CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Ilaris (canakinumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Freestanding facility or clinic
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 2 per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ilaris (canakinumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as state.

ADULT-ONSET STILL'S DISEASE (AOSD)

For **initial** authorization:

1. Member must have a confirmed diagnosis of active Adult-Onset Still's Disease supported by chart notes; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
4. Member has tried and failed, or unable to tolerate **both** of the following (taken together or separately):
   a) A trial of a corticosteroid (prednisone or methylprednisolone);
   b) A 2-month trial of a conventional DMARD (e.g., methotrexate, cyclosporine, leflunomide, etc.).
5. **Dosage allowed:** 4 mg/kg (up to max dose 300 mg) subcutaneously every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CRYOPYRIN-ASSOCIATED PERIODIC SYNDROME (CAPS)

For **initial** authorization:

1. Member must be 4 years of age or older; AND
2. Member must be diagnosed with Familial Cold Autoinflammatory Syndrome (FCAS) OR Muckle-Wells Syndrome; AND
3. Prescriber has submitted laboratory evidence of a genetic mutation in the Cold-Induced Auto-Inflammatory Syndrome 1 (CIAS1—sometimes referred to as the NLRP3); AND
4. Medication must be prescribed by a rheumatologist or under recommendation of a rheumatologist or CAPS specialist; AND
5. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy.
6. **Dosage allowed:** 150 mg for body weight > 40 kg; 2 mg/kg for body weight ≥ 15 kg and ≤ 40 kg. For children 15 to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg. Administer subcutaneously every 8 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

FAMILIAL MEDITERRANEAN FEVER (FMF)

For **initial** authorization:

1. Member's Physician's Global Assessment (PGA) Disease Activity score is ≥2 documented in chart notes with key signs and symptoms of FMF: abdominal pain, skin rash, chest pain, arthralgia/arthritis; AND
2. Member's C-reactive protein (CRP) > 10 mg/L is documented in chart notes; AND
3. Member has documentation of at least one flare per month; AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy.
5. **Dosage allowed:** Body weight ≤ 40 kg: starting dose is 2 mg/kg every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate. Body weight > 40 kg: starting dose is 150 mg every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

HYPERIMMUNOGLOBULIN D SYNDROME (HIDS)/MEVALONATE KINASE DEFICIENCY (MKD)

For **initial** authorization:

1. Member's Physician's Global Assessment (PGA) Disease Activity score is ≥2 documented in chart notes with key signs and symptoms of HIDS/MKD: abdominal pain; lymphadenopathy, aphthous ulcers; AND
2. Member's C-reactive protein (CRP) > 10 mg/L is documented in chart notes; AND
3. Member has documentation of ≥ 3 febrile acute flares within a 6 month period; AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy.
5. **Dosage allowed:** Body weight ≤ 40 kg: starting dose is 2 mg/kg every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate. Body weight > 40 kg: starting dose is 150 mg every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA)

For **initial** authorization:

1. Member must be 2 years of age or older; AND
2. Member must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy; AND
3. Medication must be prescribed by a rheumatologist; AND
4. Member must have active systemic juvenile idiopathic arthritis, as indicated by arthritis involving two or more joints AND **one** or more of the following:
    a) Evanescent erythematous rash;
    b) Fever for at least two weeks
    c) Generalized lymphadenopathy;
    d) Hepatomegaly or splenomegaly;
    e) Pericarditis, pleuritis, or peritonitis; AND
5. Member must have inadequate response to ALL of the following:
    a) Glucocorticoid injection;
    b) Methotrexate;
    c) NSAIDs after a 12-week trial.
6. **Dosage allowed:** 4 mg/kg (with a maximum of 300 mg) for members with a body weight ≥ 7.5 kg. Administer subcutaneously every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Must have been retested for TB with a negative result within the past 12 months; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

TUMOR NECROSIS FACTOR RECEPTOR ASSOCIATED PERIODIC SYNDROME (TRAPS)

For **initial** authorization:

1. Member's Physician's Global Assessment (PGA) Disease Activity score is ≥ 2 documented in chart notes with key signs and symptoms of TRAPS: abdominal pain, skin rash, musculoskeletal pain, eye manifestations; AND
2. Member's C-reactive protein (CRP) > 10 mg/L is documented in chart notes; AND
3. Member has documentation of at least 6 flares per year; AND
4. Must have a documented negative TB test (i.e., tuberculosis skin test (PPD), an interferon-release assay (IGRA)) within 12 months prior to starting therapy.
5. **Dosage allowed:** Body weight ≤ 40 kg: starting dose is 2 mg/kg every 4 weeks. The dose can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate. Body weight > 40 kg: starting dose is 150 mg every 4 weeks. The dose can be increased to 300 mg every 4 weeks if the clinical response is not adequate.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ilaris (canakinumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acute coronary syndromes
- Atherosclerosis
- Chronic obstructive pulmonary disease
- Gout/gouty arthritis
- Heart failure
- Inflammatory dermatosis
- Majeed syndrome
- Ocular diseases
- Rheumatoid arthritis
- Schnitzler syndrome
- Type 1 and type 2 diabetes

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Ilaris created. Policy SRx-0042 archived. For CAPS diagnosis: laboratory evidence requirement of a genetic mutation added. Diagnoses of TRAPS, HIDS/MKD and FMF were added. List of diagnoses considered not medically necessary added.
07/14/2017	Documentation of negative TB test was added to all diagnosis.

03/20/2019	TB test allowed to be done within 12 months prior to initiation of therapy; chest x-ray option removed.
09/29/2020	New diagnosis of Adult Onset Still's Disease added. Status corrected.

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