SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL 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 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Ilaris® (canakinumab) (J0638) (Medical)

This form is applicable for the following diagnoses: Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF) and Cryopyrin-Associated Periodic Syndromes (CAPS) and Gout Flares

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

Member Name: _____

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

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.
  - Ilaris 150 mg/mL subcutaneous solution for injection; 1 vial = 150 billable units
- ❑ 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

(Continued on next page)

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.

Initial Approval: 6 months for all of the following diagnoses

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

Maximum Dosing: 4mg/kg up to 300mg every 4 weeks
Weight Based Dosing is as follows:
- ❑ > 40 kg: 150mg every 4 weeks with an inadequate response the dose can be increased to 300mg every 4 weeks
- ❑ ≤ 40 kg: 2 mg/kg every 4 weeks with an inadequate response the dose can be increased to 4 mg/kg every 4 weeks

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of TRAPS
- ❑ Member is ≥ 2 years of age
- ❑ 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 **(please submit chart notes)**
- ❑ Provider must submit labs documenting the member's CRP level >10mg/L which is indicative of active disease **(please submit labs collected within the last 30 days)**
- ❑ Member must have trial and failure of NSAIDs and corticosteroids within the last 6 months **(paid claims will be reviewed for verification)**
- ❑ Member must have trial and failure of at least one TNF inhibitor (i.e. Humira, Enbrel, infliximab) **AND** Kineret

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

Maximum Dosing: 4mg/kg up to 300mg every 4 weeks
Weight Based Dosing is as follows:
- ❑ > 40 kg: 150mg every 4 weeks with an inadequate response the dose can be increased to 300mg every 4 weeks
- ❑ ≤ 40 kg: 2 mg/kg every 4 weeks with an inadequate response the dose can be increased to 4 mg/kg every 4 weeks

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of HIDS/MKD
- ❑ Member is ≥ 2 years of age

(Continued on next page)

- ❑ 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
- ❑ Must submit labs documenting the member's CRP level >10mg/L which is indicative of active disease **(please submit labs collected within the last 30 days)**
- ❑ Member must have trial and failure of both the following:
  - ❑ Kineret
  - ❑ Enbrel

❑ **Diagnosis: Familial Mediterranean Fever (FMF)**

Maximum Dosing: 4mg/kg up to 300mg every 4 weeks
Weight Based Dosing is as follows:
- ❑ > 40 kg: 150mg every 4 weeks with an inadequate response the dose can be increased to 300mg every 4 weeks
- ❑ ≤ 40 kg: 2 mg/kg every 4 weeks with an inadequate response the dose can be increased to 4 mg/kg every 4 weeks

- ❑ Prescribed by or in consultation with a Rheumatologist or Immunologist with expertise in the diagnosis of FMF
- ❑ Member is ≥ 2 years of age
- ❑ 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 **(please submit labs collected within the last 30 days)**
- ❑ Member must have trial and failure of maximally dosed colchicine (children-2mg/day or adults-3mg/day)
- ❑ Member must have trial and failure of Kineret

❑ **Diagnosis: Cryopyrin-Associated Periodic Syndromes (CAPS)**

Maximum Dosing: 4mg/kg up to 300mg every 4 weeks Weight Based Dosing is as follows:
- ❑ > 40 kg: 150mg every 8 weeks
- ❑ > 15 kg and ≤ 40 kg: 2 mg/kg every 8 weeks
- ❑ > 15 kg and ≤ 40 kg with an inadequate response the dose can be increased to 3 mg/kg every 8 weeks

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

(Continued on next page)

- ❑ Member is ≥ 4 years of age
- ❑ 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
- ❑ Member has elevated serum levels which are indicative of active disease **(please 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) **(please submit genetic testing results)**
- ❑ 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)
- ❑ Member has had a 90-day trial and failure of both Kineret **AND** Arcalyst (failure is defined as documentation of CRP & SAA labs above normal levels) **(verified by pharmacy paid claims)**

Reauthorization Approval: 12 months. (Criteria is applicable for ALL diagnoses listed above). 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.

- ❑ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following; severe hypersensitivity reactions, serious infections (including but not limited to tuberculosis), and macrophage activation syndrome (MAS)
- ❑ Member is receiving ongoing monitoring for presence of TB or other active infections
- ❑ 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) **(please submit labs collected within the last 30 days)**

❑ Diagnosis: Gout Flares

Maximum Dosing: 150 mg as a single dose; repeat doses may be administered at intervals of ≥12 weeks

- ❑ Member is ≥ 18 years of age

(Continued on next page)

- ❑ Member has acute arthritis of primary gout
- ❑ Member has had a trial and failure of NSAIDs and colchicine, are contraindicated, are not tolerated or do not provide an adequate response
- ❑ Repeated courses of corticosteroids are not appropriate for this member

Reauthorization Approval: 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.

- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections (including but not limited to tuberculosis), and macrophage activation syndrome (MAS))
- ❑ Member has experienced a positive response to therapy (e.g., patient's pain score associated with gout has decreased)

Medication being provided by a Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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; 3/16/2019; 7/7/2019; 9/22/2019; 11/12/2020; 6/30/2021; 10/11/2021; 10/27/2021; 12/20/2023; 6/7/2024;~~ **3/25/2025**