis added.
02/26/2019	Humira was removed from criteria; Cimzia, Cosentyx, Otezla, Siliq and Xeljanz added to trial agents list. Initial authorization length increased to 12 months for PsO. TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed. Requirements on axial disease type removed from PsA. Reauthorization criteria on documented member's PASI score improvement incorporated into general chart noted documentation requirements. Other drugs options allowed for PsA if there is an intolerance or contraindication to methotrexate.
04/29/2020	Age requirement for diagnosis of PsO updated.
09/22/2020	Added new indications: Ankylosing Spondylitis and Non-radiographic Axial Spondyloarthritis. For PsO: Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. For PsA: Added requirement of diagnosis of PsA. Changed the trial section to be 4 weeks of an NSAID AND 3 months of a DMARD unless other circumstances apply (e.g., concomitant axial disease, severe PsA, etc.). Removed repeat TB test for reauthorization for all diagnoses.
2/22/2022	Transferred policy to new format; Removed initial criteria from reauthorization; Updated wording for biologic DMARDs; Clarified reauth criteria
08/19/2024	AS/ nr-axSpA: changed trial of each NSAID from 4 weeks to 2 weeks for a total of 4 weeks of treatment per EULAR 22 guidelines; removed criteria requiring back pain for 3 or more months before the age of 50; removed Positive HLA-B27 test from signs/symptoms of spondyloarthritis and changed to signs/symptoms inflammation; added axSpA to diagnosis list

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