SENTARA HEALTH PLANS

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 1-844-668-1550**. 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**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

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), 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:** _____

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:** _____

❑ 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

NOTE: Sentara Health considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Arcalyst, Enbrel, Humira, Kineret, Remicade) 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.

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- Reference lab values: C-reactive protein (normal): < 8mg/L; Serum Amyloid A (normal): <10 mg/L

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.

Initial Authorization: 6 months for ALL diagnoses

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

Maximum Dosing: 4 mg/kg up to 300 mg 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 >10 mg/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 (e.g., Humira, Enbrel, Remicade) AND Kineret® **(verified by pharmacy paid claims)**

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

Maximum Dosing: 4 mg/kg up to 300 mg 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
- ❑ 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 >10 mg/L which is indicative of active disease **(please submit labs collected within the last 30 days)**
- ❑ Member must have trial and failure of **BOTH** Kineret® & Enbrel® **(verified by pharmacy paid claims)**

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❑ Diagnosis: Familial Mediterranean Fever (FMF)

Maximum Dosing: 4 mg/kg up to 300 mg 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 >10 mg/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-2 mg/day or adults-3 mg/day) **(verified by pharmacy paid claims)**
- ❑ Member must have trial and failure of Kineret® (**verified by pharmacy paid claims)**

❑ Diagnosis: Cryopyrin-Associated Periodic Syndromes (CAPS)

Maximum Dosing:
Weight Based Dosing is as follows:

- ❑ > 40 kg: 150 mg 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
- ❑ Member is ≥ 4 years of age
- ❑ Member has at least **TWO** of the following CAPS-typical symptoms **(check all that apply)**:
  - ❑ urticaria-like rash
  - ❑ cold-triggered episodes
  - ❑ sensorineural hearing loss
  - ❑ musculoskeletal symptoms
  - ❑ chronic aseptic meningitis
  - ❑ skeletal abnormalities

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- ❑ 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: 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.

- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections (include but not limited to tuberculosis), and macrophage activation syndrome (MAS))
- ❑ Member is receiving ongoing monitoring for presence of tuberculosis (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) **(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

- ❑ Prescribed by or in consultation with a Rheumatologist or Nephrologist
- ❑ Member is ≥ 18 years of age
- ❑ Member has acute arthritis of primary gout
- ❑ Member has a history of ≥ 3 self-reported flares in the previous 12 months **(submit chart notes)**
- ❑ Member has had a 90-day trial and failure of **ALL** the following for gout flare management within the last 12 months **(progress notes and pharmacy paid claims define contraindications, intolerance, or unresponsiveness)**:
  - ❑ NSAIDs
  - ❑ colchicine
  - ❑ Intraarticular, intramuscular, or intravenous glucocorticoid

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- ❑ Member is currently compliant with therapy on **ONE** of the following (verified by chart notes and/or pharmacy paid claims):
  - ❑ allopurinol (maximally dosed at 400 – 800 mg/day)
  - ❑ febuxostat (generic Uloric) *requires prior authorization
  - ❑ Krytexxa® *requires prior authorization

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.

- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., severe hypersensitivity reactions, serious infections (include 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 (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan'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;~~ **11/16/2023**
REVISED/UPDATED/REFORMATTED: ~~3/28/2017~~; ~~7/24/2017~~; ~~(Reformatted) 3/16/2019; 7/7/2019; 9/22/2019; 11/12/2020~~; ~~6/30/2021; 10/11/2021;~~ ~~10/27/2021~~; **12/11/2023**