Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 77.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Ilaris (canakinumab)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Ilaris (canakinumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Ilaris (canakinumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Ilaris (canakinumab) is a fully humanized monoclonal antibody that rapidly and selectively blocks IL-1ß. Cryopyrin-associated periodic syndrome (CAPS) is caused by a single gene mutation that leads to overproduction of interleukin-1 beta (IL-1ß), which causes sustained inflammation and tissue damage.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Ilaris (canakinumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

1. **Cryopyrin-Associated Periodic Syndrome**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 4 years of age and older with Cryopyrin-Associated Periodic Syndrome when the following criteria are met:

- Physician provided documentation of diagnosis of Cryopyrin-Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist **AND**
- Medical record documentation of contraindication to, intolerance to, or therapeutic failure on Kineret

Note: For a neonatal-onset multisystem inflammatory disease (NOMID) the Geisinger Health Plan would require failure on Anakinra.

2. **Systemic Juvenile Idiopathic Arthritis**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 2 years of age and older with Systemic Juvenile Idiopathic Arthritis when the following criteria are met

- Must be prescribed by a rheumatologist **AND**
- Must not be used in conjunction with tumor necrosis factor inhibitors **AND**
- Medical record documentation of active Systemic Juvenile Idiopathic Arthritis (SJIA) diagnosed prior to age 16 years **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on Actemra

3. **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) when the following criteria are met:

- Physician provided documentation of diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) supported by documentation of genetic testing to identify the *TNFRSF1A* gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist.

4. **Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD)**

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD) when the following criteria are met:

- Physician provided documentation of diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/ Mevalonate Kinase Deficiency (MKD) supported by documentation of elevated immunoglobulin D level or genetic testing to identify the *MVK* gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist.

5. **Familial Mediterranean Fever (FMF)**

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Familial Mediterranean Fever (FMF) when the following criteria are met:

- Physician provided documentation of diagnosis of Familial Mediterranean Fever (FMF) as confirmed by genetic testing to identify the *MEFV* gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on colchicine.

6. **Active Still's Disease**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 16 years of age and older with Adult Onset Still's Disease when the following criteria are met:

- Must be prescribed by a rheumatologist **AND**
- Must not be used in conjunction with tumor necrosis factor inhibitors **AND**
- Medical record documentation of Adult Onset Still's Disease diagnosed after age 16 years with active disease characterized by:
    - Disease activity based on Disease Activity Score 28 (DAS28) ≥ 3.2 **AND**
    - At least 4 painful and 4 swollen joints at screening and baseline

7. **Acute Gout Flare**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 18 years of age and older with an acute gout flare when the following criteria are met:

- Medical record documentation of a diagnosis of acute gout flare **AND**
- Medical record documentation that the member is age 18 or older **AND**
- Medical record documentation that Ilaris is being prescribed by a rheumatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to two (2) formulary NSAID's **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to colchicine **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to one (1) formulary corticosteroid.

AUTHORIZATION DURATION (for acute gout flares): One-Time Authorization of one (1) Ilaris dose (Facets RX count: 150 (J0638) units, NCRx QL of 1 vial (150mg) per 12 weeks with an RX count of 1) over a duration of 3 months

AUTHORIZATION DURATION (for all other indications): Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of Ilaris therapy is required.

After the initial six (6) month approval, subsequent approvals for coverage will be for a duration of one (1) year. Reevaluation of coverage will be every one (1) year requiring medical record documentation of continued or sustained improvement in the signs and symptoms of the targeted disease while on Ilaris therapy

Ilaris (canakinumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

1. **Cryopyrin-Associated Periodic Syndrome**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 4 years of age and older with Cryopyrin-Associated Periodic Syndrome when the following criteria are met:

- Physician provided documentation of diagnosis of Cryopyrin-Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) supported by documentation of genetic testing to identify the CIAS1/NLRP-3 gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist.

2. **Systemic Juvenile Idiopathic Arthritis**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 2 years of age and older with Systemic Juvenile Idiopathic Arthritis when the following criteria are met

- Must be prescribed by a rheumatologist **AND**
- Must not be used in conjunction with tumor necrosis factor inhibitors **AND**
- Medical record documentation of active Systemic Juvenile Idiopathic Arthritis (SJIA) diagnosed prior to age 16 years

3. **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) when the following criteria are met:

- Physician provided documentation of diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) supported by documentation of genetic testing to identify the *TNFRSF1A* gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist.

4. **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)**

Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) when the following criteria are met:

- Physician provided documentation of diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) supported by documentation of elevated immunoglobulin D level or genetic testing to identify the *MVK* gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist.

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Ilaris® (canakinumab) may be considered to be medically necessary in pediatric and adult patients with Familial Mediterranean Fever (FMF) when the following criteria are met:

- Physician provided documentation of diagnosis of Familial Mediterranean Fever (FMF) as confirmed by genetic testing to identify the *MEFV* gene mutation **AND**
- Must be prescribed by an immunologist, rheumatologist, or allergist **AND**
- Medical record documentation of contraindication to, intolerance to or therapeutic failure on colchicine.

6. **Active Still's Disease**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 16 years of age and older with Adult Onset Still's Disease when the following criteria are met:

- Must be prescribed by a rheumatologist **AND**
- Must not be used in conjunction with tumor necrosis factor inhibitors **AND**
- Medical record documentation of Adult Onset Still's Disease diagnosed after age 16 years with active disease characterized by:
    - Disease activity based on Disease Activity Score 28 (DAS28) ≥ 3.2 **AND**
    - At least 4 painful and 4 swollen joints at screening and baseline

7. **Acute Gout Flare**

Ilaris® (canakinumab) may be considered to be medically necessary in individuals 18 years of age and older with an acute gout flare when the following criteria are met:

- Medical record documentation of a diagnosis of acute gout flare **AND**
- Medical record documentation that the member is age 18 or older **AND**
- Medical record documentation that Ilaris is being prescribed by a rheumatologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to one (1) formulary NSAID's **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to colchicine **AND**
- Medical record documentation of therapeutic failure on, intolerance to or contraindication to one (1) formulary corticosteroid.

AUTHORIZATION DURATION (for acute gout flares): One-Time Authorization of one (1) Ilaris dose (Facets RX count: 150 (J0638) units, QL of 1 vial (150mg) per 12 weeks with an RX count of 1) over a duration of 3 months

AUTHORIZATION DURATION (for all other indications): Approval will be given for an initial duration of six (6) months. For continuation of coverage, medical record documentation of clinical improvement or a lack of progression in the signs and symptoms of the targeted disease state at six (6) months of Ilaris therapy is required.

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LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Ilaris [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; November 2024.
2. Ozen S, Demirkaya E, Erer B, et al. EULAR recommendations for the management of familial Mediterranean fever. European League Against Rheumatism (EULAR). Ann Rheum Dis; 2016 Jan 22; 0:1-8 [cited 2023 Dec 27]. Available from: https://ard.bmj.com/content/annrheumdis/early/2016/01/22/annrheumdis-2015-208690.full.pdf

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/10/10

Revised: 2/2012 (criteria); 7/2013 (added indication), 08/2014, 3/21/17 (added indications), 5/2017 (per DHS), 5/16/17 (added failure of Kineret), 3/28/19 (auth duration, grandfather language), 11/17/20 (Still's Disease), 10/2/23 (LOB carve out, Medicaid business segment), 12/31/23 (references added), 4/13/24 (gout from 12/2023 P&T), 3/24/25 (added ANDs, removed NCRx Medicare, LOB table, taglines, removed Medicaid business segment)

Reviewed: 08/2014, 11/2/2015, 10/26/16, 5/1/18, 2/1/20, 10/4/21, 10/4/22

MA UM Committee approval: 12/31/23, 5/22/24