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Policy Number: C16448-A

Taltz (ixekizumab)

PRODUCTS AFFECTED

Taltz (ixekizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate to severe plaque psoriasis, Active psoriatic arthritis, Non-radiographical axial spondyloarthritis, Ankylosing spondylitis with objective signs of inflammation

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or

TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Prescriber attests member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
AND
3. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
4. Prescriber attests member does not have an active infection, including clinically important localized infections
AND
5. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

A. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA ≥ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
AND
2. (a) Documentation of treatment failure, serious side effects, or a clinical contraindication to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
OR
(b) Documentation of treatment failure to Phototherapy for ≥ 3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

B. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND

3. (a) Documented treatment failure, serious side effects, or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
   OR
   (b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]
   OR
   (c) Documentation member has severe psoriasis [PASI ≥12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]
   AND
4. Docmentation of treatment failure, serious side effects, or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor
   NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

C. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of ankylosing spondylitis diagnosis
   AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
   AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effects, or clinical contraindication to a trial (≥3 consecutive months) of methotrexate OR sulfasalazine
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor
   NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

D. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:
1. Prescriber attests to diagnosis of adult-onset axial spondyloarthritis
   AND
2. Documentation that C-reactive protein (CRP) levels are above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease
   AND
3. Documentation that there is no definitive radiographic evidence of structural damage on sacroiliac joints.
   AND
4. Documentation member has active disease and prescriber provides baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
   AND
6. Documentation of treatment failure, serious side effects, or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor

NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

CONTINUATION OF THERAPY:

ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity.
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms. [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a specialist in dermatology or rheumatology. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

PLAQUE PSORIASIS: 6 years or older
FOR PSORIATIC ARTHRITIS, ANKYLOSING SPONDYLITIS and NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:18 years of age or older

QUANTITY:

FOR ADULT PLAQUE PSORIASIS: The recommended dose is 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks. The shortest dosing interval is 2 weeks. It has been shown that shortening the dosing interval beyond 12 weeks of therapy may be beneficial in some adult patients with plaque psoriasis (Langley, 2018).

The following is applicable to the diagnosis of plaque psoriasis, and use in adults only (Langley, 2018):

When requests for off-label dosing, dose escalation, or dose intensification are received, requests will be reviewed for evidence that current or standard dosing is not adequate to produce a therapeutic level of drug (e.g., pharmacokinetic failure), clinical failure or significant loss of response is present, and the requested dosing is established as safe and effective for the condition. There are certain situations where no additional amount of drug is likely to produce or recapture clinical effect because the condition is no longer responsive to the drug (e.g., pharmacodynamic failure) or the drug cannot reach the site of activity at sufficient levels. The following items will assist reviewers in determining if the requested dosing is medically necessary:

- *FDA or compendium-supported dosing and therapeutic monitoring recommendations for the drug*

- *Member claims/adherence history*
- *Clinical documentation of the member's response to current or standard dosing regimens (disease activity indices if commonly used in clinical practice or documentation to approximate them may be necessary to demonstrate the response)*
- *In conjunction with documented clinical failure or loss of response or wearing off of effect, test results that demonstrate failure of current or standard dosing to reach established treatment thresholds (e.g., established therapeutic monitoring recommendations)*
- *If applicable, documentation showing the member does not have conditions which make achieving a therapeutic level of drug unlikely even with dose intensification (e.g., dose intensification may be futile due to the presence of anti-drug antibodies, protein losing enteropathy, nephrotic syndrome, severe drug excretion or malabsorption issues, etc.)*

In certain situations, documentation, or peer-to-peer determination that re-induction cannot be tried to recapture response as an alternative to long term dose escalation or intensification

FOR PEDIATRIC PLAQUE PSORIASIS: Dosing is for member's ages 6 to <18 years:
For pediatric patients weighing greater than 50 kg: 160 mg (two 80 mg injections) at Week 0 followed by 80 mg every 4 weeks
For pediatric patients weighing 25-50 kg: 80 mg at Week 0, followed by 40 mg every 4 weeks
For pediatric patients weighing less than 25 kg: 40 mg at Week 0, followed by 20 mg every 4 weeks

FOR PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS: 160
mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks;
For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for adult plaque psoriasis

NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: 80 mg by subcutaneous injection every 4 weeks.

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Antipsoriatics – Systemic

FDA-APPROVED USES:
Indicated for the treatment of patients aged 6 years and older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, adults with active psoriatic arthritis, adults with active ankylosing spondylitis, and adults with active non- radiographic axial spondyloarthritis with objective signs of inflammation

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

State Marketplace

Texas (Source: Texas Statutes, Insurance Code)

"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.

(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.

(b) This section does not apply to:

(1) opioids, benzodiazepines, barbiturates, or carisoprodol;

(2) prescription drugs that have a typical treatment period of less than 12 months;

(3) drugs that:

(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and

(B) must have specific provider assessment; or

(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Taltz is a humanized interleukin-17A antagonist indicated for the treatment of adults with active psoriatic arthritis or with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Efficacy

PLAQUE PSORIASIS – Three multicenter, randomized, double-blind, placebo-controlled trials, Trials 1,2, and 3 enrolled a total of 3866 subjects 18 years of age and older with plaque psoriasis who had a minimum body surface area involvement of 10%, a static Physician Global Assessment (sPGA) score of ≥3 in the overall assessment (plaque thickness/induration, erythema, and scaling) of psoriasis on a severity scale of 0 to 5, a Psoriasis Area and Severity Index (PASI) score ≥12, and who were candidates for phototherapy or systemic therapy. In all three trials, subjects were randomized to either placebo or Taltz 80 mg every 2 weeks for 12 weeks, following a 160 mg starting dose. In the two active comparator trials (Trials 2 and 3), subjects were also randomized to receive etanercept 50 mg twice weekly for 12 weeks. In all three trials the two primary outcomes were the proportion of subject who achieved at least 75% reduction in the composite PASI score (PASI 75) and the proportion of patients with an sPGA score of 0 or 1 and at least a 2- point improvement from baseline. The proportion of Member who achieved a PASI 75 using Taltz 80 mg every2weeks compared to placebo, respectively, was 89% (386/433) to 4% (17/431) in Trial 1, 90% (315/351) to 2% (4/168) in Trial 2, and 87% (336/385) to 7% (14/193) in Trial 3. The proportion of Member who achieved sPGA of 0 or 1 using Taltz 80 mg every 2 weeks compared to placebo, respectively, was82% (354/433) to 3% (14/431) in Trial 1, 83% (292/351) to 2% (4/168) in Trial 2, and 81% (310/385) to 7% (13/193) in Trial 3.

Pooled data from the trials comparing Taltz 80 mg every 2 weeks compared to etanercept 50mg twice weekly demonstrated superiority of Taltz on sPGA and PASI scores during the 12- week treatment period. The proportion of patients who achieved a PASI 75 was 87% in the Taltz group compared to 41%in the etanercept group. The proportion of Member who achieved an sPGA of 0 or 1 was 73% in the Taltz group compared to 27% in the etanercept group. To evaluate the maintenance and durability of response, subjects originally randomized to receive Taltz who achieved a clinical response (sPGA of 0 or 1) at Week 12 were re- randomized to an additional 48 weeks of either a maintenance dose of Taltz 80 mg every 4 weeks or placebo. The percentage of subjects who maintained this clinical response was 75% in the Taltz group compared to 7% in the placebo group.

FOR PSORIATIC ARTHRITIS – Two randomized, double-blind, placebo-controlled studies (PsA1 andPsA2) assessed the safety and efficacy of Taltz in adult patients, age 18 years and older with active

psoriatic arthritis with at least 3 swollen and at least 3 tender joints despite non- steroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. The PsA1 study evaluated 417 biologic-naïve patients, who were treated with either Taltz 160 mg at Week 0 followed by 80 mg every 2 or 4 weeks, adalimumab 40 mg every 2 weeks, or placebo. PsA2 Study evaluated 363 anti-TNFα experienced patients, who were treated with Taltz 160 mg at Week 0 followed by80 mg every 2 or 4 weeks, or placebo. Patients receiving placebo were re- randomized to receive TALTZ 80 mg every 2 or 4 weeks at Week 16 or Week 24 based on responder status. The primary endpoint was the percentage of patients achieving an ACR20 response at Week 24. In both studies, patients treated with Taltz 80 mg every 2 weeks and every 4 weeks demonstrated greater clinical response compared to placebo. In PsA1, 58% of Member using Taltz 80 mg every 4 weeks achieved an ACR20 response compared to 30% in the placebo group. In PsA2, 53%of patients using Taltz 80 mg every 4 weeks achieved an ACR20 response compared to 20% in the placebo group. In PsA2, responses were seen regardless of prior anti-TNFα exposure.

Safety

In the 12-week, placebo-controlled period, adverse events occurred in 58% of the Taltz 80 mg every 2 weeks group compared to 47% of the placebo group. Serious adverse events occurred in 2% of the Taltz group and in 2% of the placebo group. The most common adverse reactions that occurred at higher rates in the Taltz group compared to placebo (respectively) were injection site reactions (17% to 3%), upper respiratory tract infections (14% to 13%), nausea (2% to 1%), and
tinea infections (2% to <1%). During the maintenance period (Weeks 13 to 60), adverse events occurred in 80% of subjects treated with Taltz compared to 58% of subjects treated with placebo. Serious adverse events were reported in 4% of subjects treated with Taltz and none in the subjects treated with placebo. Overall, the safety profile observed in patients with psoriatic arthritis treated with Taltz every 4 weeks is consistent with the safety profile in patients with plaque psoriasis apart from the frequencies of influenza (1.3%) and conjunctivitis (1.3%).

FOR ANKYLOSING SPONDYLITIS:

The safety and efficacy of TALTZ were assessed in 567 patients, in 2 randomized, double- blind, placebo-controlled studies (AS1 and AS2) in adult patients, age 18 years and older with active ankylosing spondylitis. Patients had active disease as defined by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥4 despite non- steroidal anti-inflammatory drug (NSAID), corticosteroid, or disease modifying anti- rheumatic drug (DMARD) therapy. At baseline, patients had symptoms of AS for an average of 17 years across both studies. At baseline, approximately 32% of the patients were on a concomitant cDMARD. In AS2, all patients discontinued previous treatment with 1 or 2 TNF inhibitors due to either inadequate response or intolerance.
AS1 Study (NCT 02696785) evaluated 341 biologic-naïve patients, who were treated with either TALTZ 80 mg or 160 mg at Week 0 followed by 80 mg every 2 weeks (Q2W) or 4 weeks(Q4W), adalimumab 40 mg every 2 weeks, or with placebo. Patients receiving placebo were re-randomized at Week 16 to receive TALTZ (160 mg starting dose, followed by 80 mg Q2W or Q4W). Patients receiving adalimumab were re- randomized at Week 16 to receive TALTZ (80 mg Q2W or Q4W).AS2 Study (NCT 02696798) evaluated 316 TNF-inhibitor experienced patients (90% were inadequate responders and 10% were intolerant to TNF inhibitors). All patients were treated with TALTZ 80 or 160 mg at Week 0 followed by 80 mg Q2W or Q4W, or with placebo.
Patients receiving placebo were re-randomized at Week 16 to receive TALTZ (160 mg initial dose, followed by 80 mg Q2W or Q4W). The primary endpoint in both studies was the percentage of patients achieving an Assessment of Spondyloarthritis International Society 40 (ASAS40) response at Week 16.

Clinical Response

In both studies, patients treated with TALTZ 80 mg Q4W demonstrated greater improvements in ASAS40 andASAS20 responses compared to placebo at Week 16 (Table 6). Responses were seen regardless of concomitant therapies. In AS2, responses were seen regardless of prior TNF-inhibitor exposure.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Taltz (ixekizumab) are considered experimental/investigational and therefore, will follow

Molina's Off- Label policy. Contraindications to Taltz (ixekizumab) include: serious hypersensitivity reaction to ixekizumab or to any of the excipients, concurrent use of live vaccines.

OTHER SPECIAL CONSIDERATIONS:

Taltz may increase the risk of infection. Taltz should not be administered to patients with an active TB infection. Taltz may exacerbate inflammatory bowel disease such as Crohn's disease or ulcerative colitis. Avoid use of live vaccines in patients treated with Taltz.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:

Taltz SOAJ 80MG/ML auto-injector
Taltz SOSY 80MG/ML prefilled syringe

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file