Commercial/Healthcare Exchange PA Criteria

Effective: May, 2016

Prior Authorization: Taltz (ixekizumab)

Products Affected: Taltz (ixekizumab) 80 mg/mL 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:
Initial: 3 months.
Continuation: 3 Years

Other Criteria:

Dosing Limitations: ***Only allow additional quantity for loading dose purposes.***

Non-radiographic Axial Spondyloarthritis
The recommended dose is 80mg by subcutaneous injection every 4 weeks

Psoriatic Arthritis & Ankylosing Spondylitis
The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.

Adult Plaque Psoriasis
The 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.

Pediatric Plaque Psoriasis
The recommended dose in pediatric patients from 6 to less than 18 years of age with moderate-to-severe plaque psoriasis is based on the following weight categories.

Pediatric Patient's Weight	Starting Dose (Week 0)	Dose every 4 weeks (Q4W) Thereafter
Greater than 50 kg	160 mg (two 80 mg injections)	80 mg
25 to 50 kg	80 mg	40 mg
Less than 25 kg	40 mg	20 mg

Initiation
Psoriatic Arthritis

A. Patient has a diagnosis of psoriatic arthritis; **AND**
B. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; **AND**
C. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); **AND**
D. Patient has a documented failure of, or intolerance to, **TWO** of the following medications [documentation required]:
    a. Cosentyx
    b. Enbrel
    c. Humira
    d. Stelara SC
    e. Xeljanz/Xeljanz XR
    f. Otezla

Plaque Psoriasis

A. Patient has chronic (greater than or equal to 1 year) plaque psoriasis; **AND**
B. Patient has minimum body surface area involvement with plaque psoriasis of ≥ 10%; **AND**

C. Patient has a documented failure of, or intolerance to, or contraindication to at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant. *Women of childbearing age may be given special consideration for approval without systemic therapy when topical and phototherapy options have been tried and failed;* **AND**

D. Patient has a documented failure of, or intolerance to, **THREE** of the following medications [documentation required]:
   a. Cosentyx
   b. Humira
   c. Otezla
   d. Skyrizi
   e. Stelara SC
   f. Tremfya

Active Ankylosing Spondylitis

A. Patient has active ankylosing spondylitis
B. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy; AND
C. Patient has documented failure or intolerance to an adequate trial (at least 3 months) of ONE DMARD (e.g., methotrexate [oral or injectable], leflunomide, and sulfasalazine); **AND**
D. Patient has a documented failure of, or intolerance to, **TWO** of the following medications [documentation required]:
   a. Cosentyx
   b. Enbrel
   c. Humira

Non-radiographic Axial Spondyloarthritis

A. Patient has non-radiographic axial spondyloarthritis; AND
B. Patient has documented failure or intolerance to an adequate trial of NSAID/COX-2 or steroid therapy

Continuation

A. Patient meets all initial authorization criteria; **AND**
B. Patient achieves or maintains a positive clinical response after at least 3 months of therapy with Taltz as evidenced by low disease activity or improvement in signs and symptoms of the condition.

*ConnectiCare does not consider alcohol use to be a clinical reason to use Taltz over methotrexate.

References:

1. TALTZ(TM) subcutaneous injection, ixekizumab subcutaneous injection. Eli Lilly and Company (per FDA), Indianapolis, IN, 2017.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	5/2016
2	Policy Revision	Updated Template from CCI to EH, Updated Criteria CCI P&T Review History: 5/16, 11/16, 11/17, 11/18 CCI Revision Record: 11/16, 1/18, 8/18, 11/18, 12/18	All	4/26/2019
3	Policy Update	Changed Continuation coverage from 1 year to 3 years	Coverage Duration	7/15/2019
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