**Arcalyst (rilonacept)**

**Line(s) of Business:**  
HMO; PPO; QUEST Integration  
Akamai Advantage  

**Original Effective Date:**  
10/01/2015  

**Current Effective Date:**  
04/01/2017  

**POLICY**

**A. INDICATIONS**  
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indication**  
- 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.¹

**B. REQUIRED DOCUMENTATION**  
The following information is necessary to initiate the prior authorization review:

- For CAPS, initial therapy:
  - Results of molecular genetics testing demonstrating a mutation in the NLRP3 gene (also known as CIAS1) (for FCAS and MWS) and/or a mutation in the NLRP12 gene (for FCAS)
  - In the absence of genetic testing or if no genetic mutation is identified, chart notes or medical record documentation of member’s diagnosis must be submitted.

- For CAPS, continuation of therapy:
  - Documentation supporting a beneficial response to therapy with Arcalyst (e.g., chart notes, medical record)

**C. CRITERIA FOR APPROVAL**

**Cryopyrin-Associated Periodic Syndromes (CAPS)**  
Authorization of 12 months may be granted to members who meet both of the following criteria:

- Member has a documented diagnosis of CAPS, including FCAS and MWS.
- Member is 12 years of age or older.

**D. CONTINUATION OF THERAPY**  
All members, including new members, requesting authorization for therapy must meet ALL initial authorization criteria. Subsequent authorizations are subject to the reauthorization criteria below.

**Cryopyrin-Associated Periodic Syndromes (CAPS)**  
Reauthorization of 12 months may be granted when there is a documented beneficial response to therapy with Arcalyst.
E. **DOSAGE AND ADMINISTRATION**
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. **ADMINISTRATIVE GUIDELINES**
Precertification is required. Please refer to the [HMSA medical policy web site](#) for the fax form.

G. **IMPORTANT REMINDER**
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. **REFERENCES**

**Document History**

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