

PHARMACY POLICY STATEMENT

Kentucky 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 Humira and Enbrel QUANTITY LIMIT— see Dosage allowed below
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.

PLAQUE PSORIASIS (PP)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has PP for 6 months or longer; AND
5. Member has PP involves 10% or more of the member's body surface area; AND
6. Member's Psoriasis Area and Severity Index (PASI) score is greater than or equal to 12; AND
7. Member has tried and failed to respond to treatment with at least **one** of the following:
 - a) At least 30 days of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
 - b) At least 30 days of phototherapy (i.e. UVB light therapy, Excimer laser treatments) (tanning beds emit mostly UVA light and therefore would not meet this criteria).
 - c) At least 30-day trial with topical antipsoriatic agents (i.e. anthralin, calcipotriene, coal tar, corticosteroids, tazarotene); AND
8. Member has tried and failed to respond to treatment of an immunosuppressant (i.e., cyclosporine, methotrexate, acetretin) for at least 30 days; AND
9. Member has tried and failed treatment with **both** Enbrel and Humira. Treatment failure requires at least 30 days of therapy (for each drug) without an adequate response.
10. **Dosage allowed:** Recommended dose is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease; AND

4. Documented member's PASI score improvement.

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. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist or dermatologist; AND
4. Member has tried and failed treatment with **both** Enbrel and Humira. Treatment failure requires at least 30 days of therapy (for each drug) without an adequate response; AND
5. Member meets at least **one** of the following scenarios:
 - a) Member has predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by radiographic evidence; OR
 - b) Member has shown symptoms of predominantly axial disease (i.e., sacroiliitis or spondylitis) for more than 3 months (i.e., limited spinal range of motion, spinal morning stiffness for more than 30 minutes) AND has tried and failed to respond to treatment with at least 2 prescription NSAIDs taken at the maximum recommended dosages. Treatment failure requires at least 30 days of therapy without an adequate response; OR
 - c) Member has predominately non-axial disease and has tried and failed to respond to treatment with at least 30-day trial of methotrexate and 30-day trial of NSAID.
6. **Dosage allowed:** Recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.

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

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. 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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active infections
- Asthma
- Cellulitis
- Crohn's Disease
- Dissecting scalp cellulitis
- For use in combination with other TNF-inhibitors (i.e. Kineret, Enbrel, Remicade)



- Giant-cell arteritis
- Guttate psoriasis
- Infectious uveitis
- Lupus perino
- Osteoarthritis
- Recurrent pregnancy loss
- Relapsing polychondritis
- Sarcoidosis
- Sciatica
- Spondyloarthritis (other than ankylosing spondylitis)
- Takayasu's arteritis
- Vogt-Koyanagi

DATE	ACTION/DESCRIPTION
10/19/2017	New policy for Taltz created.
02/05/2018	New indication for Psoriatic Arthritis added.

References:

1. Taltz [package insert]. Indianapolis, IN; Eli Lilly and Company: March, 2016.
2. Menter A, Korman NJ, 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. Journal of the American Academy of Dermatology, Volume 65, Issue 1, 137 – 174.
3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. Arch Dermatol. 2012 Jan;148(1):95-102.

Effective date: 04/04/2018

Revised date: 02/05/2018