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)**

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®, Actemra®, Taltz®, Stelara®, Enbrel®, Skyrizi®, Tremfya®, Orencia®, Cosentyx®, Dupixent®, Xolair®, Nucala®
  - Reference lab values: C-reactive protein (normal): <8mg/L; Serum Amyloid A (normal): <10mg/L

Ilaris® is available under both Medical and Pharmacy benefits
(Please select appropriate PA form)

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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: 12 months

❑ 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

- ❑ Member is 2 years of age or older
- ❑ Member has a confirmed diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

❑ 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

- ❑ Member is 2 years of age or older
- ❑ Member has a confirmed diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

❑ 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

- ❑ Member is 2 years of age or older
- ❑ Member has a confirmed diagnosis of Familial Mediterranean Fever (FMF)

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❑ **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

- ❑ Member is 4 years of age or older
- ❑ Member has Cryopyrin-Associated Periodic Syndromes (CAPS) including:
  - ❑ Familial Cold Autoinflammatory Syndrome (FCAS)
  - ❑ Muckle-Wells Syndrome (MWS)

❑ **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 or older
- ❑ Member has a trial and failure to NSAIDs and colchicine or contraindication and/or repeated courses of corticosteroids are not appropriate

❑ **Diagnosis: Systemic Juvenile Idiopathic Arthritis (sJIA)**
Maximum Dosing: Children ≥2 years weighing at least 7.5 kg and Adolescents: SUBQ: 4 mg/kg/dose every 4 weeks; maximum dose: 300 mg/dose

- ❑ Member is 2 year of age or older
- ❑ Member has a confirmed diagnosis of Systemic Juvenile Idiopathic Arthritis (SJIA)
- ❑ Member must have documented failure of *Kineret® and either *Arcalyst® or *Actemra® OR member has history of anaphylactic reaction to *Kineret®, *Arcalyst® and *Actemra [anaphylaxis is defined as an emergency department (ER/ED) visit due to throat or tongue swelling and/or shortness of breath] or development of skin reactions that lead to Stevens Johnson syndrome **(*requires prior authorization)**

❑ **Diagnosis: Adult Onset Still's Disease (AOSD)**
Maximum Dosing: 4mg/kg up to 300mg every 4 weeks Weight Based Dosing. May consider gradually tapering therapy (e.g., 4 mg/kg every 8 weeks for 6 months, then 4 mg/kg every 12 weeks for 6 months) before discontinuing based on response

- ❑ Member is 18 years of age or older
- ❑ Member has a confirmed diagnosis of Adult-Onset Still's Disease (AOSD)
- ❑ Trial and failure *Kineret® and either *Arcalyst® or *Actemra® **(*requires prior authorization)**

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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.

- ❑ Member continues to meet the relevant criteria identified in the initial criteria
- ❑ Member has an absence of toxicity from the drug
- ❑ Member is being continuously monitored for a beneficial response to therapy

Medication being provided by (check applicable box(es) below):

❑ **Physician's office** **OR** ❑ **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;~~ **8/10/2026**