

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Arcalyst (rilonacept)

CG-DRUG-97

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

Medications	Quantity Limit
Arcalyst (rilonacept)	4 vials per 28 days *May approve 1 additional vial in the first 28 days (4 weeks) of treatment

APPROVAL CRITERIA

Arcalyst (rilonacept) may be approved for the treatment of individuals 12 years of age or older with either of the following cryopyrin-associated periodic syndromes:

- I. Familial cold autoinflammatory syndromes; **OR**
- II. Muckle-Wells syndrome.

Arcalyst (rilonacept) may **not** be approved for individuals with any of the following:

- I. Use of Arcalyst (rilonacept) in combination with other interleukin-1 inhibitors; **OR**
- II. Use of Arcalyst (rilonacept) in combination with tumor necrosis factor inhibitors; **OR**
- III. Receiving live vaccines; **OR**
- IV. Exhibiting evidence of active or chronic infection(s), including tuberculosis, or a history of recurrent infections; **OR**
- V. Has not had a tuberculin skin test or Centers for Disease Control and Prevention recommended equivalent to evaluate for latent tuberculosis prior to initiating treatment with rilonacept.

Arcalyst (rilonacept) may **not** be approved when the criteria are not met and for all other indications, including but not limited to:

- I. Adult onset Still's disease
- II. Familial Mediterranean fever
- III. Gouty arthritis
- IV. Neonatal-onset multi-systemic inflammatory disease

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- V. Schnitzler syndrome
- VI. Subacromial bursitis
- VII. Systemic juvenile idiopathic arthritis.

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

Key References:

1. American College of Rheumatology (ACR). 2017. Cryopyrin-associated autoinflammatory syndromes (CAPS). Available at: [http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Cryopyrin-Associated_Autoinflammatory_Syndromes_\(CAPS\)_Juvenile/](http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Cryopyrin-Associated_Autoinflammatory_Syndromes_(CAPS)_Juvenile/). Accessed on February 2, 2018.
2. Khanna D, Khanna PP, Fitzgerald JD, et al. 2012 American College of Rheumatology guidelines for management of gout. Part II: therapy and anti-inflammatory prophylaxis of acute gouty arthritis. *Arthritis Care Res (Hoboken)*. 2012; 64(10):1447-1461.
3. Riloncept. In: DrugPoints System (electronic). Truven Health Analytics. Greenwood Village, CO. Updated November 14, 2016. Available at: <https://www.micromedexsolutions.com>. Accessed on February 2, 2018.
4. Riloncept [Product Information], Tarrytown, NY. Regeneron Pharmaceuticals, Inc. September 2016. Available at: https://www.regeneron.com/sites/default/files/Arcalyst_FPI.pdf. Accessed on February 2, 2018.
5. Riloncept Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio. Lexi-Comp., Inc. February 1, 2011. Accessed on February 2, 2018.
6. Ringold S, Weiss PF, Beukelman T, et al. 2013 Update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum*. 2013; 65(10):2499-2512.
7. Sivera F, Wechalekar MD, Andres M, et al. Interleukin-1 inhibitors for acute gout. *Cochrane Database Syst Rev*. 2014;(9):CD009993.
8. Wu B, Xu T, Li Y, Yin X. Interventions for reducing inflammation in familial Mediterranean fever. *Cochrane Database Syst Rev*. 2015;(3):CD010893.

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