Ilaris (canakinumab)

Initial Criteria:

1. Prescribed by a specialist in the area of the patient's diagnosis; and,
2. Patient is diagnosed with and meets one of the following:
    a. Cryopyrin-Associated Periodic Syndromes (CAPS) in patients aged 4 years and older, including:
        i. Familial Cold Auto-inflammatory Syndrome (FCAS); or,
        ii. Muckle-Wells Syndrome (MWS); or,
    b. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients; or,
    c. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients; or,
    d. Familial Mediterranean Fever (FMF) in adult and pediatric patients; or,
    e. Adult-onset Still's Disease (AOSD) in patients aged 16 years and older; or,
    f. Active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older; or,
    g. Gout flares in adults 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; and,
3. For patients with refractory gout flares who fail to respond to standard therapies, patient has had an inadequate response or a medical contraindication to anakinra (Kineret); and
4. For patients diagnosed with AOSD, CAPS, or DIRA, patient has had a trial and failure of anakinra (Kineret) for at least 6 months or has a documented allergy, intolerance, or medical contraindication to anakinra (Kineret); and,
5. Patient and/or guardian has attested that they will adhere to the treatment plan; and,
6. Prescribed within the FDA approved dosing regimen (note: a current weight is required).

Reauthorization Criteria:

1. Patient has been seen within the past 12 months; and,
2. Patient has had a clinically meaningful response to the medication per medical chart documentation (e.g., reduced symptoms of disease and inflammatory markers, including serum C-reactive protein for Periodic Fever Syndromes or normalization of erythrocyte sedimentation rate for SJIA); and,
3. Prescribed within the FDA approved dosing regimen (note: a current weight is required).

P&T Date: November 2016
Effective Date: 1/1/17, Revised 1/1/2023, 9/7/2023, 1/1/2024

Coverage Duration:
For the treatment of gout flares, authorization will be provided for one month.
For all other indications, initial and reauthorizations will be provided for twelve months.

Other Criteria:
Prescribed according to an FDA-approved regimen:

1. CAPS:
    a. For patients > 40 kg: 150 mg subcutaneously every 8 weeks
    b. For patients ≥ 15 kg and < 40 kg: 2 mg/kg subcutaneously every 8 weeks
    c. For pediatric patients ≥ 15 kg and < 40 kg with an inadequate response: 3 mg/kg subcutaneously every 8 weeks
2. TRAPS, HIDS/MKD, FMF:
    a. For patients > 40 kg: 150 mg subcutaneously every 4 weeks. The dosage can be increased to 300 mg every 4 weeks if the clinical response is not adequate.
    b. For patients ≤ 40 kg: 2 mg/kg subcutaneously every 4 weeks. The dosage can be increased to 4 mg/kg every 4 weeks if the clinical response is not adequate.
3. AOSD, SIJA:
    a. For patients ≥ 7.5 kg: 4 mg/kg (maximum dose of 300 mg) subcutaneously every 4 weeks.
4. Gout Flares: 150 mg subcutaneously once. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of Ilaris may be administered.