

# Drug Policy

<b>Policy:</b>	<b>201606</b>	<b>Initial Effective Date: 06/06/2016</b>  <b>Annual Review Date: 05/22/2025</b>  <b>Last Revised Date: 05/22/2025</b>
<b>Code(s):</b>	<b>HCPCS Codes J3490, J3590</b>	
<b>SUBJECT:</b>	<b>Taltz® (ixekizumab)</b>	

Subject to:  Site of Care  
 Medication Sourcing

## 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.

## POLICY STATEMENT

This policy involves the use of Taltz. Prior authorization is recommended for pharmacy benefit coverage of Taltz. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. **Taltz is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

## RECOMMENDED AUTHORIZATION CRITERIA

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

### Food and Drug Administration (FDA)-Approved Indication

1. **Plaque psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):

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# Drug Policy

**A. Initial Therapy.** Approve for 3 months if patient meets ALL the following (i, ii, and iii):

- i. Patient is 6 years of age or older; AND
- ii. Patient meets ONE of the following (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, or acitretin. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. 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 prescriber; AND
- iii. Prescribed by or in consultation with a dermatologist; AND

**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 3 months; AND  
Note: A patient who has received < 3 months 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.

**2. Psoriatic Arthritis (PsA).** 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 the following criteria (i and ii):

- i. Patient is 18 years of age or older; AND
- ii. Taltz is 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

# Drug Policy

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.

3. **Ankylosing Spondylitis (AS)** 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 the following criteria (i and ii):

- i. Patient is an adult  $\geq 18$  years of age; AND
- ii. Taltz 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 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.

4. **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 the following criteria (i, ii, and iii):

- i. Patient is an adult  $>18$  years of age; AND
- ii. 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
- iii. Taltz is prescribed by or in consultation with a rheumatologist.

# Drug Policy

- 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.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Taltz has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: this is not an exhaustive list of Conditions Not Recommended for Approval.)

- 1. Concurrent Use with a Biologic or with Targeted Synthetic Oral Small Molecule Drug.** Taltz should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially a higher rate of adverse events and lack clinical data supporting additive efficacy.  
Note: This does NOT exclude the use of MTX (a traditional systemic agent used to treat psoriasis) in combination with Taltz.
- 2. Inflammatory Bowel Disease (i.e., Crohn's Disease [CD], Ulcerative Colitis [UC]).** Exacerbations of inflammatory bowel disease, in some cases serious, occurred in clinical trials with Taltz-treated patients.
- 3. Concurrent use with Otezla.** There is no evidence to suggest that combination use with Otezla and Taltz is superior to monotherapy.
- 3.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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# Drug Policy

## DOSING

The recommended dose for Plaque Psoriasis is:

- Initial 160 mg (two 80 mg injections) at Week 0.
- Followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12.
- Therapy is then continued with 80 mg every 4 weeks.

The recommended dose for Psoriatic arthritis and ankylosing spondylitis is: 160 mg once at week 0, followed by 80 mg every 4 weeks; may administer alone or in combination with conventional disease-modifying antirheumatic drugs (eg, methotrexate). **Note:** For psoriatic arthritis patients with coexisting moderate-to-severe plaque psoriasis, use the dosing regimen for plaque psoriasis.

## Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## Prior approval is required for HCPCS Code J3590.

†When *unclassified biologics* (J3590) is determined to be Taltz.

## References

1. Taltz® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; July 2022.
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.

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# Drug Policy

<b>HCPCS Code(s):</b>	
J3590	Unclassified biologics

## APPENDIX

	Mechanism of Action	Examples of Indications*
<b>Biologics</b>		
<b>Adalimumab SC Products</b> (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
<b>Cimzia®</b> (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
<b>Etanercept SC Products</b> (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
<b>Infliximab IV Products</b> (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
<b>Zymfentra®</b> (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
<b>Simponi®, Simponi Aria®</b> (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA
<b>Tocilizumab Products</b> (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
<b>Kevzara®</b> (sarilumab SC injection)	Inhibition of IL-6	RA
<b>Orencia®</b> (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA IV formulation: JIA, PsA, RA
<b>Rituximab IV Products</b> (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
<b>Kineret®</b> (anakinra SC injection)	Inhibition of IL-1	JIA <sup>^</sup> , RA
<b>Omvoh®</b> (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
<b>Stelara®</b> (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC
<b>Siliq®</b> (brodalumab SC injection)	Inhibition of IL-17	PsO
<b>Cosentyx®</b> (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA IV formulation: AS, nr-axSpA, PsA
<b>Taltz®</b> (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
<b>Bimzelx®</b> (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO
<b>Ilumya®</b> (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
<b>Skyrizi®</b> (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC IV formulation: CD, UC
<b>Tremfya®</b> (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC IV formulation: UC
<b>Entyvio®</b> (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
<b>Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs</b>		
<b>Otezla®</b> (apremilast tablets)	Inhibition of PDE4	PsO, PsA
<b>Cibinqo™</b> (abrocitinib tablets)	Inhibition of JAK pathways	AD
<b>Olumiant®</b> (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
<b>Litfulo®</b> (ritlecitinib capsules)	Inhibition of JAK pathways	AA
<b>Leqselvi®</b> (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
<b>Rinvoq®</b> (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
<b>Rinvoq® LQ</b> (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
<b>Sotyktu®</b> (deucravacitinib tablets)	Inhibition of TYK2	PsO
<b>Xeljanz®</b> (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC

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# Drug Policy

<b>Xeljanz® XR</b> (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
<b>Zeposia®</b> (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
<b>Velsipity®</b> (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

\* Not an all-inclusive list of indications. 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, PJIA – 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; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.