BlueCross BlueShield Federal Employee Program

ILARIS (canakinumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Ilaris (canakinumab) is a recombinant human monoclonal anti-human interleukin-1β (IL-1β) antibody designed to bind selectively to and neutralize the activity of IL-1β, a proinflammatory cytokine. Ilaris is indicated for the treatment of Cryopyrin-Associated Periodic Syndrome (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF), active Still's disease, and gout flares. Ilaris is given as a subcutaneous injection by a healthcare provider (1).

Regulatory Status

FDA-approved indications: Ilaris is an interleukin-1β blocker indicated for the treatment of: (1)

1. Periodic Fever Syndromes:
    a. Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including:
        i. Familial Cold Auto-Inflammatory Syndrome (FCAS)
        ii. Muckle-Wells Syndrome (MWS)
    b. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients
    c. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients
    d. Familial Mediterranean fever (FMF) in adult and pediatric patients
2. Active Still's disease, including Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.
3. 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

Ilaris has been associated with an increased risk of serious infections. Physicians should exercise caution when administering Ilaris to patients with infections, a history of recurring infections or underlying conditions which may predispose them to infections. Discontinue treatment with Ilaris if a patient develops a serious infection. Do not administer Ilaris to patients during an active infection requiring medical intervention (1).

In clinical trials, Ilaris has not been administered concomitantly with tumor necrosis factor (TNF) inhibitors. An increased incidence of serious infections and an increased risk of neutropenia have been associated with administration of another interleukin-1 (IL-1) blocker in combination with TNF inhibitors in another patient population. Use of Ilaris with TNF inhibitors may also result in similar toxicities and is not recommended because this may increase the risk of serious infections. Drugs that affect the immune system by blocking TNF have been associated with an increased risk of new tuberculosis and reactivation of latent tuberculosis (TB). It is possible that use of IL-1 inhibitors such as Ilaris increases the risk of reactivation of tuberculosis or of opportunistic infections. (1).

Live vaccines should not be given concurrently with Ilaris. Prior to initiation of therapy with Ilaris, patients should receive all recommended vaccinations as IL-1 blockade may interfere with immune response to infections (1).

The safety and effectiveness of Ilaris in AOSD/SJIA, TRAPS, HIDS/MKD, and FMF patients under 2 years of age and in CAPS patients under 4 years of age have not been established. The safety and effectiveness of Ilaris in pediatric patients with gout flares have not been established (1).

Summary

Ilaris (canakinumab) is an interleukin-1β blocker indicated for the treatment of active Still's disease, gout flares, and Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF), and Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). Ilaris has been associated with an increased risk of serious infections. Do not administer Ilaris to patients during an active infection requiring medical intervention. Ilaris is given as a subcutaneous injection by a healthcare provider (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Ilaris while maintaining optimal therapeutic outcomes.

References

1. Ilaris [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; November 2024.