

Clinical Policy: Ixekizumab (Taltz)

Reference Number: MDN.CP.PHAR.257

Effective Date: 04.01.22

Last Review Date: 04.22

Line of Business: Meridian IL Medicaid

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Ixekizumab (Taltz[®]) is an interleukin-17A (IL-17A) antagonist.

FDA Approved Indication(s)

Taltz is indicated for the treatment of:

- Patients aged 6 years or older with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
- Adults with active psoriatic arthritis (PsA)
- Adults with active ankylosing spondylitis (AS)
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Taltz is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Axial Spondyloarthritis (must meet all):

1. Diagnosis of AS or nr-axSpA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age \geq 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for \geq 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. Failure of TWO of the following, each used for \geq 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia[®], Enbrel[®], Humira[®], Xeljanz/Xeljanz XR[®];
**Prior authorization may be required for Cimzia, Enbrel, Humira, and Xeljanz/Xeljanz XR*
6. Dose does not exceed one of the following (a or b):
 - a. For AS: 160 mg at week 0, followed by maintenance dose of 80 mg every 4 weeks;
 - b. For nr-axSpA: 80 mg every 4 weeks.

Approval duration: 6 months

B. Plaque Psoriasis (must meet all):

1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
 - a. $\geq 3\%$ of total body surface area;
 - b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 6 years;
4. Member meets one of the following (a or b):
 - a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
 - b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
5. Failure of TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia[®], Enbrel[®], Humira[®];
**Prior authorization may be required for Cimzia, Enbrel, and Humira*
6. Dose does not exceed one of the following (a – d):
 - a. For adults: 160 mg at week 0, 80 mg at weeks 2, 4, 6, 8, 10, and 12, followed by maintenance dose of 80 mg every 4 weeks;
 - b. For pediatric members weighing < 25 kg: 40 mg at week 0, followed by 20 mg every 4 weeks;
 - c. For pediatric members weighing 25 – 50 kg: 80 mg at week 0, followed by 40 mg every 4 weeks;
 - d. For pediatric members weighing > 50 kg: 160 mg (two 80 mg injections) at week 0, followed by 80 mg every 4 weeks.

Approval duration: 6 months

C. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of TWO of the following, each used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced: Cimzia[®], Enbrel[®], Humira[®], Xeljanz/Xeljanz XR[®];
**Prior authorization may be required for Cimzia, Enbrel, Humira, and Xeljanz/Xeljanz XR*
5. Dose does not exceed one of the following (a or b):
 - a. PsA alone: 160 mg at weeks 0, followed by maintenance dose of 80 mg every 4 weeks;
 - b. PsA with coexistent PsO: 160 mg at week 0, 80 mg at weeks 2, 4, 6, 8, 10, and 12, followed by maintenance dose of 80 mg every 4 weeks.

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 80 mg every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs), including any tumor necrosis factor (TNF) antagonists [Cimzia[®], Enbrel[®], Simponi[®], Avsola[™], Inflectra[™], Remicade[®], Renflexis[™]], interleukin agents [Arcalyst[®] (IL-1 blocker), Ilaris[®] (IL-1 blocker), Kineret[®] (IL-1RA), Actemra[®] (IL-6RA), Kevzara[®] (IL-6RA), Stelara[®] (IL-12/23 inhibitor), Cosentyx[®] (IL-17A inhibitor), Taltz[®] (IL-17A inhibitor), Siliq[™] (IL-17RA), Ilumya[™] (IL-23 inhibitor), Skyrizi[™] (IL-23 inhibitor), Tremfya[®] (IL-23 inhibitor)], janus kinase inhibitors (JAKi) [Xeljanz[®]/Xeljanz[®] XR, Rinvoq[™]], anti-CD20 monoclonal antibodies [Rituxan[®], Riabni[™], Ruxience[™], Truxima[®], and Rituxan Hycela[®]], selective co-stimulation modulators [Orencia[®]], or integrin receptor antagonists [Entyvio[®]] because of the possibility of increased immunosuppression, neutropenia and increased risk of infection.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACR: American College of Rheumatology	nr-axSpA: non-radiographic axial spondyloarthritis
AS: ankylosing spondylitis	PsA: psoriatic arthritis
FDA: Food and Drug Administration	PsO: plaque psoriasis
IL-17A: interleukin-17A	
MTX: methotrexate	

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane [®])	PsO 25 or 50 mg PO QD	50 mg/day
cyclosporine (Sandimmune [®] , Neoral [®])	PsO 2.5 – 4 mg/kg/day PO divided BID	PsO: 4 mg/kg/day
methotrexate (Rheumatrex [®])	PsO 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib)	AS, nr-axSpA Varies	Varies

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients
- Boxed warning(s): none reported

Appendix D: General Information

- Definition of failure of MTX or DMARDs
 - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
 - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Examples of positive response to therapy may include, but are not limited to:
 - Reduction in joint pain/swelling/tenderness
 - Improvement in erythrocyte sedimentation rates/C-reactive protein (ESR/CRP) levels
 - Improvements in activities of daily living
- PsA: According to the 2018 American College of Rheumatology (ACR) and National Psoriasis Foundation guidelines, TNF inhibitors or oral small molecules (e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide, apremilast) are preferred over other biologics (e.g., interleukin-17 inhibitors or interleukin-12/23 inhibitors) for treatment-naïve disease. TNF inhibitors are also generally recommended over oral small molecules as first-line therapy unless disease is not severe, member prefers oral agents, or TNF inhibitor therapy is contraindicated.

- AS and nr-axSpA: Although the 2019 ACR guidelines for AS recommend the use of TNF inhibitors over IL-17A antagonists such as Taltz or Cosentyx, this recommendation was based on “greater experience with TNF inhibitors and familiarity with their long-term safety and toxicity” rather than differences in efficacy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose													
PsO (with or without coexistent PsA)	Adults: <u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12 <u>Maintenance dose:</u> 80 mg SC every 4 weeks	80 mg every 4 weeks													
	Pediatrics between ages of 6 and 18 years:														
	<table border="1"> <thead> <tr> <th>Pediatric Patient’s Weight</th> <th>Starting Dose (Week 0)</th> <th>Dose every 4 weeks (Q4W) Thereafter</th> </tr> </thead> <tbody> <tr> <td>> 50 kg</td> <td>160 mg (two 80 mg injections)</td> <td>80 mg</td> </tr> <tr> <td>25 to 50 kg</td> <td>80 mg</td> <td>40 mg</td> </tr> <tr> <td>< 25 kg</td> <td>40 mg</td> <td>20 mg</td> </tr> </tbody> </table>		Pediatric Patient’s Weight	Starting Dose (Week 0)	Dose every 4 weeks (Q4W) Thereafter	> 50 kg	160 mg (two 80 mg injections)	80 mg	25 to 50 kg	80 mg	40 mg	< 25 kg	40 mg	20 mg	
	Pediatric Patient’s Weight		Starting Dose (Week 0)	Dose every 4 weeks (Q4W) Thereafter											
> 50 kg	160 mg (two 80 mg injections)	80 mg													
25 to 50 kg	80 mg	40 mg													
< 25 kg	40 mg	20 mg													
PsA, AS	<u>Initial dose:</u> 160 mg (two 80 mg injections) SC at week 0 <u>Maintenance dose:</u> 80 mg SC every 4 weeks	80 mg every 4 weeks													
nr-axSpA	80 mg SC every 4 weeks	80 mg every 4 weeks													

VI. Product Availability

- Single-dose prefilled autoinjector: 80 mg/mL
- Single-dose prefilled syringe: 80 mg/mL

VII. References

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 11. Deodhar A, van der Heijde D, Gensler LS, et al. Ixekizumab for patients with non-radiographic axial spondyloarthritis (COAST-X): a randomised, placebo-controlled trial. *Lancet* 2020; 395: 53-64.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Injection, ixekizumab, 80 mg/mL

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PHAR.257	04.01.22	04.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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