BlueCross BlueShield Federal Employee Program

KINERET
(anakinra)

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

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

1. Rheumatoid Arthritis (RA)
   a. 18 years of age or older
   b. Moderate to severely active
   c. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying anti-rheumatic drugs (DMARDs) (see Appendix 2)
   d. Prescriber will be dosing the patient within the FDA labeled maintenance dose of 100 mg per day
   e. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Cryopyrin-Associated Periodic Syndrome (CAPS)
   a. Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
   b. Prescriber will not exceed the FDA labeled maintenance dose of 8 mg/kg/day

3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
   a. Prescriber will not exceed the FDA labeled maintenance dose of 8 mg/kg/day

4. Systemic juvenile idiopathic arthritis (sJIA)

5. Adult-onset Still's disease

6. Gout and pseudogout (calcium pyrophosphate deposition)

7. CAR T Cell-Related Toxicities

AND ALL of the following:

1. 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

2. **NO** active bacterial, invasive fungal, viral, and other opportunistic infections
3. Patient is not at risk for HBV infection **OR** patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated.
4. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
5. **NOT** given concurrently with live vaccines

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Rheumatoid Arthritis	100 mg	84 syringes per 84 days
Cryopyrin-Associated Periodic Syndrome (CAPS)	100 mg	8 mg/kg per day
Deficiency of Interleukin-1 Receptor Antagonist (DIRA)	100 mg	8 mg/kg per day
Systemic juvenile idiopathic arthritis (sJIA)	100 mg	No limit
Adult-onset Still's disease	100 mg	
Gout and pseudogout (calcium pyrophosphate deposition)	100 mg	
CAR T Cell-Related Toxicities	100 mg	

Duration 12 months

Prior – Approval *Renewal* Requirements

Diagnoses

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

1. Rheumatoid Arthritis (RA)
   a. 18 years of age or older
   b. Prescriber will be dosing the patient within the FDA labeled maintenance dose of 100 mg per day
   c. Patient **MUST** have tried the preferred product(s) (see Appendix 3) if adjudicated through the pharmacy benefit unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Cryopyrin-Associated Periodic Syndrome (CAPS)

b. Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
c. Prescriber will not exceed the FDA labeled maintenance dose of 8 mg/kg/day

3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
   a. Prescriber will not exceed the FDA labeled maintenance dose of 8 mg/kg/day

4. Systemic juvenile idiopathic arthritis (sJIA)

5. Adult-onset Still's disease

6. Gout and pseudogout (calcium pyrophosphate deposition)

7. CAR T Cell-Related Toxicities

AND ALL of the following:

1. Condition has improved or stabilized with Kineret therapy
2. Absence of active infection (including tuberculosis and hepatitis B virus (HBV))
3. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)
4. **NOT** given concurrently with live vaccines

Prior - Approval *Renewal* Limits

Quantity

Diagnosis	Strength	Quantity
Rheumatoid Arthritis	100 mg	84 syringes per 84 days
Cryopyrin-Associated Periodic Syndrome (CAPS)	100 mg	8 mg/kg per day
Deficiency of Interleukin-1 Receptor Antagonist (DIRA)	100 mg	8 mg/kg per day
Systemic juvenile idiopathic arthritis (sJIA)	100 mg	No limit
Adult-onset Still's disease	100 mg	
Gout and pseudogout (calcium pyrophosphate deposition)	100 mg	
CAR T Cell-Related Toxicities	100 mg	

Duration 18 months

Appendix 1 – 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

Appendix 2 - 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 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
*Rheumatoid Arthritis (RA)	*must try **TWO** preferred products: Actemra (SC) Enbrel Humira** Rinvoq Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)