UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Arcalyst

Program	Prior Authorization
Medication	Arcalyst (rilonacept injection)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2009
Pharmacy and Therapeutics Approval Date	4/2020
Effective Date	6/2020

1. Background:

Arcalyst (rilonacept) is an interleukin-1 blocker indicated for the treatment of Cryopyrin Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older.

2. Coverage Criteria:

A. Initial Authorization

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

Authorization will be issued for 12 months.

B. Reauthorization

1. Documentation of positive clinical response to Arcalyst therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Arcalyst [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals; February 2020.

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
4/2018	Annual review. No changes to criteria.
4/2019	Revised criteria to align with commercial notification program. Updated background and references.

4/2020	Annual review. Updated reference.