

Prior Authorization Criteria

Drug: Arcalyst™ (Rilonacept)

P&T Reviewed: 6/08, 9/09, 9/10

Description:

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-1 β). Mutations in NLRP-3 result in an overactive inflammasome resulting in excessive release of activated IL-1 β that drives inflammation. Rilonacept blocks IL-1 β signaling by acting as a soluble decoy receptor that binds IL-1 β and prevents its interaction with cell surface receptors.

FDA Labeled indications:

Arcalyst (rilonacept) is an interleukin-1 blocker indicated for 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.

Criteria:

ConnectiCare considers Arcalyst to be medically necessary for patients 12 years of age and older who meet the following criteria:

- Clinically documented Cryopyrin-Associated Periodic Syndrome (CAPS),), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)

Dosage and Administration:

Adult patients 18 years and older:

Treatment should be initiated with a loading dose of 320mg delivered as two, 2ml, subcutaneous injections of 160mg each given on the same day at two different sites. Dosing should be continued with a once-weekly injection of 160mg administered as a single, 2ml, subcutaneous injection.

Pediatric patients aged 12 to 17 years:

Treatment should be initiated with a loading dose of 4.4 mg/kg, up to a maximum of 320mg, delivered as one or two subcutaneous injections with a maximum single-injection volume of 2ml. Dosing should be continued with a once-weekly injection of 2.2 mg/kg, up to a maximum of 160 mg, administered as a single subcutaneous injection, up to 2ml. If the initial dose is given as two injections, they should be given on the same day at two different sites.

Prior Authorization and Limitations:

- Initial approval for 3 months; can then be extended for up to one year
- Subsequent approval (up to 1 year) will be based on current progress notes from the physician documenting disease status.
- The quantity is limited to a maximum of a 30 day supply per fill.

The above criteria is based on the following reference(s):

1. Arcalyst full prescribing information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY 2008

