Taltz (ixekizumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Taltz 80 mg/mL prefilled autoinjector*, prefilled syringe*	1 autoinjector/syringe per 28 days

*Initiation of therapy for adults with Plaque Psoriasis (Ps) (Psoriasis vulgaris) with or without concomitant Psoriatic Arthritis (PsA): May approve up to 3 (three) additional prefilled autoinjectors or syringes (80 mg/mL) in the first 28 days (4 weeks) of treatment and up to 2 (two) additional prefilled autoinjectors or syringes (80 mg/mL) during days 29-84 (4-12 weeks) of treatment.

*Initiation of therapy for individuals age 6 to 17 weighing >50 kg with Plaque Psoriasis (Ps): May approve up to one additional prefilled autoinjector or syringe (80 mg/mL in the first 28 days (4 weeks) of treatment.

*Initiation of therapy for PsA without concomitant Plaque Ps (Psoriasis Vulgaris) or Ankylosing Spondylitis: May approve up to 1 (one) additional prefilled autoinjector or syringe (80 mg/mL) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Initial requests for Taltz (ixekizumab) may be approved for the following:

I. Ankylosing spondylitis (AS) when the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;
   AND
   D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), or Simponi (golimumab)]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
      AND
      1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
      OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Taltz (ixekizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial;

OR

F. Documentation is provided that the individual has had a trial of Cosentyx (secukinumab)* AND has demyelinating disease or heart failure with documented left ventricular dysfunction. Medication samples/coupons/discount cards are excluded from consideration as a trial;

OR

II. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe nr-axSpA; AND

B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019, Deodhar 2020); **OR**

C. Individual has a contraindication to NSAIDs or sulfasalazine;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologic includes – Cosentyx (secukinumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E.

1. Documentation is provided that individual has been receiving and is maintained on a stable dose of Taltz (ixekizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial;

OR

III. Plaque psoriasis (Ps) (Psoriasis vulgaris) when the following are met:

A. Individual is 6 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2011):

1. Plaque Ps (psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA);

OR

2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) BSA involving sensitive areas of areas that significantly impact daily function (such as palms, soles of feet, head, neck, or genitalia);

AND

B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Stelara (ustekinumab), Tremfya (guselkumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;

OR

2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Taltz (ixekizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial;

OR

IV. Psoriatic arthritis (PsA) when each of the following criteria are met:

A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic disease-modifying antirheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

AND

D. Documentation is provided that individual has had a trial and inadequate response or intolerance to TWO preferred biologic agents [Current preferred biologics include – adalimumab-adbm, Cosentyx (secukinumab)*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab)*]. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

1. Documentation is provided describing the nature of the inadequate response or intolerance for each product tried;
   OR
2. Documentation is provided that a completed FDA MedWatch Adverse Event Reporting Form has been submitted to the FDA for each product tried;

OR

E. Documentation is provided that individual has been receiving and is maintained on a stable dose of Taltz (ixekizumab). Medication samples/coupons/discount cards are excluded from consideration as a trial.

*Note – Prior trial of Cosentyx (secukinumab) is not required in states where not covered (CA, CO). Prior trial of Tremfya (guselkumab) not required in states where not covered (CA, CO, GA, IN, KY, ME, MO, NH, NY, OH, VA, WI].

*Note: Rinvoq is the preferred Janus Kinase (JAK) inhibitor. JAK inhibitor clinical criteria require a trial and inadequate response or intolerance to one or more tumor necrosis factor (TNF) antagonist agents**.**

Continuation requests for Taltz (ixekizumab) may be approved if the following criteria are met:

I. Documentation is provided that individual has been receiving and is maintained on a stable dose of Taltz. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease. Medication samples/coupons/discount cards are excluded from consideration as a trial.

Requests for Taltz (ixekizumab) may **not** be approved for the following:

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC) and Prevention-recommended equivalent test to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

Key References:

1. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 12, 2023.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 12, 2023.
3. Deodhar A, van der Heijde D, Gensler LS, et ak.; COAST-X Study Group. Ixekizumab for patients with non-radiographic axial spondyloarthritis (COAST-X): a randomised, placebo-controlled trial. Lancet. 2020; 395: 53-64.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
6. 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.
7. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
8. Ward MM. Deodhar A, Gensler LS, 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 Rheumatol. 2019; 71(10):1599-1613.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.