Reference number
1801-A

SPECIALTY GUIDELINE MANAGEMENT

ILARIS (canakinumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. **Periodic Fever Syndromes:**
   - **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).
   - **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)**
     Ilaris is indicated for the treatment of TRAPS in adult and pediatric patients.
   - **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)**
     Ilaris is indicated for the treatment of HIDS and MKD in adult and pediatric patients.
   - **Familial Mediterranean Fever (FMF)**
     Ilaris is indicated for the treatment of FMF in adult and pediatric patients.

2. **Active Systemic Juvenile Idiopathic Arthritis (SJIA)**
   Ilaris is indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.

B. Compendial Uses
Treatment of acute gout attacks

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Periodic Fever Syndromes
Authorization of 24 months may be granted for members who have a diagnosis of ANY of the following:
1. CAPS, including FCAS and MWS
2. TRAPS
3. HIDS or MKD
4. FMF

B. Active Systemic Juvenile Idiopathic Arthritis (sJIA)
1. Authorization of 24 months may be granted for the treatment of active sJIA for members who have received Actemra or Kineret in a paid claim through a pharmacy or medical benefit within the previous 120 days.

2. Authorization of 24 months may be granted for the treatment of active sJIA for members who have had an inadequate response to a trial of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, methotrexate, or leflunomide.

C. Treatment of acute gout attacks

Authorization of 6 months may be granted for members who meet all of the following criteria:

1. Member had two or more gout flares within the previous 12 months
2. Member has had an inadequate response, intolerance, or contraindication to at least two of the following: maximum tolerated dose of an NSAID, colchicine, intra-articular injection of triamcinolone acetonide at doses 40 mg or greater, systemic corticosteroids
3. Member will receive Ilaris concurrently with urate-lowering therapy (i.e., allopurinol, febuxostat)

III. CONTINUATION OF THERAPY

A. Periodic Fever Syndromes

Members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

B. Active Systemic Juvenile Idiopathic Arthritis

Authorization of 24 months may be granted for members who have achieved or maintained positive clinical response after at least 3 months of therapy with Ilaris as evidenced by low disease activity or improvement in signs and symptoms.

C. Treatment of acute gout attacks

Authorization of 24 months may be granted for members who have experienced a positive clinical response from treatment with Ilaris (e.g., reduction in swelling within 72 hours, reduction in pain compared to prior attacks, or delayed time to flare compared to prior attacks).

IV. REFERENCES

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2016.
2. 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.
3. DRUGDEX® System (electronic version). Micromedex Truven Health Analytics. Available with subscription. URL: www.micromedexsolutions.com. Accessed January 28, 2019.
4. Sivera F, Wechalekar MD, Andres M, et al. Interleukin-1 inhibitors for acute gout (review). *Cochrane Database Syst Rev.* 2014; (9):CD009993.
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. Clinical Consult. CVS/caremark Clinical Programs Review. Focus on Rheumatology Clinical Programs. July 2015.