CVS/caremark

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 12 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 12 months may be granted for treatment of sJIA to members who have received at least a 28-day supply (i.e., two doses) of Ilaris, Actemra, or Kineret in a paid claim through a pharmacy or medical benefit within the previous 120 days of the initial request for Ilaris.
   a. The prescriber must provide the date of the last dose and the total duration of treatment.

2. Authorization of 12 months may be granted for members who meet ALL of the following criteria:
   a. Member has a diagnosis of active sJIA.

b. Member has an inadequate response to at least a 2-week trial of corticosteroids or at least a 3-month trial of 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 is 18 years of age or older
2. Member had two or more gout flares within the previous 12 months
3. Member has had an inadequate response or intolerance at previous attacks, or contraindication to at least two of the following: maximum tolerated doses of NSAIDs, colchicine, and intra-articular injection of triamcinolone acetonide at doses 40 mg or greater
4. Member will receive Ilaris concurrently with urate-lowering therapy (i.e., allopurinol, febuxostat)

III. CONTINUATION OF THERAPY

A. Periodic Fever Syndromes

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

B. Active Systemic Juvenile Idiopathic Arthritis

Authorization of 12 months may be granted for all members (including new members) who meet ALL initial authorization criteria and achieve or maintain positive clinical response after at least 3 months of therapy with Ilaris as evidenced by low disease activity or improvement in signs and symptoms of the condition.

C. Treatment of acute gout attacks

Authorization of 12 months may be granted for all members who meet ALL of the following criteria:

1. Member is 18 years of age or older
2. Member has experienced at least one of the following treatment responses with a prior treatment:
   a. Reduction in swelling within 72 hours
   b. Reduction in pain compared to prior attacks
   c. Delayed time to flare compared to prior attacks

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 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 May 1, 2016.
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 randomised, 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.