

PHARMACY POLICY STATEMENT

Indiana Medicaid

DRUG NAME	Taltz (ixekizumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Enbrel, Cimzia, Cosentyx, Otezla, Siliq and Xeljanz QUANTITY LIMIT— 1 injection per 28 days (after loading doses)
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Taltz (ixekizumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

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 ankylosing spondylitis (AS) or active non-radiographic axial spondyloarthritis (nr-axSpA); AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Medication must be prescribed by or in consultation with a rheumatologist; AND
5. Member has had back pain for 3 months or more that began before the age of 50; AND
6. Member shows at least one of the following signs or symptoms of Spondyloarthritis:
 - a) Elevated serum C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR);
 - b) Positive HLA-B27 test;
 - c) Sacroiliitis; AND
7. Member has tried and failed to respond to treatment with at least **two** NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 4 weeks of therapy with each NSAID without an adequate response.
8. Member has tried and failed treatment with **two** of the following drugs, for 12 weeks per trial: Enbrel, Cimzia, or Cosentyx. (Note: will also accept any non-formulary trial of the same drug class).
9. **Dosage allowed:** AS: 160 mg (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks; nr-axSpA: 80 mg every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, 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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. Member has tried and failed to respond to treatment with at least **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
6. 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
7. Member has tried and failed treatment with at least **two** of the following: Cimzia, Cosentyx, Enbrel, Otezla and Siliq (Only applicable to members who is greater than or equal to 18 years old; if member is < 18 years of age - must try Enbrel only). Treatment failure requires at least 12 weeks of therapy with each drug.
8. **Dosage allowed:**
 - 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 member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided showing the member has shown improvement of signs and symptoms of disease (e.g., documented member's BSA improvement, etc.).

If member meets all the reauthorization requirements above, 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 psoriatic arthritis (PsA); AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), interferon-gamma release assay (IGRA)) within 12 months prior to starting therapy; AND
5. 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
6. Member has tried and failed treatment with at least **two** of the following: Enbrel, Cimzia, Cosentyx, Otezla and Xeljanz. Treatment failure requires at least for 12 weeks of therapy with each drug.
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.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Taltz (ixekizumab) not medically necessary for the treatment of the diseases that are not listed in this document.

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 <u>PsO</u> : Removed rheumatologist from prescriber. Changed BSA to 3% or sensitive area involvement. Removed PASI score requirement. For <u>PsA</u> : 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 reauth for all diagnoses.

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