

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Ilaris (canakinumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Ilaris (canakinumab) 150 mg/mL (180 mg) single use vial*	2 vials per 28 days

*Indicates FDA maximum dosing to accommodate SJIA, TRAPS, HIDS/MKD, and FMF indications.

APPROVAL CRITERIA

Requests for Ilaris (canakinumab) may be approved for the following:

- I. Cryopyrin-associated periodic syndromes (CAPS) when each of the following criteria are met:
 - A. Individual is 4 years of age or older with either of the following cryopyrin-associated periodic syndromes:
 1. Familial cold auto inflammatory syndromes; **OR**
 2. Muckle-Wells syndrome;

OR

- II. Familial Mediterranean fever (FMF) when each of the following criteria are met:
 - A. Individual has active type 1 FMF disease with genetic confirmation of the diagnosis (MEFV gene exon 10 mutation) (De Benedetti 2018); **AND**
 - B. Individual has confirmed recurrent, active disease (defined as at least one flare per month); **AND**
 - C. Individual has failed to respond to or is intolerant of colchicine therapy;

OR

- III. Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) when each of the following criteria are met:
 - A. Individual has HIDS with genetic confirmation of the diagnosis by deoxyribonucleic acid (DNA) analysis or enzymatic studies (for example, mutations in the MVK gene or markedly reduced mevalonate kinase activity); **AND**

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B. Individual has confirmed prior history of greater than or equal to three febrile acute flares within a 6-month period when not receiving prophylactic treatment;

OR

- IV. Tumor necrosis factor receptor associated periodic syndrome (TRAPS) when each of the following criteria are met:
- A. Individual has TRAPS with genetic confirmation of the diagnosis (TNFRSF1A gene mutation) (De Benedetti 2018); **AND**
 - B. Individual has chronic or recurrent disease activity (defined as six flares in a 12-month period).

OR

- V. Systemic juvenile idiopathic arthritis (SJIA) when each of the following criteria are met:
- A. Individual is 2 years of age or older with SJIA; **AND**
 - B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs).

Requests for Ilaris (canakinumab) may **not** be approved the following:

- I. All other indications not included above; **OR**
- II. In combination other IL-1Inhibitors, JAK inhibitors, apremilast, or other biologic drugs (such as IL-6 inhibitors, TNF antagonists, or selective co-stimulation modulators); **OR**
- III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
- IV. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating canakinumab.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 24, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2019 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: September 24, 2019.
6. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum.* 2013; 65(10):2499-2512.
7. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Entesitis. *Arthritis Rheum.* 2019; 71(6):846-863.
8. 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 & Research.* 2011; 63(4):465-482.
9. De Benedetti F, Gattorno M, Anton J, et al. Canakinumab for the treatment of autoinflammatory recurrent fever syndromes. *N Engl J Med.* 2018; 378(20):1908-1919.

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