

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Arcalyst (rilonacept)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 Year

Medications	Quantity Limit
Arcalyst (rilonacept) 160 mg/2 mL (220 mg) single-use vial*	4 vials per 28 days

*Initiation of therapy for Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS): May approve 1 (one) additional vial (160 mg/2 mL) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Requests for Arcalyst (rilonacept) may be approved for the following:

- I. Individual is 12 years of age or older with either of the following cryopyrin-associated periodic syndromes:
 - A. Familial cold autoinflammatory syndromes; **OR**
 - B. Muckle-Wells syndrome.

Requests for Arcalyst (rilonacept) may **not** be approved for i the following:

- I. All other indications not included above; **OR**
- II. In combination with other IL-1 inhibitors, JAK inhibitors, apremilast, or other biology drugs (such as IL-6 inhibitors, TNF antagonists, or selective co-stimulation modulators); **OR**
- III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
- IV. Individual has not had a tuberculin skin test (TST) or Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating treatment with rilonacept.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 24, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Drugs & Biologics Compendium (NCCN Compendium®) 2019 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically. Accessed on: September 24, 2019.

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