Policy Applies to: Commercial and Medicare plans

Background:

Rilonacept (Arcalyst™) is a dimeric fusion protein consisting of the ligand-binding domains of the extracellular portions of the human interleukin-1 receptor component (IL-1RI) and IL-1 receptor accessory protein (IL-1RAcP) linked in-line to the Fc portion of human IgG1. Rilonacept blocks IL-1β signaling by acting as a soluble decoy receptor that binds IL-1β and prevents its interaction with cell surface receptors. Rilonacept also binds IL-1α and IL-1 receptor antagonist (IL-1ra) with reduced affinity.

Canakinumab (Ilaris®) is a recombinant, human anti-human-IL-1ß monoclonal antibody that belongs to the IgG1/k isotype subclass. Canakinumab binds to human IL-1ß and neutralizes its activity by blocking its interaction with IL-1 receptors, but it does not bind IL-1a or IL-1 receptor antagonist (IL-1ra).

CAPS refer to rare genetic syndromes generally caused by mutations in the NLRP-3 [Nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]). CAPS disorders are inherited in an autosomal dominant pattern with male and female offspring equally affected. Features common to all disorders include fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis.

In most cases, inflammation in CAPS is associated with mutations in the NLRP-3 gene which encodes the protein cryopyrin, an important component of the inflammasome. Cryopyrin regulates the protease caspase-1 and controls the activation of interleukin-1 beta (IL-1β). Mutations in NLRP-3 result in an overactive inflammasome resulting in excessive release of activated IL-1β that drives inflammation.

Approval Criteria: When a benefit, rilonacept or canakinumab may be approved when all of the following criteria are met:

1. Rilonacept is used in the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older OR
2. Canakinumab is used in the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 4 years of age and older AND
3. Rilonacept is not used in conjunction with agents that inhibit IL-1 or TNF including Remicade®, Amevive®, Humira™, Enbrel®, Orencia®, Kineret®, Cimzia®, or Simponi™. An increased incidence of serious infections has been associated with administration of an IL-1 blocker in combination with TNF inhibitors.
Use of rilonacept or canakinumab for disease states outside of its FDA-approved indications should be denied based on the lack of clinical data to support its effectiveness and safety in other conditions.

Duration of Authorization:
If approved, up to a lifetime authorization may be granted.

References:


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