UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1009-11
Program	Prior Authorization/Notification
Medication	Arcalyst® (rilonacept)
P&T Approval Date	7/2011, 7/2012, 7/2013, 8/2013, 7/2014, 2/2015, 4/2016, 4/2017, 4/2018, 4/2019, 4/2020, 5/2021, 5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: 8/1/2023

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 and older. Arcalyst is also indicated for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg. Additionally, Arcalyst is indicated for the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adult and children 12 years and older.[1]

2. Coverage Criteria[a]:

A. Cryopyrin-Associated Periodic Syndromes (CAPS)

1. **Initial Authorization**

a. **Arcalyst** will be approved based on the following criterion:

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Arcalyst** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Arcalyst therapy

Authorization will be issued for 12 months.

B. Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

1. **Initial Authorization**

a. **Arcalyst** will be approved based on the following criteria:

(1) Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

-AND–

(2) Disease is in remission (e.g., diary score of < 0.5 [reflecting no fever, skin rash and bone pain], acute phase reactants [<0.5 mg/dL CRP], absence of objective skin rash, no radiological evidence of active bone lesions)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Arcalyst** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Arcalyst therapy

Authorization will be issued for 12 months.

C. Pericarditis

1. **Initial Authorization**

a. **Arcalyst** will be approved based on the following criterion:

(1) Diagnosis of recurrent pericarditis (RP)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Arcalyst** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Arcalyst therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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, Inc.; May 2021.

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Change Control	
7/2013	Annual review. Updated formatting. Add IL-1 agents as a requirement to criteria. Removed age 12 from coverage criteria and added reauthorization criteria.
8/2013	Removed IL-1 and added 'clinical symptoms' and 'elevated acute phase reactants.'
7/2014	Annual review with no change to coverage criteria.
2/2015	Annual review with no change to coverage criteria. Updated background and references.
4/2016	Annual review. Revised criteria to only require diagnosis. Updated background and references.
4/2017	Annual review with no change to coverage criteria. Updated references.
4/2018	Annual review with no change to coverage criteria.
4/2019	Annual review with no change to coverage criteria.
4/2020	Annual review with no change to coverage criteria.
5/2021	Annual review. Added coverage criteria for deficiency of IL-1 receptor antagonist and recurrent pericarditis. Updated background and references.
5/2022	Annual review. Updated references.
5/2023	Annual review with no changes to coverage criteria. Added state mandate footnote and updated reference format.