AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Kineret® (anakinra)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed#: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

NOTE: AvMed Health considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Dupixent, Entyvio, Humira, Rinvoq, Stelara) prescribed for the same or different indications to be experimental and investigational. Safety and efficacy of these combinations has **NOT** been established and will **NOT** be permitted.

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Moderate-to-Severe Active Rheumatoid Arthritis**
Dosing: SubQ: 100 mg daily

Authorization Criteria: (Length of authorization is indefinite for this indication only)

- ❑ Member has a diagnosis of moderate-to-severe active **rheumatoid arthritis**
- ❑ Prescribed by or in consultation with a **Rheumatologist**

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- ❑ Member has tried and failed at least **ONE** of the following **DMARD** therapies for at least three **(3) months (verified by chart notes or pharmacy paid claims)**
  - ❑ hydroxychloroquine
  - ❑ leflunomide
  - ❑ methotrexate
  - ❑ Sulfasalazine
- ❑ Member meets **ONE** of the following:
  - ❑ Member tried and failed, has a contraindication, or intolerance to **TWO** of the **PREFERRED** biologics below **(verified by chart notes or pharmacy paid claims)**:

❑ Actemra® SC	❑ adalimumab product: Humira®, Cyltezo® or Hyrimoz®	❑ Enbrel®
❑ Rinvoq®	❑ Xeljanz®/XR®	

  - ❑ Member has been established on Kineret® for at least 90 days **AND** prescription claims history indicates **at least a 90-day supply of Kineret was dispensed within the past 130 days (verified by chart notes or pharmacy paid claims)**

❑ **Diagnosis: Systemic Juvenile Idiopathic Arthritis (SJIA)**
Dosing: SubQ: 100 mg daily

Initial Authorization: 12 months

- ❑ Date of diagnosis must be noted: _____
- ❑ Member must have had trial and failure of NSAIDs and corticosteroids for > 3 months consecutively within the last 4 months **(verified by chart notes or pharmacy paid claims)**
- ❑ Member must have had ≥ 2 active joints with concomitant fever for at least 5 days and trial of prednisone or equivalent dosed at 0.5 mg/kg/day or 30 mg/day within the last 3 months of this request
- ❑ Member must have had fever > 38º C or 100.4º F for at least 2 weeks within the last 2 months of this request
- ❑ Member must have **ONE** of the following measurements of active disease:
  - ❑ Member must have had CRP (>15 mg/L) within the last 2 months of this request
  - ❑ Member must have had ESR (>45 mm/hr) within the last 2 months of this request

❑ **Diagnosis: Adult-onset Still's disease (AOSD)**
Dosing: SubQ: 100 mg daily

Initial Authorization: 12 months

- ❑ Member must be at least 18 years of age

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- ❑ Member must meet **TWO** of the following:
  - ❑ Fever >39°C, lasting 1 week or longer
  - ❑ Arthralgia or arthritis, lasting 2 weeks or longer
  - ❑ Typical rash
  - ❑ Leukocytosis >10,000/mm^3 with >80% polymorphonuclear cells
- ❑ Disease activity based on DAS28 of ≥ 3.2 at screening
- ❑ Member must have **ONE** of the following measurements of active disease:
  - ❑ Member must have had CRP (>15 mg/L) within the last 2 months of this request
  - ❑ Member must have had ESR (>45mm/hour) within the last 2 months of this request
- ❑ Member must have had ≥ 2 joints that are painful/swollen for at least 2 weeks within the last 3 months of this request
- ❑ Member must have had trial and failure with at a least 1 week of glucocorticoids (dose: ≤10 mg/day prednisolone equivalent) **AND** at least 4 weeks of NSAIDs within the last 3 months of this request

❑ Diagnosis: Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of TRAPS
- ❑ Member has a diagnosis of TRAPS with genetic confirmation of the TNFRSF1A gene mutation
- ❑ Member has had chronic or recurrent disease resulting in six (6) flares within a 12-month time frame **(submit chart notes)**
- ❑ Provider must submit labs documenting the member's CRP level >10 mg/L which is indicative of active disease **(submit labs collected within the last 30 days)**
- ❑ Member must have trial and failure of NSAIDs and corticosteroids within the last 6 months **(verified by chart notes or pharmacy paid claims)**

❑ Diagnosis: Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of HIDS/MKD
- ❑ Provider must submit genetic confirmation of HIDS (i.e. DNA analysis or enzymatic studies showing mutations in the MVK gene or markedly reduced mevalonate kinase activity)
- ❑ Member must have a history of ≥ three (3) febrile acute flares within a 6-month period when not receiving prophylactic treatment
- ❑ Provider must submit labs documenting the member's CRP level >10mg/L which is indicative of active disease **(submit labs collected within the last 30 days)**

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❑ **Diagnosis: Familial Mediterranean Fever (FMF)**
Maximum Dosing: SubQ: 100 mg daily
Children ≥ 2 years and Adolescents: SubQ: 2 mg/kg/dose once daily

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of FMF
- ❑ Member must have Type 1 disease characterized by recurrent and short episodes of inflammation and serositis with an average of at least one documented acute FMF attack per month during the previous 6 months and lasting approximately 12 to 72 hours
- ❑ Provider must submit genetic confirmation of active Type 1 FMF disease (i.e., MEFV gene exon 10 mutation)
- ❑ Provider must submit labs documenting the member's CRP level >10mg/L which is indicative of active disease **(submit labs collected within the last 30 days)**
- ❑ Member must have trial and failure of maximally dosed colchicine (children-2 mg/day or adults-3 mg/day)

❑ **Diagnosis: Cryopyrin-associated periodic syndromes (CAPS)**
Dosing: Children, and Adolescents: SubQ: Initial: 1 to 2 mg/kg/day in 1 to 2 divided doses; adjust dose in 0.5 to 1 mg/kg increments as needed to control inflammation; usual maintenance dose: 3 to 4 mg/kg/day; maximum daily dose: 8 mg/kg/day

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of CAPS
- ❑ Member must have at least **TWO** of any of the CAPS-typical symptoms:
  - ❑ urticaria-like rash
  - ❑ cold-triggered episodes
  - ❑ sensorineural hearing loss
  - ❑ musculoskeletal symptoms
  - ❑ chronic aseptic meningitis
  - ❑ skeletal abnormalities
- ❑ Member has elevated serum levels which are indicative of active disease: **(submit labs collected within the last 30 days)**
  - ❑ C-Reactive Protein (CRP): _____ **AND** ❑ Serum Amyloid A (SAA): _____
- ❑ Member has documented laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1), also known as NLRP3 (R26OW, T348M, D303N, E311K, M662T, A439V, D305N, T436N, T4361) **(submit genetic testing results)**

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- ❑ Member has a diagnosis of **ONE** of the following:
  - ❑ Familial Cold Auto-inflammatory Syndrome (FCAS)
  - ❑ Muckle- Wells Syndrome (MWS)
  - ❑ Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

❑ **Diagnosis: Deficiency of interleukin 1 receptor antagonist (DIRA)**
Dosing: Children, and Adolescents: SubQ: Initial: 1 to 2 mg/kg/dose once daily; may titrate in 0.5 to 1 mg/kg increments up to a maximum dose of 8 mg/kg/dose

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of DIRA
- ❑ Member is **NOT** receiving another IL1 antagonist medication (e.g., Ilaris or Araclyst)
- ❑ Member has **ONE** of the following: pustular dermatitis, osteomyelitis, vertebral destruction **(submit chart note documentation)**
- ❑ Member has elevated serum levels indicative of active disease **(submit labs collected within the last 30 days)**
  - ❑ C-Reactive Protein (CRP): _____ **OR** ❑ Erythrocyte Sedimentation Rate (ESR): _____

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied. **Note: Reauthorization criteria is applicable for all diagnoses EXCEPT Rheumatoid Arthritis.**

- ❑ Member has experienced an absence of unacceptable toxicity from the drug [e.g., hypersensitivity reactions, serious infections (include but not limited to tuberculosis), and macrophage activation syndrome (MAS)]
- ❑ Member is receiving ongoing monitoring for presence of TB or other active infections
- ❑ Member has experienced disease response as indicated by improvement in member's symptoms from baseline **AND** improvement of CRP and SAA serum levels (both levels are <10 mg/L) **(submit labs collected within the last 30 days)**

Medication being provided by Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****
****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****