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.

CRX-ALL-0280-18

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**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 | NA |

*FHK- Florida Healthy Kids

**Arcaleyst (rilonaceopt)**

CG-DRUG-97

**Override(s)**

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<th>Approval Duration</th>
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<td>Prior Authorization</td>
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<tr>
<td>Quantity Limit</td>
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**Medications**

<table>
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<th>Medications</th>
<th>Quantity Limit</th>
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| Arcaleyst (rilonacept) | 4 vials per 28 days  *
|                   | May approve 1 additional vial in the first 28 days (4 weeks) of treatment |

**APPROVAL CRITERIA**

Arcaleyst (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.

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

I. Use of Arcaleyst (rilonacept) in combination with other interleukin-1 inhibitors; OR
II. Use of Arcaleyst (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.

Arcaleyst (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

PAGE 1 of 2 07/17/2018
V. Schnitzler syndrome
VI. Subacromial bursitis
VII. Systemic juvenile idiopathic arthritis.

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<thead>
<tr>
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Key References: