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: Arcalyst® (rilonacept) **(Pharmacy)**

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, if applicable:** _____

Weight: _____ **Date:** _____

- ❑ **Quantity Limit:** Maximum of 320mg injected on day 1, then maximum of 160mg injected per week (starting 1 week after loading dose)

CLINICAL CRITERIA/DIAGNOSIS: 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. Check box below for the Diagnosis that applies.

Initial Approval - 6 months

- ❑ Member is not on concurrent treatment with a TNF inhibitor or other biologic response modifier (e.g Humira®, Cimzia®, Simponi®, Rinvoq®, Acetmra®, Taltz®, Stelara®, Enbrel®, Skyrizi®, Tremfya®, Orencia®, Cosentyx®, Dupixent®, Xolair®, Nucala®
- ❑ Member's current weight (kg): _____
- ❑ Reference lab values: C-reactive protein (normal): <8mg/L; Serum Amyloid A (normal): <10mg/L

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❑ **Diagnosis – Systemic Juvenile Idiopathic Arthritis (SJIA)**
Dosage: 160mg once weekly

❑ Date of diagnosis must be noted: _____

AND

❑ Member must have had trial and failure of NSAIDs and corticosteroids for > 3 months consecutively within the last 4 months **(paid claims will be reviewed for verification)**

AND

❑ Member must have had ≥ 2 active joints with concomitant fever for at least 5 days and trial of prednisone or equivalent dosed at 0.5mg/kg/day or 30mg/day within the last 3 months of this request

AND

❑ Member must have had fever > 38º C or 100.4º F for at least 2 weeks within the last 2 months of this request

AND

❑ 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/hr) within the last 2 months of this request

❑ **Diagnosis – Adult onset Still disease (AOSD)**
Dosage: 160mg once weekly

❑ Member must be at least 18 years of age

AND

❑ 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/mm3 with >80% polymorphonuclear cells

AND

❑ Disease activity based on DAS28 of ≥3.2 at screening

AND

❑ 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/hr) within the last 2 months of this request

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AND

- ❑ Member must have had ≥ 2 joints that are painful/swollen for at least 2 weeks within the last 3 months of this request

AND

- ❑ 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

AND

- ❑ Member has had trial and failure of Kineret®

❑ **Diagnosis – Cryopyrin-associated periodic syndromes (CAPS)**

Dosage (CAPS):

- **Children ≥12 years and Adolescents ≤17 years**:
  - Initial: SubQ: Loading dose 4.4 mg/kg; maximum dose: 320 mg/dose; maximum injection volume: 2 mL (160 mg)/injection.
  - Maintenance dose: Begin 1 week after loading dose: SubQ: 2.2 mg/kg/dose once weekly; maximum dose: 160 mg/dose
- **Adolescents ≥18 years:**
  - Initial: Loading dose: 320 mg administered as 2 separate injections (160 mg each) on the same day at different sites.
  - Maintenance: Begin 1 week after loading dose: 160 mg once weekly.

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of CAPS

AND

- ❑ Member has two or more of any of the CAPS-typical symptoms:
  - ❑ urticaria-like rash
  - ❑ cold-triggered episodes
  - ❑ sensorineural hearing loss
  - ❑ musculoskeletal symptoms
  - ❑ chronic aseptic meningitis
  - ❑ skeletal abnormalities

AND

- ❑ Member has elevated serum levels (indicates active disease): **(Please submit labs collected within the last 30 days)**
  - ❑ C-Reactive (CRP): _____ **AND** ❑ Serum Amyloid A (SAA): _____

AND

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- ❑ 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) **(Please submit genetic testing results)**

AND

- ❑ Diagnosis of:
  - ❑ Familial Cold Auto-inflammatory Syndrome (FCAS)
  - ❑ Muckle- Wells Syndrome (MWS)
  - ❑ Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

AND

- ❑ Member has had trial and failure of Kineret®

❑ **Diagnosis – Deficiency of interleukin 1 receptor antagonist (DIRA):**
Dosage: Children ≥10 kg and Adolescents: SubQ: 4.4 mg/kg/dose once weekly and maximum dose: 320 mg/dose

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of DIRA

AND

- ❑ Member must weigh ≥10 kg

AND

- ❑ Member is not receiving another IL1 antagonist medication (example Ilaris® or Kineret®)

AND

- ❑ Member has one of the following: pustular dermatitis, osteomyelitis, vertebral destruction **(Please submit chart note documentation)**

AND

- ❑ Member has elevated serum levels (indicates active disease): **(Please submit labs collected within the last 30 days)**
  - ❑ C-Reactive (CRP): _____ **OR** ❑ Erythrocyte sedimentation rate (ESR): _____

AND

- ❑ Member has documented laboratory evidence of a genetic mutation in the deficiency of interleukin 1 receptor antagonist (DIRA), also known as IL1RN (2Q14.2)/ IL1RA

AND

- ❑ Member has had trial and failure of Kineret®

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❑ **Diagnosis – Pericarditis**
Dosage: Initial- 320mg; Maintenance- 160mg once weekly

❑ Member is ≥ 12 years old

AND

❑ Treatment of recurrent pericarditis (defined as two recurrent episodes) and symptoms consist of one of the following:
- ❑ Pericarditis chest pain
- ❑ Pericardial rub
- ❑ Pericardial effusion
- ❑ ST-segment elevation or PR depression

AND

- ❑ Member has failed one of the following within the last 6 months **(verified by pharmacy paid claims)**:
- ❑ aspirin (750-1000mg every 8 hours) for 30 days
- ❑ ibuprofen (600-800mg every 8 hours) for 30 days
- ❑ indomethacin (25-50mg every 8 hours) for 30 days
- ❑ prednisone (0.2-0.5mg/kg/daily) for 90 days

AND

❑ Member has failed colchicine (0.5-1.2mg) for 90 days

AND

❑ Member has at least one of the following elevated serum levels (indicates active disease): **(Please submit labs collected within the last 30 days)**
- ❑ C-Reactive (CRP) >10mg/L: _____
- ❑ Erythrocyte sedimentation rate (ESR) >20mm/hr: _____

Reauthorization Approval: 1 year. Current progress notes documenting CRP/SAA levels and symptoms must be provided for approval. 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. Check box below for the Diagnosis that applies.

❑ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following; sever hypersensitivity reactions, serious infections (include but not limited to tuberculosis), and macrophage activation syndrome (MAS)

AND

❑ Member is receiving ongoing monitoring for presence of TB or other active infections

AND

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- ❑ Disease response as indicated by improvement in patient's symptoms from baseline AND improvement in serum levels (CRP/ESR and/or SAA) to within normal range

Medication being provided by a Specialty Pharmacy - PropriumRx

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****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.****

***Approved by Pharmacy and Therapeutics Committee:** 11/18/2016
REVISED/UPDATED/REFORMATTED: ~~3/28/2017; 7/24/2017; (Reformatted) 3/16/2019; 7/7/2019; 9/22/2019; 5/14/2021; 6/30/2021; 9/14/2021;10/08/2021;~~ **10/26/2023**