CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Ilaris (canakinumab)
BILLING CODE	Must use valid NDC
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. Medication must be prescribed by or in consultation with a rheumatologist or other specialist familiar with periodic fever syndromes; AND
3. Member must be diagnosed with Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); AND
4. Member has elevated inflammatory markers (e.g., serum levels of amyloid A, C-reactive protein, erythrocyte sedimentation rate); AND
5. Member displays symptoms of CAPS (e.g., skin rash, musculoskeletal pain, central nervous system manifestations, hearing loss, conjunctivitis, cold/stress-triggered flares); AND
6. Must have a documented negative tuberculosis test within the past 12 months.
7. **Dosage allowed:** 150 mg for body weight > 40 kg; 2 mg/kg for body weight between 15 kg and 40 kg. For children 15 kg to 40 kg with an inadequate response, the dose can be increased to 3 mg/kg. Administer subQ every 8 weeks.

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

For **reauthorization**:

1. Chart notes demonstrate positive clinical response including decreased inflammatory marker values and symptom improvement.

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. Medication is prescribed by or in consultation with a rheumatologist or other physician experienced with periodic fever syndromes; AND
2. Member has a diagnosis of familial Mediterranean fever; AND
3. Member has had a compliant trial and failure of colchicine at maximal appropriate dose for at least 6 months unless contraindicated or intolerable; AND
4. Must have a documented negative tuberculosis test within the past 12 months.
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 6 months.

For **reauthorization**:

1. Chart notes have been provided showing response to therapy such as reduced severity and/or frequency of flares.

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. Medication is prescribed by or in consultation with a rheumatologist or other physician experienced with periodic fever syndromes; AND
2. Member has a diagnosis of HIDS/MKD; AND
3. Must have a documented negative tuberculosis test within the past 12 months.
4. **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 6 months.

For **reauthorization**:

1. Chart notes have been provided showing response to therapy such as reduced severity and/or frequency of flares.

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. Medication is prescribed by or in consultation with a rheumatologist or other physician experienced with periodic fever syndromes; AND
2. Member has a diagnosis of TRAPS; AND
3. Must have a documented negative tuberculosis test within the past 12 months.
4. **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 6 months.

For **reauthorization**:

1. Chart notes have been provided showing response to therapy such as reduced severity and/or frequency of flares.

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 diseases that are not listed in this document.

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.
06/15/2021	At end of policy, replaced specific list of excluded diseases with general statement. CAPS: Updated references. Removed genetic test requirement (mutation not present in many patients), added biomarker and symptoms instead. Reduced initial approval duration from 12 months to 6 months, should see response much sooner. Specified renewal criteria. FMF: Updated references. Added specialist. Added diagnosis. Removed baseline PGA score. Removed CRP level. Removed minimum number of flares. Added trial of colchicine per guidelines. Specified renewal criteria. HIDS/MKD: Updated references. Added specialist. Added diagnosis. Removed baseline PGA score. Removed CRP level. Removed minimum number of flares. Reduced initial approval duration. Specified renewal criteria. TRAPS: Updated references. Added specialist. Added diagnosis. Removed baseline PGA score. Removed CRP level. Removed minimum number of flares. Reduced initial approval duration. Specified renewal criteria.

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