

Drug Coverage Policy

Effective Date......07/01/2025 Coverage Policy Number......IP0688 Policy Title.....Taltz Prior Authorization Policy

Inflammatory Conditions – Taltz Prior Authorization Policy

• Taltz[®] (ixekizumab subcutaneous injection - Eli Lilly)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide quidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment quidelines. In certain markets, delegated vendor quidelines may be used to support medical necessity and other coverage determinations.

Page 1 of 7

Coverage Policy Number: IP0688

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 non-radiographic axial spondylitis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).² 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.³ These guidelines list Taltz as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (2025) recommend biologics (including Taltz) as second-line therapy for most patients requiring systemic treatment when there is inadequate response, contraindication, or intolerance to conventional systemic agents (e.g., methotrexate, cyclosporine, acitretin).⁴
- **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.⁵

Coverage Policy

Policy Statement

Prior Authorization is required for benefit coverage of Taltz. All approvals are for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. 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.

<u>NOTE:</u> This product also requires the use of preferred products before approval of the requested product. Refer to the respective *Inflammatory Conditions Preferred Specialty Management Policy for Individual and Family Plans (PSM002)* for additional preferred product criteria requirements and exceptions.

Taltz is considered medically necessary when ONE of the following is met (1, 2, 3, or 4):

FDA-Approved Indications

- **1. Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A <u>or</u> B):
 - **A)** <u>Initial Therapy</u>. Approve for 6 months if the patient meets BOTH of the following (i <u>and</u> ii):
 - i. Patient is \geq 18 years of age; AND
 - ii. The medication is prescribed by or in consultation with a rheumatologist; OR
 - **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)** <u>Initial Therapy</u>. Approve for 6 months if the patient meets ALL of the following (i, ii, <u>and</u> iii):
 - i. Patient is \geq 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. The medication is prescribed by or in consultation with a rheumatologist; OR
 - **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 (A <u>or</u> B):
 - **A)** <u>Initial Therapy</u>. Approve for 3 months if the patient meets ALL of the following (i, ii, <u>and</u> iii):
 - i. Patient is ≥ 6 years of age; 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.
 - Patient has a contraindication to methotrexate, as determined by the prescriber;
 AND
 - iii. The medication is prescribed by or in consultation with a dermatologist; OR
 - **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.
- **4. Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A <u>or</u> B):
 - **A)** <u>Initial Therapy</u>. Approve for 6 months if the patient meets BOTH of the following (i <u>and</u> ii):
 - i. Patient is > 18 years of age; AND
 - **ii.** The medication is prescribed by or in consultation with a rheumatologist or a dermatologist; OR
 - **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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Taltz for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concurrent Use a Biologic or with a Targeted Synthetic Oral Small Molecule Drug. This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

 Note: This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with this medication.
- 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

References

- 1. Taltz® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; August 2024.
- 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, Spuls PI, Dressler C, et al. EuroGuiDerm guideline for the systemic treatment of psoriasis vulgaris. Updated February 2025. Available at: https://www.guidelines.edf.one/guidelines/psoriasis-guideline. Accessed on: 05/21/2025.
- 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.

Revision Details

Page 5 of 7

Coverage Policy Number: IP0688

Type of Revision	Summary of Changes	Date
New	New policy	11/1/2024
Annual Revision	No criteria changes.	07/01/2025

The policy effective date is in force until updated or retired.

APPENDIX

	Mechanism of Action	Examples of 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, RA
Infliximab IV Products (Remicade [®] , biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra [®] (infliximab-dyyb SC injection)	Inhibition of TNF	CD, 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
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion,	T-cell costimulation	SC formulation: JIA, PSA, RA
abatacept SC injection)	modulator	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
Omvoh ® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars)	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; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr- axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx ® (bimekizumab-bkzx SC injection)	Inhibition of IL- 17A/17F	AS, nr-axSpA, PsO, PsA
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi ® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC

Page 6 of 7 Coverage Policy Number: IP0688

		IV formulation: CD, UC
Tremfya® (guselkumab SC injection,	Inhibition of IL-23	SC formulation: CD, PsA,
guselkumab IV infusion)		PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion,	Integrin receptor	CD, UC
vedolizumab SC injection)	antagonist	
Oral Therapies/Targeted Synthetic Or	<u>al Small Molecule Drug</u>	gs
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo [™] (abrocitinib tablets)	Inhibition of JAK	AD
	pathways	
Olumiant® (baricitinib tablets)	Inhibition of JAK	RA, AA
	pathways	
Litfulo ® (ritlecitinib capsules)	Inhibition of JAK	AA
	pathways	
Leqselvi ® (deuruxolitinib tablets)	Inhibition of JAK	AA
	pathways	
Rinvoq ® (upadacitinib extended-release	Inhibition of JAK	AD, AS, nr-axSpA, RA, PsA,
tablets)	pathways	UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK	PsA, PJIA
	pathways	
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral	Inhibition of JAK	RA, PJIA, PsA, UC
solution)	pathways	
Xeljanz® XR (tofacitinib extended-	Inhibition of JAK	RA, PsA, UC
release tablets)	pathways	
Zeposia® (ozanimod tablets)	Sphingosine 1	UC
	phosphate receptor	
	modulator	
Velsipity® (etrasimod tablets)	Sphingosine 1	UC
	phosphate receptor	
	modulator	

^{*} 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.

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