

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Taltz Prior Authorization Policy

- Taltz® (ixekizumab subcutaneous injection – Eli Lilly and Company)

REVIEW DATE: 04/21/2021

OVERVIEW

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

- **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 ≥ 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 nonradiographic axial spondylitis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).² Following primary nonresponse to a TNFi, either Cosentyx or Taltz is recommended; however, if the patient is a secondary nonresponder, 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 (AAD) and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.³ These guidelines list Taltz as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (EDF) [2015] recommend biologics (i.e., etanercept, adalimumab, infliximab, ustekinumab) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.⁴
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology (ACR) [2019] recommend TNF inhibitors over other biologics for use in treatment-naïve patients with PsA and in those who were previously treated with an oral therapy.⁵

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Taltz is recommended in those who meet 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 3 months if prescribed by or in consultation with a rheumatologist.
 - B) Patient is Currently Receiving Taltz. Approve for 3 years if the patient has had a response, as determined by the prescriber.
Note: Examples of a response to therapy include decreased pain or stiffness, improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Taltz.

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 3 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) Patients Currently Receiving Taltz. Approve for 3 years if the patient has had a response, as determined by the prescriber.
Note: Examples of a response include decreased pain or stiffness, improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Taltz.

2. **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 ≥ 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. 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 3 years if the patient has responded, as determined by the prescriber.
Note: Patient may not have a full response, but there should have been a recent or past response to Taltz.

3. **Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if prescribed by or in consultation with a rheumatologist or a dermatologist.

B) Patient is Currently Receiving Taltz. Approve for 3 years if the patient has responded as determined by the prescriber.

Note: Examples of a response include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improvements in acute phase reactants [for example, C-reactive protein [CRP]]. The patient may not have a full response, but there should have been a recent or past response to Taltz.

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.¹

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[®] injection [prescribing information]. Indianapolis, IN: Eli Lilly and Company; 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.

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications*
Biologics		
Adalimumab SC Products (Humira [®] , biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia[®] (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel [®] , biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade [®] , biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi[®], Simponi[®] Aria[™] (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA

Actemra [®] (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
Kezara [®] (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia [®] (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan [®] , biosimilars)	CD20-directed cytolytic antibody	RA
Kineret [®] (anakinra SC injection)	Inhibition of IL-1	JIA [^] , RA
Stelara [®] (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC
Siliq [™] (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx [™] (secukinumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Taltz [®] (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya [™] (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi [™] (risankizumab-rzaa SC injection)	Inhibition of IL-23	PsO
Tremfya [™] (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio [™] (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Targeted Synthetic DMARDs		
Otezla [®] (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Olumiant [®] (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq [®] (upadacitinib extended-release tablets)	Inhibition of JAK pathways	RA
Xeljanz [®] (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz ^{®XR} (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indication (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; IV – Intravenous; IL – Interleukin; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; 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; ^ Off-label use of Kineret in systemic JIA supported in guidelines; DMARDs – Disease-modifying antirheumatic drug.