Commercial PA Criteria

Effective: May 2016

Prior Authorization: Taltz

Products Affected: Taltz (ixekizumab) subcutaneous solution

Medication Description: Taltz (ixekizumab) is indicated for the treatment of moderate to severe plaque psoriasis in patients who are candidates for systemic therapy or phototherapy. Ixekizumab treatment given every 2 or 4 weeks resulted in a significantly greater proportion of patients achieving coprimary endpoints of a 75% or greater improvement in Psoriasis Area and Severity Index (PASI) and a Static Physician Global Assessment (sPGA) score of 0 or 1 compared with either placebo or etanercept in 2 randomized trials (UNCOVER-2 and UNCOVER-3) in 2570 patients with moderate to severe chronic plaque psoriasis.
Ixekizumab is also indicated for the treatment of patients with active psoriatic arthritis. It may be used alone or in combination with a conventional disease-modifying antirheumatic drug and in patients with comorbid moderate-to-severe plaque psoriasis. In 2 randomized trials, ixekizumab compared with placebo significantly increased the proportion of patients who achieved an American College of Rheumatology criteria 20% improvement (ACR20) at week 24.

Covered Uses:

1. Adult patients with active psoriatic arthritis.
2. Indicated for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
3. Adult patients with active ankylosing spondylitis.
4. Adult patients with non-radiographic axial spondyloarthritis.

Exclusion Criteria: Concurrent use with a biologic DMARD

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed

Age Restrictions:

Psoriatic Arthritis, Non-radiographic Axial Spondyloarthritis, & Ankylosing Spondylitis = 18 years of age or older
Moderate-to-Severe Plaque Psoriasis = 6 years of age or older

Prescriber Restrictions: Must be prescribed by, or in consultation with, a rheumatologist or dermatologist

Coverage Duration:

Plaque Psoriasis: Initial (3 months), Continuation (1 year)
Ankylosing Spondylitis/ Non-radiographic Axial Spondyloarthritis/ Psoriatic Arthritis:
Initial (6 months), Continuation: (1 year)

Other Criteria:

1. **Ankylosing Spondylitis**
   Initial therapy: Approve if the patient meets the following criteria
   A. Patient has clinically diagnosed ankylosing spondylitis **AND**
   B. Prescribed by or in consultation with a rheumatologist.

2. **Non-Radiographic Axial Spondyloarthritis**
   Initial therapy: Approve if the patient meets the following criteria
   A. Patient has objective signs of inflammation, defined as at least one of the following (i, **OR** ii):
      i. C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; **OR**
      ii. Sacroiliitis reported on magnetic resonance imaging; AND

3. **Plaque Psoriasis**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has tried at least ONE traditional systemic agent for psoriasis for at least 3 months unless intolerant; **OR**
      Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested medication. Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
   B. Patient has a contraindication to methotrexate, as determined by the prescriber; **AND**
   C. The medication is prescribed by or in consultation with a dermatologist.

4. **Psoriatic Arthritis**
   Initial Therapy: Approve if the patient meets the following criteria
   A. Patient has clinically diagnosed psoriatic arthritis **AND**
   B. Prescribed by or in consultation with a rheumatologist or dermatologist

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after initial duration of therapy with Taltz as evidenced by low disease activity or improvement in signs and symptoms of the condition.

References:

1. Taltz® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; July 2022.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019

2	Update	Taltz will require a trial of THREE step 1 agents within the Psoriasis indication	Other Criteria	04/01/2019
3	Update	Update	Coverage Duration: Continuation Update to 3 years	07/01/2019
4	Update	Update	Covered Uses (added Ankylosing Spondylitis), Age Restrictions (Moderate-to-Severe Plaque Psoriasis), Other Criteria (added Active Ankylosing Spondylitis)	04/10/2020
5	Update	Added Dosing Limitations according to FDA label	Other Criteria	5/4/2020
6	Update	Added dosing limitations, age restriction, covered uses and other criteria for: Non-radiographic axial spondyloarthritis to align with FDA label	Covered uses Other criteria Dosing limitations Age restriction	6/16/2020
7	Update	Added Otezla as a preferred option for PsA diagnosis	Other Criteria	8/1/2020
8	Update	Removed dosage limitations Removed current criteria for PsA/Plaque Psoriasis/Axial Spondyloarthritis/ Active Ankylosing Spondylitis and replaced with Select criteria for implementation to label use Updated duration: Plaque Psoriasis: Initial (3 months), Continuation (1 year) and Ankylosing Spondylitis/ Non-radiographic Axial Spondyloarthritis/ Psoriatic Arthritis: Initial (6 months) , Continuation: (1 year) Removal *Conneticare does not consider alcohol use to be a clinical reason to use Taltz over methotrexate.	Other criteria Coverage Duration	12/19/2023