

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Kineret Formulary Exception Policy

- Kineret® (anakinra for subcutaneous injection – Biovitrim)

REVIEW DATE: 01/20/2021

Documentation Required: For rheumatoid arthritis (RA), a trial of two Formulary products are required. The prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals are provided for the duration noted below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

All reviews for use of Kineret for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director.

CRITERIA

1. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii and iii):

i. Patient has had a 3-month trial of a biologic OR targeted synthetic DMARD for this condition, unless intolerant; AND

Note: Refer to [Appendix](#) for examples of biologics and targeted synthetic DMARDs used for rheumatoid arthritis. Conventional synthetic DMARDs such as methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine do not count.

ii. The medication is prescribed by or in consultation with a rheumatologist; AND

iii. Patient has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR **[documentation required]**.

Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of ONE product. A trial of Actemra intravenous, Cimzia, Orencia subcutaneous or intravenous, an infliximab product (e.g., Remicade, biosimilars), Kevzara, or Simponi Aria or subcutaneous also counts **[documentation required]**.

Note: If the patient has met criterion i and ii but criterion iii is not met, offer to review for a Formulary product (Actemra subcutaneous, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.

B) Patient is Currently Receiving Kineret. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has had a response, as determined by the prescriber; AND

Note: Examples of response include less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids. Patient may not have a full response, but there should have been a recent or past response to Kineret.

ii. Patient meets ONE of the following conditions (a or b):

a) Patient has been established on Kineret at least 90 days and prescription claims history indicates at least a 90-day supply of Kineret was dispensed within the past 130 days

[verification in prescription claims history required] or, if not available, **[verification by prescriber required]** AND the patient has been receiving Kineret via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Kineret); OR

Note: In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Kineret for at least 90 days.

- b) Patient has tried TWO of Actemra subcutaneous, Enbrel, Humira, Rinvoq, and Xeljanz/XR **[documentation required]**.**

Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of **ONE** product. A trial of Actemra intravenous, Cimzia, Orencia subcutaneous or intravenous, an infliximab product (e.g., Remicade, biosimilars), Kevzara, or Simponi Aria or subcutaneous also counts **[documentation required]**.

Note: If the patient has met criterion i but criterion ii is not met, offer to review for a Formulary product (Actemra SC, Enbrel, Humira, Rinvoq, or Xeljanz/XR) using the appropriate standard *Inflammatory Conditions* criteria.

- 2. Cryopyrin-Associated Periodic Syndromes (CAPS).** Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 3 months if the patient meets BOTH of the following criteria (i and ii):

- i.** Kineret is being used for treatment of Neonatal Onset Multisystem Inflammatory Disease (NOMID), Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and/or chronic infantile neurological cutaneous and articular (CINCA) syndrome; AND
- ii.** The medication is prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist.

- B) Patient is Currently Receiving Kineret.** Approve for 1 year if the patient has had a response, as determined by the prescriber.

Note: Patient may not have a full response, but there should have been a recent or past response to Kineret.

- 3. Deficiency of Interleukin-1 Receptor Antagonist.** Approve for the duration noted if the patient meets one of the following (A or B):

- A) Initial Therapy.** Approve for 3 months if the patient meets BOTH of the following (i and ii):

- i.** Genetic testing has confirmed a mutation in the *IL1RN* gene; AND
- ii.** The medication is prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders.

- B) Patient is Currently Receiving Kineret.** Approve for 3 years if the patient had a response, as determined by the prescriber.

Note: Examples of a response include normalized acute phase reactants; resolution of fever, skin rash, and bone pain; and reduced dosage of corticosteroids.

- 4. Systemic Juvenile Idiopathic Arthritis (SJIA).** Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 3 months if the patient meets BOTH of the following criteria (i and ii):

- i.** Patient meets ONE of the following conditions (a, b, or c):

- a)** Patient has tried one other systemic agent for this condition; OR

Note: Examples of one other systemic agent include a corticosteroid (oral, IV); a conventional synthetic disease-modifying antirheumatic drug (DMARD; e.g.,

methotrexate, leflunomide, sulfasalazine); or a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID). A previous trial of a biologic (e.g. Actemra [tocilizumab intravenous injection, tocilizumab subcutaneous injection), a tumor necrosis factor (TNF) inhibitor (e.g., an etanercept product [Enbrel, biosimilars], an adalimumab product [Humira, biosimilars], or an infliximab product [Remicade, biosimilars]), or Ilaris (canakinumab subcutaneous injection) also counts towards a trial of one other systemic agent for SJA.

- b) Patient has at least moderate to severe active systemic features of this condition OR patient has active systemic features with an active joint count of one joint or greater, according to the prescriber; OR

Note: Examples of moderate to severe active systemic features include fever, rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis.

- c) Patient has active systemic features with concerns of progression to macrophage activation syndrome (MAS), as determined by the prescriber; AND

ii. The medication is prescribed by or in consultation with a rheumatologist.

- B) Patient is Currently Receiving Kineret. Approve for 1 year if the patient has responded, as determined by the prescriber.

Note: Examples of response include improvement in limitation of motion; less joint pain or tenderness; decreased duration of morning stiffness or fatigue; improved function or activities of daily living; reduced dosage of corticosteroids. Patient may not have a full response, but there should have been a recent or past response to Kineret.

5. Still's Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy. Approve for 3 months if the patient meets BOTH of the following criteria (i and ii):

i. Patient meets ONE of the following conditions (a, b, or c):

- a) Patient meets BOTH of the following criteria [(1) and (2)]:

(1) Patient has tried one corticosteroid; AND

(2) Patient has had an inadequate response to one conventional synthetic disease-modifying antirheumatic drug (DMARD) such as methotrexate (MTX) given for at least 2 months or was intolerant to a conventional synthetic DMARD; OR

Note: A previous trial of a biologic (e.g., Actemra IV, Arcalyst, Ilaris) also counts towards a trial of one other systemic agent for Still's disease.

- b) Patient has at least moderate to severe active systemic features of this condition, according to the prescriber; OR

Note: Examples of moderate to severe active systemic features include fever, rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis.

- c) Patient has active systemic features with concerns of progression to macrophage activation syndrome, as determined by the prescriber; AND

ii. The medication is prescribed by or in consultation with a rheumatologist.

- B) Patient is Currently Receiving Kineret. Approve for 1 year if the patient has responded, as determined by the prescriber.

Note: Examples of response include improvement in limitation of motion; less joint pain or tenderness; decreased duration of morning stiffness or fatigue; improved function or activities of daily living; reduced dosage of corticosteroids. Patient may not have a full response, but there should have been a recent or past response to Kineret.

6. Conditions Not Recommended for Coverage. Patients who meet any of the following criteria do not qualify for treatment with Kineret.

- A) Ankylosing Spondylitis; OR
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- B) Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD); OR**

Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Kineret.

- C) COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.

Note: This includes requests for cytokine release syndrome associated with COVID-19.

- D) Lupus Arthritis; OR**

- E) Osteoarthritis; OR**

- F) Other circumstances not listed in criterion 1 through 4 (above).**
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APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications for Products*
Biologics		
Adalimumab SC Products (Humira [®] , biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia[®] (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel [®] , biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade [®] , biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi[®], Simponi[®] Aria[™] (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA
Actemra[®] (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
Kevzara[®] (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia[®] (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan [®] , biosimilars)	CD20-directed cytolytic antibody	RA
Kineret[®] (anakinra SC injection)	Inhibition of IL-1	JIA [^] , RA
Stelara[®] (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC
Siliq[™] (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx[™] (secukinumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Taltz[®] (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya[™] (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi[™] (risankizumab-rzaa SC injection)	Inhibition of IL-23	PsO
Tremfya[™] (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio[™] (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Targeted Synthetic Disease-Modifying Antirheumatic Drugs		
Otezla[®] (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Olumiant[®] (baricitinib tablets)	Inhibition of the JAK pathways	RA
Rinvoq[®] (upadacitinib extended-release tablets)	Inhibition of the JAK pathways	RA
Xeljanz[®] (tofacitinib tablets)	Inhibition of the JAK pathways	RA, PJIA, PsA, UC
Xeljanz[®] XR (tofacitinib extended-release tablets)	Inhibition of the JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indication (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous; PJIA – Polyarticular juvenile idiopathic arthritis; SJIA – Systemic juvenile idiopathic arthritis; [^] Off-label use of Kineret in JIA supported in guidelines; JAK – Janus kinase.