Clinical Policy: Ixekizumab (Taltz)

Reference Number: PA.CHIP.PHAR.257
Effective Date: 01/2026
Last Review Date: 10/2025

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 the member has met all approval criteria.

It is the policy of PA Health & Wellness® 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 ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;
5. For AS, member meets ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b, *see Appendix D*):
   a. Failure of one adalimumab product (e.g., *Hadlima™, Simlandi®, Yusimry™, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. If member has not responded or is intolerant to one or more TNF blockers, failure of Xeljanz®/Xeljanz XR®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
   **Prior authorization may be required for adalimumab products and Xeljanz/Xeljanz XR*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. 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. ≥ 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, b, or c):
   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;
   c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. For age ≥ 18 years, member meets ONE of the following, unless contraindicated or clinically significant adverse effects are experienced (a or b, *see Appendix D*):
   a. Failure of a ≥ 3 consecutive month trial of one* adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*);
   b. History of failure of two TNF blockers;

   **Prior authorization may be required for adalimumab products*
6. Failure of a ≥ 3 consecutive month trial of one ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*), unless clinically significant adverse effects are experienced or all are contraindicated;

   **Prior authorization may be required for ustekinumab products*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. 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 ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, and c, *see Appendix D*):
   e. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   f. Otezla®;
   g. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz/Xeljanz XR, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;

   **Prior authorization may be required for adalimumab products, Otezla, and Xeljanz/Xeljanz XR*
5. Failure of a ≥ 3 consecutive month trial of one ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*), unless clinically significant adverse effects are experienced or all are contraindicated;
   **Prior authorization may be required for ustekinumab products*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed one of the following (a or b):
   h. PsA alone: 160 mg at weeks 0, followed by maintenance dose of 80 mg every 4 weeks;
   i. 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 (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   j. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   k. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

   2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) ANDcriterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Fidelis benefit or member has previously met

initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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 with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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

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	4 mg/kg/day
methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®)	**PsO** 10 – 25 mg/week PO, IM, or SC 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
Hadlima (adalimumab-bwwd), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	**AS, PsA** 40 mg SC every other week **PsO** Initial dose: 80 mg SC Maintenance dose: 40 mg SC every other week starting one week after initial dose **HS** Initial dose: 160 mg SC on day 1, then 80 mg SC on Day 15	**AS, PsA, PsO:** 40 mg every other week **HS:** 40 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Maintenance dose: 40 mg SC every week or 80 mg SC every other week starting on Day 29	
Otezla® (apremilast)	**PsA** Initial dose: Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM Maintenance dose: Day 6 and thereafter: 30 mg PO BID	60 mg/day
Otulfi® (ustekinumab-aauz), Pyzchiva® (ustekinumab-ttwe), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce)	**PsO** Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg *Pediatrics (age 6 years to 17 years):* **Otulfi, Pyzchiva, Yesintek:** Weight < 60 kg: 0.75 mg/kg **Otulfi, Pyzchiva, Selarsdi, Steqeyma, Yesintek:** Weight 60 to 100 kg: 45 mg Weight > 100 kg: 90 mg **PsA** Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks	PsO: 90 every 12 weeks PsA: 45 mg every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Pediatrics (age 6 years to 17 years): Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter **Otulfi, Pyzchiva, Yesintek:** Weight < 60 kg: 0.75 mg/kg **Otulfi, Pyzchiva, Selarsdi, Steqeyma, Yesintek:** Weight ≥ 60 kg: 45 mg	
Xeljanz® (tofacitinib)	**AS, PsA** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**AS, PsA** 11 mg PO QD	11 mg/day

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
- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

V. Dosage and Administration

<table>
<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>PsO (with or without coexistent PsA)</td><td>Adults:
Initial dose: 160 mg (two 80 mg injections) SC at week 0, then 80 mg SC at weeks 2, 4, 6, 8, 10, and 12
Maintenance dose:
80 mg SC every 4 weeks

Pediatrics (ages 6 to 17 years):
<table>
<tr><th>Pediatric Patient's Weight</th><th>Starting Dose (Week 0)</th><th>Dose every 4 weeks (Q4W) Thereafter</th></tr>
<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>
</table></td><td>80 mg every 4 weeks</td></tr>
<tr><td>PsA, AS</td><td>Initial dose: 160 mg (two 80 mg injections) SC at week 0
Maintenance dose:
80 mg SC every 4 weeks</td><td>80 mg every 4 weeks</td></tr>
<tr><td>nr-axSpA</td><td>80 mg SC every 4 weeks</td><td>80 mg every 4 weeks</td></tr>
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VI. Product Availability

- Single-dose prefilled autoinjector: 80 mg/mL
- Single-dose prefilled syringes: 20 mg/0.25 mL, 40 mg/0.5 mL, 80 mg/mL

VII. References

1. Taltz Prescribing Information. Indianapolis, IN: Eli Lilly and Company; August 2024. Available at: https://uspl.lilly.com/taltz/taltz.html#s11. Accessed February 28, 2025.
2. 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;80:1029-72. Doi:10.1016/j.aad.201811.057.
3. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79:700–712. Doi:10.1136/annrheumdis-2020-217159.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. American College of Rheumatology. 2019; 71(1):5-32. Doi: 10.1002/art.40726.
5. Ward MM, Deodhar A, Gensler L, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network

recommendations for the treatment of anklyosing spondylitis and nonradiographic axial spondyloarthritis. Arthritis & Rheumatology. 2019; 71(10):1599-1613. DOI 10.1002/ART.41042.

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
C9399	Unclassified drugs or biologicals
J3590	Unclassified biologicals

Reviews, Revisions, and Approvals	Date
Policy created	10/2025