BlueCross BlueShield Federal Employee Program

TALTZ
(ixekizumab)

Pre - PA Allowance

None

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 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* 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

Prior - Approval *Renewal* Limits

Quantity 3 (80mg) units per 84 days
Duration 18 months

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
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
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