| PHARMACY POLICY STATEMENT<br>**Marketplace** | |
|---|---|
| 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)<br>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. |

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| **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. |
| **11/19/2021** | Annual review, no changes |

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