UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Arcalyst

Program	Prior Authorization
Medication	Arcalyst (rilonacept injection)
Issue Date	12/20019
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	12/2017

1. Background:

Arcalyst is 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.

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. Mutations in NLRP-3 result in an overactive inflammasome resulting in excessive release of activated IL-1 that drives inflammation.

In clinical studies, Arcalyst has not been administered concomitantly with tumor necrosis factor (TNF) inhibitors. An increased incidence of serious infections has been associated with administration of an IL-1 blocker in combination with TNF inhibitors. Taking Arcalyst with TNF inhibitors is not recommended because this may increase the risk of serious infections. Treatment with Arcalyst should be discontinued if a patient develops a serious infection. Patients should be counseled not to take any IL-1 blocking drug, including Arcalyst, if they are also taking a drug that blocks TNF such as etanercept, infliximab, or adalimumab. Use of Arcalyst with other IL-1 blocking agents, such as anakinra, is not recommended.

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2. Coverage Criteria:

A. Initial Authorization

1. Patient is 12 years of age or older

-AND-

2. Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)

-AND-

3. Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist

-AND-

4. The medication will not be used in combination with another biologic

Authorization will be issued for 12 months.

B. Reauthorization

1. Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidenced by one of the following:

- Improvement in rash, fever, joint pain, headache, or conjunctivitis
- Decreased number of disease flare days
- Normalization of inflammatory markers (C-reactive protein [CRP], erythrocyte sedimentation rate [ESR], serum amyloid A [SAA])

Authorization will be issued for 12 months.

3. References:

1. Arcalyst (rilonacept) for Subcutaneous Injection Prescribing Information. Regeneron Pharmaceuticals, September, 2016.
2. Hoffman HM et al. Durability of response to rilonacept (IL-1 Trap) in a phase 3 study of patients with cryopyrin-associated periodic syndromes (CAPS): familial cold

autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome. Journal of Allergy and Clinical Immunology. 2008; 121(2):S175.
3. Data on File. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. February 2008.
4. Aksentijevich I, et al. The clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North American Patients and a new cryopyrin model. Arthritis and Rheumatism. 2007; 56(4):1273-1285.
5. McDermott M, Aksentijevich I, The auto-inflammatory syndromes. Current Opinion in Allergy and Clinical Immunology. 2002; 2:511-516.

Program	Prior Authorization - Arcalyst (rilonacept injection)
Change Control	
Date	Change
12/2009	New drug policy.
3/2010	Addition of Ilaris to this policy
12/2010	Annual Review
6/2011	Added new logo and replaced all AmeriChoice references with UnitedHealthcare Community & State.
6/2012	Annual Review
6/2013	Separated Ilaris and Arcalyst into individual guidelines. Converted policy to new UHC enterprise wide formatting. Added requirement of confirmation of CAPS diagnosis.
9/2013	Requirements 2.2, 3, and 4 were added to policy. Removed requirement of overproduction of interleukin-1 and the age requirement. Split criteria into initial and reauthorization sections. Added evidence of clinical inflammation, including clinical symptoms and elevated acute phase reactants, as an additional option to satisfy the confirmation of CAPS diagnosis requirement.
9/2014	Annual Review
12/2015	Annual Review
8/2016	Updated clinical criteria to align with ORx policy. Updated policy to new template.

10/2017	Updated references and policy template