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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	April 22, 2016
Subject:	Taltz	**Page:**	1 of 9

Last Review Date: March 8, 2024

Taltz

Description

Taltz (ixekizumab)

Background
Taltz (ixekizumab) is a subcutaneous injectable treatment form that helps regulate inflammation. Taltz is an antibody that binds to interleukin 17A (IL-17A) a protein involved in inflammation. Taltz binds to IL-17A and prevents it from binding to its receptor inhibiting its ability to trigger the inflammatory response that plays a role in the development of plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA) (1).

Regulatory Status
FDA-approved indications: Taltz is a humanized interleukin-17A antagonist indicated for the treatment of: (1)

1. Patients aged 6 years or older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
2. Adults with active psoriatic arthritis
3. Adults with active ankylosing spondylitis
4. Adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation

Patients should be evaluated for tuberculosis infection prior to initiating treatment with Taltz. Do not administer Taltz to patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to administering Taltz. Consider anti-tuberculosis therapy prior to initiation of Taltz in

patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed. Patients receiving Taltz should be monitored closely for signs and symptoms of active tuberculosis during and after treatment (1).

Taltz affects the immune system, thus patients may have a greater risk of getting an infection. Serious allergic reactions have been reported with the use of Taltz. Caution should be exercised when considering the use of Taltz in patients with a chronic infection or history of recurrent infection, and in patients with active Crohn's disease and ulcerative colitis (1).

Patients treated with Taltz should not receive live vaccines (1).

Safety and effectiveness of Taltz in pediatric patients less than 6 years of age with plaque psoriasis (PsO) have not been established (1).

Safety and effectiveness of Taltz in pediatric patients less than 18 years of age with psoriatic arthritis (PsA), ankylosing spondylitis (AS), or non-radiographic axial spondyloarthritis (nr-axSpA) have not been established (1).

Related policies
Cosentyx, Siliq

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Taltz may be considered **medically necessary** if the conditions indicated below are met.

Taltz may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severe plaque psoriasis (PsO)
    a. 6 years of age or older

   b. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
      i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
   c. Prescriber will not exceed the FDA labeled maintenance dose of the following:
      i. Adults age 18 years and older: 80 mg every 4 weeks
      ii. Age 6-17, weight > 50kg: 80 mg every 4 weeks
      iii. Age 6-17, weight 25 – 50kg: 40 mg every 4 weeks
      iv. Age 6-17, weight < 25mg: 20 mg every 4 weeks
   d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products [Enbrel (all ages) or Humira (age 12+ only)] if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
2. Active psoriatic arthritis (PsA)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
   c. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg every 4 weeks
   d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
3. Active ankylosing spondylitis (AS)
   a. 18 years of age or older
   b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
   c. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg every 4 weeks
   d. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
4. Non-radiographic axial spondyloarthritis (nr-axSpA)
   a. 18 years of age or older

b. Patient has objective signs of inflammation
c. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
d. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg every 4 weeks

AND ALL of the following:

a. Prescriber agrees to monitor for onset or exacerbations of Crohn's or ulcerative colitis disease and discontinue if necessary
b. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (See Appendix 1)
c. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
d. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
e. **NOT** given concurrently with live vaccines

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Plaque Psoriasis (PsO)
    a. 6 years of age or older
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Adults age 18 years and older: 80 mg every 4 weeks
        ii. Age 6-17, weight > 50kg: 80 mg every 4 weeks
        iii. Age 6-17, weight 25 – 50kg: 40 mg every 4 weeks
        iv. Age 6-17, weight < 25mg: 20 mg every 4 weeks
    c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products [Enbrel (all ages) or Humira (age 12+ only)] if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
2. Psoriatic arthritis (PsA)
    a. 18 years of age or older

b. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg every 4 weeks
c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Ankylosing spondylitis (AS)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg every 4 weeks
   c. Blue Focus **only:** Patient **MUST** have tried **ONE** of the preferred products (Enbrel or Humira) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
4. Non-radiographic axial spondyloarthritis (nr-axSpA)
   a. 18 years of age or older
   b. Prescriber will not exceed the FDA labeled maintenance dose of 80 mg every 4 weeks

AND ALL of the following:

a. Condition has improved or stabilized with therapy
b. Prescriber agrees to monitor for onset or exacerbations of Crohn's or ulcerative colitis disease and discontinue if necessary
c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (See Appendix 1)
d. **NOT** given concurrently with live vaccines

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 18 (80mg) units
(plaque psoriasis dosing is 2 injections at Week 0, followed by 1 injection each at Week 2, 4, 6, 8, 10, and 12, then every 4 weeks)

Duration 12 months

Prior – Approval *Renewal* Limits

Quantity 3 (80mg) units per 84 days

Duration 18 months

Rationale

Summary
Taltz (ixekizumab) is a subcutaneous injectable treatment that helps regulate inflammation. Taltz is an antibody that binds to interleukin 17A (IL-17A) a protein involved in inflammation. Taltz binds to IL-17A and prevents it from binding to its receptor inhibiting its ability to trigger the inflammatory response that plays a role in the development of plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA. Taltz affects the immune system, thus patients may have a greater risk of getting an infection. Serious allergic reactions have been reported with the use of Taltz. Caution should be exercised when considering the use of Taltz in patients with a chronic infection or history of recurrent infection, and in patients with active Crohn's disease and ulcerative colitis. Taltz should not be used in combination with other biologic or targeted synthetic DMARDs or be given concurrently with live vaccines (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Taltz while maintaining optimal therapeutic outcomes.

References
1. Taltz [package insert]. Indianapolis, IN: Eli Lilly and Company; September 2022.

Policy History

Date	Action
April 2016	Addition to PA
September 2016	Annual editorial review Addition of not given concurrently with live vaccines per SME
December 2016	Annual review
June 2017	Annual review

September 2017	Annual editorial review and reference update Added age limit to continuation section and dosing limit requirement
December 2017	Annual editorial review and reference update Addition of new indication of active psoriatic arthritis (PsA)
June 2018	Addition of Appendix 1 - List of Conventional Therapies and Appendix 2 - Examples of Contraindications to Methotrexate Addition of additional requirements to initiation criteria For diagnosis of PsA: inadequate response, intolerance or contraindication to a 3-month trial of at least ONE conventional DMARD For diagnosis of PsO: if the patient is intolerant or contraindicated to either therapy then the other treatment option needs to be tried Removal of requirement: prescriber will be dosing the patient within the FDA labeled maintenance dose of 80 mg every 4 weeks
September 2018	Annual editorial review and reference update
September 2019	Annual review. Addition of indication: ankylosing spondylitis
December 2019	Annual review. Addition of requirement to trial preferred product
April 2020	Lowered age requirement to 6 years of age or older for plaque psoriasis
June 2020	Annual review. Addition of indication: non-radiographic axial spondyloarthritis (nr-axSpA)
December 2020	Annual editorial review. Revised requirements to t/f preferred products to apply to Blue Focus patients only. Changed initial approval duration to 12 months. Added requirements to dose within the FDA labeled maintenance dosing
March 2021	Annual editorial review. Revised background and summary sections. Clarification added to the t/f, intolerance, C/I to preferred products requirement indicating that it only applies to claims adjudicated through the pharmacy benefit. Appendix 1 updated.
September 2022	Annual review and reference update
December 2022	Annual review and reference update
December 2023	Annual review
March 2024	Annual editorial review. Revised FDA dosing language

Keywords

This policy was approved by the FEP® Pharmacy Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of DMARDs

Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine

Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade/Avsola/Inflectra/Renflexis
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan/Riabni/Ruxience/Truxima
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu

tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 – Examples of Contraindications to Methotrexate

Contraindications to Methotrexate
1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4. Elevated liver transaminases
5. History of intolerance or adverse event
6. Hypersensitivity
7. Interstitial pneumonitis or clinically significant pulmonary fibrosis
8. Myelodysplasia
9. Pregnancy or planning pregnancy (male or female)
10. Renal impairment
11. Significant drug interaction