

## PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Taltz Prior Authorization Policy

- Taltz® (ixekizumab subcutaneous injection – Eli Lilly)

**REVIEW DATE:** 05/11/2022

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### OVERVIEW

Taltz, an interleukin (IL)-17A antagonist, is indicated for the following uses:<sup>1</sup>

- **Ankylosing spondylitis**, in adults with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.
- **Plaque psoriasis**, in patients  $\geq 6$  years of age with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in adults with active disease.

In the pivotal trial for non-radiographic axial spondyloarthritis, patients were required to have objective signs of inflammation, indicated by elevated C-reactive protein and/or sacroiliitis on magnetic resonance imaging.

### Guidelines

- **Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondylitis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).<sup>2</sup> Following primary non-response to a tumor necrosis factor inhibitor (TNFi), either Cosentyx® (secukinumab subcutaneous injection) or Taltz is recommended; however, if the patient is a secondary non-responder, a second TNFi is recommended over switching out of the class. In patients with a contraindication to a TNFi, use of an IL blocker is recommended over traditional oral agents such as methotrexate or sulfasalazine.
- **Plaque Psoriasis:** Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.<sup>3</sup> These guidelines list Taltz as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara® (ustekinumab subcutaneous injection) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.<sup>4</sup>
- **Psoriatic Arthritis:** Guidelines from ACR (2019) recommend TNFis over other biologics for use in treatment-naïve patients with psoriatic arthritis and in those who were previously treated with an oral therapy.<sup>5</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Taltz. Because of the specialized skills required for evaluation and diagnosis of patients treated with Taltz as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Taltz to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

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**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Taltz is recommended in those who meet one of the following criteria:

### FDA-Approved Indications

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) **Initial Therapy.** Approve for 6 months if prescribed by or in consultation with a rheumatologist.
  - B) **Patient is Currently Receiving Taltz.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
    - i. Patient has been established on therapy for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
    - ii. Patient meets at least one of the following (a or b):
      - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Taltz); OR  
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
      - b) Compared with baseline (prior to initiating Taltz), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
2. **Non-Radiographic Axial Spondyloarthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) **Initial Therapy.** Approve for 6 months if the patient meets BOTH of the following (i and ii):
    - i. Patient has objective signs of inflammation, defined as at least one of the following (a or b):
      - a) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
      - b) Sacroiliitis reported on magnetic resonance imaging; AND
    - ii. The medication is prescribed by or in consultation with a rheumatologist.
  - B) **Patient is Currently Receiving Taltz.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
    - i. Patient has been established on therapy for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
    - ii. Patient meets at least one of the following (a or b):
      - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Taltz); OR  
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis

Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

- b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
- 3. Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following conditions (A or B):
- A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
    - i. Patient is  $\geq 6$  years of age; AND
    - ii. Patient meets ONE of the following conditions (a or b):
      - a) Patient has tried at least 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 drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for plaque psoriasis. 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 prescribing physician; AND
    - iii. The medication is prescribed by or in consultation with a dermatologist.
  - B) Patient is Currently Receiving Taltz. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
    - i. Patient has been established on therapy for at least 90 days; AND  
Note: A patient who has received < 90 days of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
    - ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Taltz) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
    - iii. Compared with baseline (prior to initiating Taltz), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.
- 4. Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.
  - B) Patient is Currently Receiving Taltz. Approve for 1 year if the patient meets BOTH of the following (i and ii):
    - i. Patient has been established on therapy for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
    - ii. Patient meets at least one of the following (a or b):
      - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Taltz); OR  
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds

Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

- b) Compared with baseline (prior to initiating Taltz), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Taltz is not recommended in the following situations:

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Taltz should not be administered in combination with a biologic used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lack controlled trial data in support of additive efficacy.  
Note: This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with Taltz.
2. **Inflammatory Bowel Disease (i.e., Crohn’s disease, ulcerative colitis).** Exacerbations of inflammatory bowel disease, in some cases serious, occurred in clinical trials with Taltz-treated patients.<sup>1</sup>
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Taltz® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; March 2021.
2. 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.
3. 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(4):1029-1072.
4. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol.* 2015;29(12):2277-2294.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	04/21/2021
Selected Revision	<p><b>Ankylosing Spondylitis:</b> Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving this drug, it was clarified that this applies to a patient who is taking for <math>\geq 6</math> months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p><b>Non-Radiographic Axial Spondyloarthritis:</b> Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving this drug, it was clarified that this applies to a patient who is taking for <math>\geq 6</math> months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p><b>Plaque Psoriasis:</b> Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving Taltz, it was clarified that this applies to a patient who is taking the drug for <math>\geq 90</math> days. Requirements were added for a patient who is currently taking, that there must be at least one objective and at least one subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p><b>Psoriatic Arthritis:</b> Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving this drug, it was clarified that this applies to a patient who is taking for <math>\geq 6</math> months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p>	12/01/2021
Annual Revision	No criteria changes.	05/11/2022

**APPENDIX**

\* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.