ixekizumab (Taltz®)

Commercial Pharmacy Benefit Drug Policy

Drug Details

USP Category: IMMUNOLOGICAL AGENTS
Mechanism of Action: humanized IgG4 monoclonal antibody that selectively binds with the interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor

Label Name	Quantity Limit
Taltz 80 MG/ML SOLN A-INJ	1 pen/28 days
Taltz 80 MG/ML SOLN PRSYR	1 syringe/28 days

Condition(s) listed in policy *(see coverage criteria for details)*

- Ankylosing Spondylitis (AS)
- non-radiographic axial spondyloarthritis (nr-axSpA)
- Plaque Psoriasis (PsO)
- Psoriatic Arthritis (PsA)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with Specialty Tier benefit MUST obtain specialty drugs through our contracted specialty pharmacies for medication to be covered.

The following condition(s) require Prior Authorization/Preservice:

<u>Ankylosing Spondylitis (AS)</u>

1. Being prescribed by, or in consultation with, a rheumatologist
   and
2. One of the following:

a. For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy
b. For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI)
c. Patient unable to use NSAIDs due to history of GI bleed or ulcer

and

3. Inadequate response or intolerable side effect with two preferred drugs (e.g., Cosentyx, Enbrel, Enbrel Mini, Hadlima, Humira, Rinvoq, Xeljanz, Xeljanz XR) or contraindication to all preferred drugs, **and**
4. Not being used in combination with other targeted immunotherapies, **and**
5. Dose does not exceed FDA approved maximum.

Coverage Period:
one year

<u>non-radiographic axial spondyloarthritis (nr-axSpA)</u>

1. Being prescribed by, or in consultation with, a rheumatologist, **and**
2. Not being used in combination with other targeted immunotherapies, **and**
3. One of the following:
    a. For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy, **or**
    b. For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI), **or**
    c. Patient unable to use NSAIDs due to history of GI bleed or ulcer,

and

4. Inadequate response or intolerable side effect with two preferred drugs (e.g. Cimzia, Cosentyx, Rinvoq) or contraindication to all preferred drugs, **and**
5. Dose does not exceed FDA approved maximum.

Coverage Period:
one year

Plaque Psoriasis (PsO)

Initial Use:

1. Patient is at least 6 years old, **and**
2. Prescribed by or in consultation with a rheumatologist or dermatologist, **and**
3. Inadequate response, intolerable side effect, or contraindication to one of the following: methotrexate, cyclosporine (Neoral), acitretin (Soriatane), **or** PUVA/UVB **and**
4. Inadequate response or intolerable side effect with two preferred drugs (e.g. Cosentyx, Enbrel, Hadlima, Humira, Otezla, Skyrizi, Stelara, Tremfya) or contraindication to all preferred drugs, and
5. Not being used in combination with a targeted immunomodulator, **and**
6. One of the following:
    a. Baseline PASI score is 10 or more prior to initiating targeted immunological therapy, **or**
    b. Baseline BSA is 3% or more prior to initiating targeted immunological therapy, **or**
    c. Sensitive area is involved (i.e. groin, face, etc.), **or**
    d. Disease is otherwise debilitating

    and
7. Dose does not exceed FDA approved maximum.

Reauthorization:

1. Patient has shown improvement in the baseline PASI (or BSA if provided on initial request), **and**
2. Not being used in combination with a targeted immunomodulator, **and**
3. Dose does not exceed FDA approved maximum.

Coverage Period:
Initial: 24 weeks
Reauthorization: one year

Psoriatic Arthritis (PsA)

1. Being prescribed by, or in consultation with, a rheumatologist, **and**
2. Inadequate response or intolerable side effect with one DMARD agent OR patient has a medical reason why methotrexate, leflunomide, and sulfasalazine cannot be used, **and**

3. Inadequate response or intolerable side effect with two preferred drugs (e.g. Cosentyx, Enbrel, Hadlima, Humira, Otezla, Rinvoq, Skyrizi, Stelara, Tremfya, Xeljanz, Xeljanz XR) or contraindication to all preferred drugs, and
4. Not being used in combination with a targeted, **and**
5. Dose does not exceed FDA approved maximum.

Coverage Period:
one year

Additional Information

Disease Modifying Anti-Rheumatic Drugs (DMARDs):

- auranofin (Ridaura)
- azathioprine (Imuran)
- gold sodium thiomalate (Aurolate)
- hydroxychloroquine (Plaquenil)
- methotrexate (Rheumatrex)
- D-penicillamine (Cuprimine)
- sulfasalazine (Azulfidine)
- leflunomide (Arava)
- cyclosporine

References

1. Prescribing Information. Taltz. Eli Lilly & Co. 2022
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019; 80:1029-72. Available at www.jaad.org
3. Singh, JA, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology 2019; 71: 5-32. Available at https://www.rheumatology.org
4. Ward, MM, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology 2019; 71: 1599-1613. Available at http://www.rheumatology.org

Review History

Date of Last Annual Review: 4Q2023
Date of last revision: 01/03/2024
Changes from previous policy version:
Clarified coverage for ankylosing spondylitis and non-radiographic axial spondyloarthritis (nr-axSpA).

Blue Shield of California Medication Policy to Determine Medical Necessity

Reviewed by P&T Committee