AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Ilaris	Page:	1 of 4
Effective Date:	7/11/2025	Last Review Date:	5/28/2025
Applies to:	☒New Jersey		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Ilaris under the patient's prescription drug benefit.

Description:

FDA-Approved Indications

1. Periodic Fever Syndromes:
   a. Cryopyrin-Associated Periodic Syndromes (CAPS)
      Ilaris is 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). *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
   b. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
      Ilaris is indicated for the treatment of TRAPS in adult and pediatric patients. *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
   c. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
      Ilaris is indicated for the treatment of HIDS and MKD in adult and pediatric patients. *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
   d. Familial Mediterranean Fever (FMF)
      Ilaris is indicated for the treatment of FMF in adult and pediatric patients. *(Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products)*
2. Still's disease (Adult-onset Still's Disease [AOSD] and systemic Juvenile Idiopathic Arthritis [sJIA]):
   Ilaris is indicated for the treatment of active Still's disease, including AOSD and sJIA in patients aged 2 years and older.
   For systemic Juvenile Idiopathic Arthritis (sJIA): *Reference NJ Protocol for Cryopyrin-Associated Periodic Syndromes (CAPS) Products.*
3. Gout flares:
   Ilaris is indicated for the symptomatic treatment of adult patients with gout flares in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

4. Compendial Use
   Pseudogout

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Non-preferred: Ilaris

Policy/Guideline:

Documentation for all indications:
The patient is unable to take ONE preferred anti-TNF (Enbrel or preferred adalimumab product) AND Kevzara, where indicated, for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation:

A. Adult-onset Still's disease (AOSD)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried, including response to therapy (if applicable).
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

B. Gout and pseudogout flares: (initial requests only): Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Prescriber Specialty:
This medication must be prescribed by or in consultation with one of the following:
A. AOSD, gout, and pseudogout: rheumatologist

Criteria for Initial Approval:

A. Adult-onset Still's disease (AOSD)
1. Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for active AOSD.

2. Authorization of 12 months may be granted for adult members for treatment of active AOSD when both of the following criteria are met:
   a. Member has active systemic features (e.g., fever, arthralgia/arthritis, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, sore throat).
   b. Member meets any of the following:

i. Member has had an inadequate response to a trial of nonsteroidal anti-inflammatory drugs (NSAIDs).
ii. Member has had an inadequate response to a trial of corticosteroids.
iii. Member has had an inadequate response to a trial of a conventional synthetic drug (e.g., methotrexate).

B. Gout and pseudogout flares
Authorization of 12 months may be granted for adult members for the treatment of flares for gout and pseudogout (also known as calcium pyrophosphate deposition disease) when both of the following criteria are met:
1. Member has experienced at least three flares in the last 12 months.
2. Member has had an inadequate response, intolerance, or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids.

Continuation of Therapy:

A. Adult-onset Still's disease (AOSD)
Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for AOSD and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
1. Number of joints with active arthritis (e.g., swelling, pain, limitation of motion)
2. Number of joints with limitation of movement
3. Functional ability
4. Systemic features (e.g., fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, serositis)

B. All other diagnoses
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for an indication outlined in criteria for initial approval and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Other Criteria:
For all indications: Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

*If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to

members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug.

Approval Duration and Quantity Restrictions:

Approval:

Initial and Renewal Approval: 12 months

References:

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2024.
2. De Benedetti F, Gattorno M, Anton J, et al; Canakinumab for the treatment of autoinflammatory recurrent fever syndromes. N Engl J Med. 2018;378:1908-19.
3. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al; Canakinumab in CAPS Study Group. Use of canakinumab in the cryopyrin-associated periodic syndrome. N Engl J Med. 2009;360(23):2416-2425.
4. 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 Care Res. 2013;65(10):1551-63.
5. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com [available with subscription]. Accessed November 14, 2024.
6. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. Ann Rheum Dis. 2017;76:29–42.
7. Zhang W, Doherty M, Pascual E, et al. EULAR recommendations for calcium pyrophosphate deposition. Part II: Management. Ann Rheum Dis. 2011;70:571–575.
8. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 14, 2024 from: https://www.cdc.gov/tb/testing/index.html.
9. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout [published correction appears in Arthritis Care Res (Hoboken). 2020 Aug;72(8):1187]. Arthritis Care Res (Hoboken). 2020;72(6):744-760.
10. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. Arthritis Rheumatol. 2022;74(4):553-569.
11. Efthimiou P, Kontzias A, Hur P, et al. Adult-onset Still's disease in focus: Clinical manifestations, diagnosis, treatment, and unmet needs in the era of targeted therapies. Semin Arthritis Rheum. 2021;51(4):858-874.