MEDICAL MUTUAL®

Drug Policy

Policy:	**201606**	**Initial Effective Date: 06/06/2016**
Code(s):	**HCPCS Codes J3490, J3590**	**Annual Review Date: 05/16/2024**
SUBJECT:	**Taltz® (ixekizumab)**	**Last Revised Date: 05/16/2024**

☐Subject to Site of Care

OVERVIEW

Taltz™ (ixekizumab) is a humanized IgG4 monoclonal antibody that selectively binds with the IL-17A cytokine and inhibits its interaction with the IL-17 receptor. Taltz is indicated for treatment of adults with plaque psoriasis, psoriatic arthritis or ankylosing spondylitis. Inhibition of IL-17A has shown to help to reduce the immunologic response in psoriasis patients improving symptoms. Taltz is administered by subcutaneous injection every 4 weeks after initial titration for the chronic management of psoriasis. For psoriatic arthritis and ankylosing spondylitis, Taltz is administered by subcutaneous injection as an initial loading dose at week 0 followed by a maintenance dose every 4 weeks thereafter.

Psoriasis is the most common immune medicated skin disease. Immune dysregulation results in chronic inflammation. Multiple immune functioning cells such as proinflammatory cytokines and chemokines cause systemic reactions resulting in excessive proliferation of the epidermal keratinocytes. Psoriasis can present at any age, and affects about 4% of the US population. At the present time there is no cure for psoriasis, clinical response is determined by remission and exacerbations. Recently, many biological medications have been produced targeting the immunologic response of psoriasis, such as, TNFα inhibitors, IL-12/23 inhibitors, and IL-17A inhibitors. Taltz is indicated for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, it has not been studied in people <18 years old. Taltz is intended for use under the guidance and supervision of a physician.

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. **Moderate-to-severe plaque psoriasis.**
   - **A. Initial Therapy.** Approve for 3 months if patient meets (i, ii, iii, and iv):
     - i. Patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy; AND
     - ii. Patient is 6 years of age or older; AND
     - iii. Prescribed by or in consultation with a dermatologist; AND
     - iv. Patient has met one of the following: (a, b, c or d)
       - a) The patient has tried an oral therapy for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets); oral methoxsalen plus ultraviolet A light (PUVA); for at least 3 months; OR
       - b) The patient has tried a biologic agent for at least 3 months [See Appendix A for examples] OR
       - c) The patient has a contraindication to one oral agent for psoriasis such as MTX, as determined by the prescribing physician; OR
       - d) The patient has a contraindication to the other biologic agents.
   - **B. Continuation of Therapy**
     - i. Patient is Currently Receiving Taltz. Approve for 1 year if the patient has responded, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Taltz.

2. **Active Psoriatic Arthritis (PsA).**
   - **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 (continuation of therapy).** Approve for 1 year if the patient has responded (e.g. less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improvement in acute phase reactants [e.g. C-reactive protein]), as determined by the prescriber. The patient may not have a full response, but there should be a recent or past response to Taltz.

3. **Active Ankylosing Spondylitis** (AS)
   - **A. Initial Therapy.** Approve for 6 months if the patient meets the following criteria (i and ii):
     - i. Patient is an adult ≥ 18 years of age; AND
     - ii. Taltz is prescribed by or in consultation with a rheumatologist.

B. Continuation Therapy: Approve for 1 year if the patient has responded, as determined by the prescriber. 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

4. **Non-radiographic Axial Spondyloarthritis**
   - **A.** Initial therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii and iv):
     - i. Patient is an adult >18 years of age; AND
     - ii. Patient has active non-radiographic axial spondyloarthritis; AND
     - iii. Patient has objective signs of inflammation
     - iv. Taltz is prescribed by or in consultation with a rheumatologist.
   - **B.** Continuation of therapy. Approve for 1 year if the patient has responded, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Taltz.

Approval Duration
Initial Approval = 6 months (180 days)
Re-authorization = 1 year (365 days)

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 other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Taltz should not be administered in combination with another biologics or with a targeted synthetic DMARD for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of 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 (Crohn's Disease [CD], Ulcerative Colitis [UC]).** Exacerbations of inflammatory bowel disease, in some cases serious, occurred in clinical trials with Tatlz-treated patients.

3. **Concurrent use with Otezla.** There is no evidence to suggest that combination use with Otezla and Taltz is superior to monotherapy.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.

Edits and Denials:

Prior approval: Prior approval is required for Taltz **(HCPCS Code J3590)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J3590** will pend with **Remark Code PRR** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

References

1. Taltz® injection [prescribing information]. Indianapolis, IN: Eli Lilly and Company; July, 2022.
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3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012;148(1):95-102.
4. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
5. Otezla® tablets [prescribing information]. Summit, NJ: Celgene Corporation; December 2015.
6. Ixekizumab. In: DRUGDEX (online database). Truven Health Analytics: Greenwood Village, CO. Last updated 5 December 2017. Accessed on 15 January 2018.
7. 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 Aug 22. [Epub ahead of print].
8. Farahnik B, et al. Ixekizumab for the Treatment of Psoriasis: A Review of Phase III Trials. Journal of Dermatology and Therapy (Heidelb) (2016) 6:25–37
9. Menter A, Korman N, Bhushan R, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. Journal Of The American Academy Of Dermatology [serial online]. July 2011;65(1):137-174 38p. Available from: CINAHL Plus with Full Text, Ipswich, MA. Accessed April 18, 2016.

HCPCS Code(s):	
J3590	Unclassified biologics

Appendix A

	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
Kevzara® (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, ERA, 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	PsA, PsO
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, RA, PsA, UC
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; 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; DMARDs – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.