UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Ilaris

Program	Prior Authorization
Medication	Ilaris® (canakinumab)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania- CHIP, New Jersey, South Carolina
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Ilaris is an interleukin-1β blocker indicated for the treatment of cryopyrin-associated periodic syndromes (CAPS), in adults and children 4 years of age and older including, familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS). Ilaris is also indicated for the treatment of tumor necrosis factor (TNF) receptor-associated periodic syndrome (TRAPS) in adult and pediatric patients, hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS)/mevalonate kinase deficiency (MKD) in adult and pediatric patients, familial Mediterranean fever (FMF) in adult and pediatric patients, active Still's disease, including Adult-Onset Still's Disease (AOSD) and active systemic juvenile idiopathic arthritis (SJIA) in patients aged 2 years and older.[1]

2. Coverage Criteria:

A. <u>Cryopyrin-Associated Periodic Syndromes (CAPS)</u>

1. <u>Initial Authorization</u>

a. Diagnosis of familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells Syndrome (MWS) by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FCAS and MWS

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

a. Patient is currently on Ilaris therapy for one of the following: FCAS or MWS

-AND-

b. Documentation of positive clinical response to Ilaris therapy

Authorization will be issued for 12 months.

B. Tumor Necrosis Factor (TNF) Receptor-Associated Periodic Syndrome (TRAPS)

1. Initial Authorization

a. Diagnosis of TRAPS by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of TRAPS

Authorization will be issued for 12 months.

2. Reauthorization

a. Patient is currently on Ilaris therapy for TRAPS

-AND-

b. Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Authorization will be issued for 12 months.

C. Hyperimmunoglobulin D (Hyper-IgD) Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

1. Initial Authorization

a. Diagnosis of HIDS or MKD by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of HIDS or MKD

Authorization will be issued for 12 months.

2. Reauthorization

a. Patient is currently on Ilaris therapy for one of the following: HIDS or MKD

-AND-

b. Documentation of positive clinical response to Ilaris therapy, defined as a decrease in frequency or severity of attacks

Authorization will be issued for 12 months.

D. Familial Mediterranean Fever (FMF)

1. Initial Authorization

a. Diagnosis of FMF by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of FMF

-AND-

b. History of failure, contraindication, or intolerance to colchicine

Authorization will be issued for 12 months.

2. Reauthorization

a. Patient is currently on Ilaris therapy for FMF

-AND-

b. Documentation of positive clinical response to Ilaris therapy, defined by a decrease in index disease flare or normalization of CRP

Authorization will be issued for 12 months.

E. Systemic Juvenile Idiopathic Arthritis (SJIA)

1. Initial Authorization

a. Diagnosis of SJIA by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of SJIA

-AND-

b. Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Authorization will be issued for 12 months.

2. Reauthorization

a. Patient is currently on Ilaris therapy for SJIA

-AND-

b. Documentation of positive clinical response to Ilaris therapy

-AND-

c. Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Authorization will be issued for 12 months.

F. Still'sDisease [Adult-Onset Still's Disease (AOSD)]

1. Initial Authorization

a. Diagnosis of AOSD by, or in consultation with, a rheumatologist or immunologist with expertise in the diagnosis of Still's Disease

-AND-

b. Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Authorization will be issued for 12 months.

2. Reauthorization

a. Patient is currently on Ilaris therapy for AOSD

-AND-

b. Documentation of positive clinical response to Ilaris therapy

-AND-

c. Patient is not receiving Ilaris in combination with another biologic (e.g., Actemra)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation, June 2020.
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. Kuemmerle-Deschner JB, Hachulla E, Cartwright R. Two-year results from an open-label, multicentre, phase III study evaluating the safety and effi cacy of canakinumab in patients with cryopyrin-associated periodic syndrome across different severity phenotypes. Ann Rheum Dis 2011;70:2095–2102.
4. Ruperto N, Brunner H I, Quartier P, Two Randomized Trials of Canakinumab in Systemic Juvenile Idiopathic Arthritis. NEngl J Med 2012; 367:2396-406.
5. Novartis Pharmaceuticals. A Study of Canakinumab in Patients With Systemic Juvenile Idiopathic Arthritis or Hereditary Periodic Fevers Who Participated in the CACZ885G2301E1, CACZ885G2306 or CACZ885N2301 Studies. In ClinicalTrials.gov [Internet]. Bethesda (MD): National Library o fMedicine (US). 2014- [cited 2017 July 6]. Available from: https://www.clinicaltrials.gov/ct2/show/NCT02334748 NLM Identifier: NCT 02334748.
6. Ahmet Gül, Huri Ozdogan, Burak Erer, Efficacy and safety of canakinumab in adolescents and adults with colchicine resistant familial Mediterranean fever. Arthritis Research & Therapy (2015) 17:243.
7. De Benedetti F, Gattorno M, Anton J, et al. Canakinumab for the Treatment of Autoinflammatory Recurrent Fever Syndromes. N Engl J Med. 2018 May 17;378(20):1908-1919.
8. Open label extension study. Data on File. Novartis Pharmaceuticals Corporation; East Hanover, NJ.
9. Kedor, C, Listing, J, Zernicke, J, et al. Canakunumab for treatment of Adult-Onset Still's Disease to achieve reduction of arthritic manifedestation (CONSIDER): phase II, randomized, double-blind, placebo-controlled, multicentre, investigator-initiated trial. Ann Rheum Dis. 2020;79:1090–1097.

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
11/2018	Annual review. Revised criteria to align with medical benefit program. Updated background and references.

11/2019	Annual review. Corrected spelling of colchicine in FMF section. Updated background and references.
11/2020	Annual review. Addition of AOSD according to label. Updated references. Added Additional Clinical Rules section.