Ilaris (canakinumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Gout Flares: Treatment of one flare (one 150 mg subcutaneous administration) Other diagnoses: 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 Still's Disease, TRAPS, HIDS/MKD, and FMF indications.

APPROVAL CRITERIA

Initial 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**
   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. Still's disease (Adult-onset Still's Disease [AOSD] or Systemic juvenile idiopathic arthritis (SJIA) when the following is met:
   A. Individual is 2 years of age or older with Still's Disease as either AOSD or SJIA;

OR

VI. Gout flares when each of the following criteria are met:
   A. Individual 18 years of age or older and is using Ilaris for symptomatic treatment of a gout flare; **AND**
   B. Individual meets either of the following:
      1. Individual has had an inadequate response to *both* nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine; **OR**
      2. Individual has a contraindication to or is intolerant of *both* NSAIDs and colchicine; **AND**
   C. Repeated courses of corticosteroids are not appropriate for the individual; **AND**
   D. If individual has received a prior administration of Ilaris for a gout flare, there is a least a 12-week interval between treatments.

Continuation requests for Ilaris (canakinumab) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of Ilaris. Medication samples/coupons/discount cards are excluded from consideration as a trial.; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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

I. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, other IL-1 inhibitors, IL-6 inhibitors, rituximab, or natalizumab; **OR**
II. Tuberculosis, other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing therapy]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 7, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2022 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: October 4, 2022.
5. 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.
6. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 4, 2022.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 13, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.