MEDICAL MUTUAL®

Drug Policy

Policy:	**201603**	**Initial Effective Date: 4/1/2016**
Code(s):	**HCPCS J3490, J3590**	**Annual Review Date: 01/18/2024**
SUBJECT:	**Kineret (anakinra) subcutaneous injection**	**Last Revised Date: 01/18/2024**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Kineret is an interleukin-1 (IL-1) receptor antagonist. IL-1 production is induced in response to inflammation and mediates various physiologic responses including inflammatory and immunological responses. Kineret is indicated to reduce the signs and symptoms and slow the progression of structural damage in adult patients with moderately to severely active rheumatoid arthritis (RA) who have failed one or more disease-modifying antirheumatic drugs (DMARDs). Kineret is also indicated in Cryopyrin-Associated Periodic Syndromes (CAPS) for treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID). In RA, Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents .

Policy Statement

This policy involves the use of Kineret. Prior authorization is recommended for pharmacy benefit coverage of Kineret. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Kineret as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Kineret be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. The Site of Care Medical Necessity Criteria applies to initial therapy and reauthorizations. **Kineret is subject to the Inflammatory Conditions Care Value Program for pharmacy benefits.**

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.

Food and Drug Administration (FDA)-Approved Indications

1. **Rheumatoid Arthritis (RA)**. The Company considers Kineret injection **medically necessary** and eligible for reimbursement providing that the following medical criteria are met:

A) Initial Therapy. Approve if the following criteria is met (i, ii and iii):

i. The patient has had a 3-month trial of a biologic disease-modifying antirheumatic drug (DMARD) OR targeted synthetic DMARD for this condition, unless intolerant [See Appendix A for examples] NOTE: Conventional synthetic DMARDs such as methotrexate {MTX}, leflunomide, hydroxychloroquine, and sulfasalazine do not count.]; AND

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

iii. Site of care medical necessity is met *.

B) Patients Currently Receiving Kineret. Approve if the patient has had a response (e.g., 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), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret. And Site of care medical necessity is met *.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

2. **Cryopyrin-Associated Periodic Syndromes (CAPS).** The Company considers Kineret injection **medically necessary** and eligible for reimbursement providing the following medical criteria are met:

A) Initial Therapy. Approve if the following criteria are met (i, ii and iii):

i. Kineret is being used for treatment of Cryopryin-Associated Periodic Syndromes (CAPS): Neonatal Onset Multisystem Inflammatory Disease (NOMID), also called chronic infantile neurological cutaneous and articular (CINCA) syndrome, Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS); AND

ii. Kineret is prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist; AND

iii. Site of care medical necessity is met*.

B) Patients Currently Receiving Kineret. Approve if the patient has had a response, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret. And Site of care medical necessity is met *.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

3. **Deficiency of Interleukin-1 Receptor Antagonist (DIRA). The Company considers Kineret injection medically necessary** and eligible for reimbursement providing the following medical criteria are met:
   A) Initial Therapy. Approve if the following criteria are met (i, ii and iii):
      i. DIRA is genetically confirmed by an FDA approved genetic test; AND
      ii. Kineret is prescribed by or in consultation with a rheumatologist, geneticist, or a physician who specializes in inflammatory conditions; AND
      iii. Site of care medical necessity is met*.

   B) Patients Currently Receiving Kineret. Approve if the patient has had a response, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret. And Site of care medical necessity is met *.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

Other Uses with Supportive Evidence

4. **Systemic Juvenile Idiopathic Arthritis (SJIA).** The Company considers Kineret injection **medically necessary** and eligible for reimbursement providing the following medical criteria are met:
   A) Initial Therapy. Approve if the following criteria are met (i and ii):
      i. Patient meets ONE of the following conditions (1, 2, 3, 4 or 5):
         1. The patient has tried ONE systemic agent for this condition (e.g., a corticosteroid; a conventional synthetic disease-modifying antirheumatic drug [DMARD; e.g., methotrexate {MTX}, leflunomide, sulfasalazine]; OR
         2. The patient has tried ONE biologic DMARD or a tumor necrosis factor [TNF] inhibitor or Ilaris [See Appendix A for examples]; OR
         3. The patient has tried a 1-month trial of a nonsteroidal anti-inflammatory drug [NSAID]; OR
         4. The patient has at least moderate to severe active systemic features of this condition (e.g., fever, rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis) OR the patient has active systemic features with an active joint count of one joint or greater, according to the prescribing physician; OR
         5. The patient has active systemic features with concerns of progression to macrophage activation syndrome (MAS), as determined by the prescribing physician; AND
      ii. Kineret is prescribed by or in consultation with a rheumatologist; AND
      iii. Site of care medical necessity is met *.

B) Patients Currently Receiving Kineret. Approve if the patient has responded (e.g., has 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), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret. And Site of care medical necessity is met *.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

5. **Still's Disease.** The Company considers Kineret injection (HCPCS Code) medically necessary and eligible for reimbursement providing that the following medical criteria are met**:**
   A) Initial Therapy. Approve if the following criteria are met (i, ii, and iii)
      i. The Patient meets ONE of the following (1, 2 or 3);
         1. The patient meets ALL of the following criteria: (a and b):
            a. The patient has tried one corticosteroid; AND
            b. The 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; AND
         2. The patient has at least moderate to severe active systemic features of this condition, according to the prescriber.
         3. The patient has active systemic features with concerns of progression to macrophage activation syndrome, as determined by the prescriber; AND
      ii. Kineret is prescribed by or in consultation with a rheumatologist; AND
      iii. Site of care medical necessity is met *.

   B) Patients Currently Receiving Kineret. Approve if the patient has responded (e.g., has 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), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Kineret And Site of care medical necessity is met *.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

Dosing

Rheumatoid Arthritis: 100 mg/day administered subcutaneously.

CAPS: starting dose of 1-2 mg/kg daily and up to 8 mg/kg daily. Once daily is recommended but dose may be split into two doses daily. Each syringe is a single use dose.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Kineret has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Ankylosing Spondylitis (AS).** Kineret has been beneficial in a few patients with AS, but results are not consistent. In a small open-label study, patients with active AS who were refractory to NSAIDs (n = 20) received Kineret 100 mg daily.[24] The Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score decreased over a 6-month period but was not significant (5.8 at baseline vs. 5.0 at Week 12 [P > 0.05], and 4.8 at Week 24 [P > 0.05]). No significant change was found in Bath Ankylosing Spondylitis Functional Index (BASFI), patients' and physicians' global assessment or general pain during the study. After 12 weeks, both the ASsessment in AS (ASAS) 20 and 40 responses improved in 10.5% of patients (intent-to-treat [ITT] analysis). After 24 weeks, ASAS 20 was attained in 26% of patients, ASAS 40 in 21% of patients, and ASAS 70 in 10.5% of patients. According to the ASAS working group and the European League Against Rheumatism (EULAR) recommendations for AS (2010), there is no evidence to support the use of any biologic agent besides TNF antagonists in ankylosing spondylitis.

2. **Concurrent Use with a Biologic or Targeted Synthetic DMARD.** Kineret should not be administered in combination with another biologic DMARD for an inflammatory condition (e.g., Actemra [IV or SC], Orencia IV or SC], Rituxan, or TNF antagonists [Cimzia, Enbrel, Humira, Remicade, or Simponi {Aria or SC}]). Combination therapy with two biologic agents is not recommended due to a higher rate of adverse effects with combinations and lack of additive efficacy.[27] Targeted synthetic DMARDs such as Xeljanz should not be used in combination with biologic DMARDs such as Kineret.[28] Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Kineret.

3. **Lupus Arthritis.** The effectiveness and safety of Kineret were evaluated in an open 3-month pilot trial in patients (n = 4) with systemic lupus erythematosis (SLE) and severe, therapy-refractory non-erosive polyarthritis (three patients had deforming Jaccoud's arthropathy) and no other uncontrolled major organ involvement. Patients were refractory to NSAIDs, antimalarials, corticosteroids, MTX, cyclophosphamide, and azathioprine. SLE was controlled with stable doses of corticosteroids and/or antirheumatic or immunosuppressive agents; pain was managed with NSAIDs and/or other medications. Patients had improved clinically after 4 weeks on Kineret, but after 12 weeks the clinical activity parameters tended to increase again. The results from this study are preliminary and a larger controlled study is needed.

4. **Osteoarthritis (OA), Symptomatic.** In a Phase II study in patients with painful OA of the knee, Kineret 150 mg administered by intraarticular injection was well tolerated. The study was not designed to assess the analgesic efficacy of Kineret since there was no control group. Intraarticular injections are often associated with a significant placebo effect. Patients with OA of the knee were enrolled in a multicenter, double-blind, placebo-controlled study and

randomized to Kineret 50 mg, Kineret 150 mg, or placebo for intraarticular injection. Although the injections were well tolerated, there were no significant differences in improvement in knee pain, stiffness, function or cartilage turnover between Kineret doses and placebo. Similar to other studies in this population, there was a significant placebo effect noted.

5. **COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director. Note: This includes requests for cytokine release syndrome associated with COVID.

6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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***MMO Site of Care Medical Necessity Criteria:**

- Medications in this policy will be administered in a place of service that identifies the location to be a non-hospital facility based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless *at least one* of the following are met[†]:

    1. Age less than 18* years; or
    2. Clinically unstable based upon documented medical history (e.g., patient is hemodynamically unstable); or
    3. History of a severe adverse event from previous administration of the prescribed medication; or
    4. Requested medication is being administered as follows:
        - part of a chemotherapy regimen (e.g., anti-neoplastic agent, colony stimulating factor, erythropoiesis-stimulating agent, anti-emetic) for treatment of cancer; or
        - administered with dialysis; or
    5. Physical or cognitive impairment and caregiver is not available to assist with safe administration of prescribed medication in the home; or
    6. Experiencing adverse events that are not managed by premedication or resources available at a non-hospital facility based location.

No initial doses are allowed in a hospital based outpatient facility without other above criteria being met.
* Effective 01/01/2019, age criterion applies to 18 years of older. Age at original effective date (03/01/2016) was 21 years or older.
†This criterion does not apply to Medicare or Medicare Advantage members.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes J3490 and J3590

†When *unclassified drug* (J3490) or *unclassified biologic* (J3590) are determined to be Kineret

Edits and Denials:

Prior approval: Prior approval is required for Kineret **(HCPCS Code J3490, J3590)** Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Code J3490 and J3590** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3490	Unclassified drugs
J3590	Unclassified biologics

Appendix A

Biologic or Targeted Synthetic DMARD	Mechanism of Action	Indications
Cimzia® (certolizumab pegol for SC injection)	Inhibition of TNF	AS, ASpA ,CD, PPs, PsA, RA
Enbrel® (etanercept for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Erelzi™ (etanercept-szzs for SC injection)	Inhibition of TNF	AS, PPs, PsA, RA
Humira® (adalimumab for SC injection)	Inhibition of TNF	AS, CD, HS, PPs, RA, UC, UV
Amjevita™ (adalimumab-atto for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Cyltezo® (adalimumab-adbm for SC injection)	Inhibition of TNF	AS, CD, PPs, RA, UC
Simponi® (golimumab for SC injection)	Inhibition of TNF	AS, PsA, RA, UC
Simponi® Aria™ (golimumab for IV infusion)	Inhibition of TNF	AS, PsA, RA, UC
Remicade® (infliximab for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Inflectra™ (infliximab-dyyb for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Renflexis® (infliximab-abda for IV infusion)	Inhibition of TNF	AS, CD, PPs, PsA, RA, UC
Actemra® (tocilizumab for IV infusion)	Inhibition of IL-6	CRS, GCA, RA
Actemra® (tocilizumab for SC injection)	Inhibition of IL-6	CRS, GCA, RA
Kevzara® (sarilumab for SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept for IV infusion)	T-cell costimulation modulator	PsA, RA
Orencia® (abatacept for SC injection)	T-cell costimulation modulator	PsA, RA
Rituxan® (rituximab for IV infusion)	CD20-directed cytolytic antibody	Various
Kineret® (anakinra for subcutaneous SC injection)	Inhibition of IL-1	NOMID, RA
Stelara® (ustekinumab for SC injection)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Stelara® (ustekinumab for IV infusion)	Inhibition of IL-12/23	CD, PPs, PsA, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PPs
Cosentyx™ (secukinumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Taltz® (ixekizumab for SC injection)	Inhibition of IL-17A	AS, PPs, PsA
Ilumya™ (tildrakizumab-asmn for SC injection)	Inhibition of IL-23	PPs
Tremfya® (guselkumab for SC injection)	Inhibition of IL-23	PPs
Otezla® (apremilast tablets)	Inhibition of PDE4	BD, PPs, PsA
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways	RA
Xeljanz®, Xeljanz XR (tofacitinib tablets, tofacitinib ER tabs)	Inhibition of the JAK pathways	PsA, RA, UC

Agents and associated indications are for reference only.

"The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding."

AS = Ankylosing Spondylitis, ASpA = Axial Spondyloarthritis, BD = Behcet Disease, CD = Crohn's Disease, CRS = Cytokine Release Syndrome, GCA = Giant Cell Arteritis, GVHD = Graft-Versus-Host Disease, HS = Hidradenitis Suppurativa, NOMID = Neonatal-onset Multisystem Inflammatory Disease, PPs = Plaque Psoriasis, PsA = Psoriatic Arthritis, RA = Rheumatoid Arthritis, SpA = Spondyloarthritis, UC = Ulcerative Colitis, UV = Uveitis