AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Ilaris	Page:	1 of 3
Effective Date:	9/28/2023	Last Review Date:	7/25/2023

Applies to:	☐Illinois	☐Florida	☐Florida Kids
	☒New Jersey	☐Maryland	☐Michigan
	☐Pennsylvania Kids	☐Virginia	☐Kentucky PRMD

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:

A. 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).
      b. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)
         Ilaris is indicated for the treatment of TRAPS in adult and pediatric patients.
      c. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
         Ilaris is indicated for the treatment of HIDS and MKD in adult and pediatric patients.
      d. Familial Mediterranean Fever (FMF)
         Ilaris is indicated for the treatment of FMF in adult and pediatric patients.
   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.

Note: for all diagnoses above reference the CAPS Products NJ Protocol.

B. Compendial Use
   Gout and pseudogout

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

Applicable Drug List:

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. **Gout and pseudogout flares:** For initial requests: 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.

Criteria for Initial Approval:

A. Management of gout and pseudogout flares

Authorization of 6 months may be granted for the management of flares for gout or pseudogout (also known as calcium pyrophosphate deposition disease) when either of the following criteria is met:

1. Member has had an inadequate response or intolerance to maximum tolerated doses of non-steroidal anti-inflammatory drugs (NSAIDs), colchicine and oral and injectable corticosteroids.
2. Member has a contraindication to NSAIDs and colchicine and has a clinical reason to avoid repeated courses of corticosteroids.

Continuation of Therapy:

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:

Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray)* within 6 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. 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.

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

Approval Duration and Quantity Restrictions:

Approval:

Initial Approval: Gout and pseudogout flares = 6 months
Renewal Approval: Gout and pseudogout flares = 6 months

References:

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2020.
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.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.
3. 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.
4. DRUGDEX® System (electronic version). Truven Health Analytics, Ann Arbor, MI. Available at http://www.micromedexsolutions.com [available with subscription]. Accessed November 3, 2022.
5. Schlesinger N, Alten RE, Bardin T, et al: Canakinumab for acute gouty arthritis in patients with limited treatment options: results from two randomized, multicentre, active-controlled, double-blind trials and their initial extensions. *Ann Rheum Dis*. 2012; 71(11):1839-1848.
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 3, 2022 from: https://www.cdc.gov/tb/topic/testing/tbtesttypes.htm.
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.