

POLICY NAME	Arcalyst (rilonacept)	POLICY #	2385P
--------------------	-----------------------	-----------------	-------

Criteria

Criteria for Coverage for Cryopyrin-Associated Periodic Syndromes (CAPS)

- ☐ Diagnosis of CAPS
- ☐ Diagnosis must be confirmed by genetic testing demonstrating a mutation in the NLRP3 gene and presence of specific clinical criteria
- ☐ Age 12 years or older
- ☐ Prescribed by or in consultation with a rheumatologist (musculoskeletal doctor), geneticist (gene doctor), or allergist/immunologist (immune system doctor)

Criteria for Coverage for Recurrent Pericarditis (long term heart inflammation)

- ☐ Diagnosis of recurrent pericarditis as supported by ≥ 3 previous episodes
- ☐ Age 12 years or older
- ☐ Prescribed by or in consultation with a cardiologist (heart doctor) or rheumatologist (musculoskeletal doctor)
- ☐ Patient is currently stable on standard of care (such as nonsteroidal anti-inflammatory drug(s) [NSAIDs], colchicine, and/or systemic corticosteroids)

Criteria for Coverage for Deficiency of the IL-1-Receptor Antagonist (DIRA)

- ☐ Diagnosis of deficiency of the IL-1RN (DIRA) as supported by clinical criteria
- ☐ Diagnosis confirmed by genetic testing supported mutation in the IL1RN gene
- ☐ Patient weighs 10kg or more
- ☐ Prescribed by or in consultation with a rheumatologist (musculoskeletal doctor), geneticist (gene doctor), or a physician specializing in the treatment of auto-inflammatory disorders
- ☐ All other interleukin-1 blockers have been discontinued

Exclusion Criteria – Any of the following prevents coverage

- ☐ Inadequate response to initial or previous rilonacept therapy
- ☐ Health Alliance does not cover concurrent therapy with other immunomodulators based upon the possible increased risk for infections and other potential pharmacological interactions