UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ilaris

Program	Prior Authorization
Medication	Ilaris (canakinumab)
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Indications

Cryopyrin-Associated Periodic Syndromes (CAPS)
Ilaris is an interleukein-1 beta blocker indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including, Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients; Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients; Familial Mediterranean Fever (FMF) in adult and pediatric patients.

Systemic Juvenile Idiopathic Arthritis (SJIA)
Ilaris is indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

2. Coverage Criteria:

A. Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)

1. Initial Authorization

a. Diagnosis of one of the following periodic fever syndromes:

(1) Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)
(2) Tumor Necrosis Factor (TNF) Receptor Associated Periodic Syndrome (TRAPS)
(3) Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase

Deficiency (MKD)
(4) Familial Mediterranean Fever (FMF)

-AND-

b. Prescribed by or in consultation with one of the following:

(1) Allergist
(2) Immunologist
(3) Dermatologist
(4) Rheumatologist
(5) Neurologist

-AND-

c. Patient is not receiving concomitant treatment with either of the following:

(1) Tumor necrosis factor (TNF) inhibitors [eg, Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab)]
(2) Interleukin-1 inhibitors [eg, Arcalyst (rilonacept), Kineret (anakinra)]

Authorization will be issued for 12 months.

2. Reauthorization

a. Documentation of positive clinical response to Ilaris therapy

-AND-

b. Patient is not receiving concomitant treatment with either of the following:

(1) Tumor necrosis factor (TNF) inhibitors [eg, Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab)]
(2) Interleukin-1 inhibitors [eg, Arcalyst (rilonacept), Kineret (anakinra)]

Authorization will be issued for 12 months.

B. Systemic Juvenile Idiopathic Arthritis (SJIA)

1. Initial Authorization

a. Diagnosis of active systemic juvenile idiopathic arthritis

-AND-

b. Prescribed or recommended by a rheumatologist

-AND-

c. History of failure, contraindication, or intolerance to one of the following:

(1) Non-steroidal anti-inflammatory drugs (NSAIDs)
(2) Corticosteroids
(3) Methotrexate

-AND-

d. Patient is not receiving concomitant treatment with either of the following:

(1) Tumor necrosis factor (TNF) inhibitors [eg, Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab)]
(2) Interleukin-1 inhibitors [eg, Arcalyst (rilonacept), Kineret (anakinra)]

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. Documentation of positive clinical response to Ilaris therapy

-AND-

b. Patient is not receiving concomitant treatment with either of the following:

(1) Tumor necrosis factor (TNF) inhibitors [eg, Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab)]
(2) Interleukin-1 inhibitors [eg, Arcalyst (rilonacept), Kineret (anakinra)]

Authorization will be issued for 12 months.

3. References:

1. Ilaris Prescribing Information. Novartis Pharmaceuticals Corporation, December 2016.
2. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. N Engl J Med. 2009;360(23):2416-2425.
3. Aksentijevich I, Putnam CD, Remmers EF, et al. Clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North-American patients and a new cryopyrin model. Arthritis Rheum. 2007;56(4):1273-1285.

4. Beukelman T, Patkar NM, Saag KG, et al. 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: initiation and safety monitoring of therapeutic agents for the treatment of arthritis and systemic features. Arthritis Care Res. 2011 Apr;63(4):465-82.

Program	Program type – Prior Authorization
Change Control	
Date	Change
12/2009	New drug policy.
3/2010	Addition of Ilaris to this policy
12/2010	Annual Review
6/2011	Added new logo and replaced all AmeriChoice references with UnitedHealthcare Community & State.
6/2012	Annual Review
6/2013	Separated Ilaris and Arcalyst into individual guidelines. No changes to the clinical criteria for Ilaris. Converted policy to new UHC enterprise wide formatting.
9/2013	• Cryopyrin-Associated Periodic Syndromes indication: added 12 months length of authorization; removed age criterion; added criterion checking that patient is not taking a concomitant TNF inhibitor or IL-1 inhibitor; added diagnosis criterion asking for NRLP-3 gene mutation or evidence of clinical inflammation including clinical symptoms and elevated acute phase reactants; added prescriber requirement; added reauthorization criteria requiring positive response to therapy and patient is not taking a concomitant TNF inhibitor or IL-1 inhibitor (duration 12 months) • Added criteria for new indication of systemic juvenile idiopathic arthritis: (initial) diagnosis, prescribed or recommended by a rheumatologist, trial of NSAID or corticosteroid, patient is not taking a concomitant TNF inhibitor or IL-1 inhibitor, 12 months duration; (reauthorization) positive response to therapy and patient is not taking a concomitant TNF inhibitor or IL-1 inhibitor 12 months duration • Added note to prescriber regarding TB evaluation
12/2015	Annual Review

3/2016	Annual Review- Updated policy template
11/2017	Periodic Fever Syndromes: revised formatting and diagnosis, removed clinical evidence requirements, and added additional types of prescribers to specialist requirement; SJIA: revised diagnosis and added methotrexate as a trial/fail option Updated background, references, and policy template