Original Effective Date: 06/29/2012
Current Effective Date: 11/29/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C2434-A

Arcalyst (rilonacept)

PRODUCTS AFFECTED

Arcalyst (rilonacept)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Cryopyrin-Associated Periodic Syndromes (CAPS), Deficiency of interleukin-1 receptor antagonist (DIRA), Recurrent pericarditis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

FOR ALL INDICATIONS:

1. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation

of therapy requests
*MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
**MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
OR
(b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
AND

2. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Arcalyst (rilonacept) include: live vaccines, active or chronic infections (hepatitis B, hepatitis C, human immunodeficiency virus).]
AND
3. Member is not on concurrent treatment or will not be used in combination with TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation

A. CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS):
1. Documented diagnosis of one Cryopyrin-Associated Periodic Syndromes (CAPS) disorder: Familial Cold Auto-inflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS)
NOTE: Arcalyst (rilonacept) is not indicated for use in patients with neonatal-onset multisystem inflammatory disorder (NOMID), another syndrome that is included in CAPS
AND
2. Documentation diagnosis confirmed by one of the following [DOCUMENTATION REQUIRED]:
   a. Raised inflammatory markers (C-reactive protein [CRP] and serum amyloid A) AND at least two of six typical CAPS manifestations: urticaria-like rash, cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   OR
   b. Confirmed by genetic testing for NLRP3 gene mutations (also called CIAS1)
AND
3. Prescriber attests to member having significant functional impairment resulting in limitations of activities of daily living (ADLs)
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

B. DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA):
1. Documented diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
AND
2. Documentation diagnosis confirmed by a genetic mutation of IL1RN OR the presence of ANY of the following: sterile multifocal osteomyelitis, periostitis, pustular rash, marked osteopenia, lytic bone lesions, respiratory insufficiency, or thrombosis [DOCUMENTATION REQUIRED]
AND
3. Documentation member weighs 10kg or more

AND

4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

C. PERICARDITIS:

1. Documented diagnosis of recurrent pericarditis [DOCUMENTATION REQUIRED]
   AND
2. Documentation of trial and failure or labeled contraindication to ALL of the following: colchicine, glucocorticoids, aspirin
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Cryopyrin-associated periodic syndromes, Deficiency of interleukin-1 receptor antagonist:
Prescribed by, or in consultation with a board-certified rheumatologist, immunologist, dermatologist, or genetic specialist.
Pericarditis (recurrent): Prescribed by, or in consultation with a board-certified rheumatologist or cardiologist.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Cryopyrin-associated periodic syndromes, Pericarditis (recurrent): 12 years of age and older
Deficiency of interleukin-1 receptor antagonist: No age restriction

QUANTITY:
Cryopyrin-associated periodic syndromes, Pericarditis (recurrent):
Pediatric patients aged 12 to 17 years: Loading dose of 4.4 mg/kg of body weight, up to a maximum of 320 mg (delivered as 1 or 2 subcutaneous injections with a maximum single- injection volume of 2 ml); Maintenance dosage of 2.2 mg/kg, up to a maximum of 160 mg (2 mL), administered as a single subcutaneous injection once weekly.

Adult patients 18 years and older: Loading dose of 320 mg delivered as two, 2-ml, subcutaneous injections of 160 mg on the same day at 2 different sites. Maintenance dosage: Once- weekly injection of 160 mg administered as a single, 2-ml, subcutaneous injection.

Note: Begin maintenance dose 1 week following loading dose; do not administer more frequently than once weekly.

Deficiency of interleukin-1 receptor antagonist:
Pediatric patients weighing 10 kg or more and Adolescents: 4.4 mg/kg/dose once weekly administered as 1 or 2 separate injections on the same day at different sites; maximum dose: 320 mg/dose; maximum injection volume: 2 mL (160 mg) per injection.

Adult patients 18 years and older: 320 mg once weekly given as 2 separate injections (160 mg [2 mL] per injection) on the same day at 2 different sites.

Maximum Quantity Limits – Dose does not exceed a loading dose of 320 mg (as two injections) and once weekly dosing of 160 mg (as a single injection)

For Cryopyrin-associated periodic syndromes, Pericarditis (recurrent): 5 vials for first month THEN 4 vials per month thereafter

For Deficiency of interleukin-1 receptor antagonist: 8 vials per month

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Interleukin-1 Blockers

FDA-APPROVED USES:
ARCALYST (rilonacept) is indicated for:

- Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS) in adults and children 12 years and older
- Maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing 10 kg or more
- Treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Cryopyrin-associated periodic syndromes (CAPS) is a term used to encompass three rare auto-inflammatory disorders: familial cold auto inflammatory syndrome (FCAS), Muckle–Wells syndrome (MWS) and neonatal-onset multisystem inflammatory disorder (NOMID). CAPS consists of three phenotypically related disorders all associated with mutations in the CIAS-1 gene.

- Familial Cold Auto-inflammatory Syndrome (FCAS)
- Muckle-Wells Syndrome (MWS)
- Neonatal-Onset Multisystem Inflammatory Disease (NOMID)/Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA)

The incidence of CAPS has been reported to be approximately 1 to 2 per 1,000,000 people in the United States. Symptoms include urticaria-like rash, fever and/or chills, as well as inflammation of the joints and eyes caused by a variety of triggers. Symptoms can be present at birth or early infancy and occur daily throughout life.
Symptoms occur when alterations in the cryopyrin protein lead to over-production of interleukin-1 (IL-1), resulting in an inflammatory response. These related diseases have been associated with mutations in the NLRP3 (CIAS1) gene leading to aberrant regulation of the interleukin-1 (IL-1) pathway and hypersecretion of active pro-inflammatory IL-1β. Inhibitors of IL-1β signaling such as rilonacept and canakinumab have demonstrated high efficacy in treating these conditions, supporting the fundamental role of IL-1 in disease pathogenesis.

Familial Cold Auto-inflammatory Syndrome (FCAS)
FCAS, the most common form of CAPS, is characterized by recurrent episodes of urticaria-like rash, fever, chills, and joint pain precipitated by generalized cold exposure. Attacks are also characterized by conjunctivitis, sweating, drowsiness, headache, extreme thirst, and nausea. Symptoms usually develop

1-2 hours after exposure, peak approximately 6-8 hours Patients with FCAS develop symptoms when they are exposed to even a mild degree of cold. Exposures might include a cool breeze, air conditioning, or a light mist. Following cold exposure, a systemic inflammatory response usually ensues within a few hours. Signs and symptoms include recurrent rash, fever/chills, joint pain, fatigue, and eye pain/redness. FCAS patients also can experience headache, muscle pain, excessive thirst, and nausea. These symptoms generally last for up to 24 hours. Laboratory markers of systemic inflammation [C-reactive protein (CRP) and Serum Amyloid A (SAA) levels] are elevated. A small percent of FCAS patients may develop renal consequences due to secondary amyloidosis.

Muckle-Wells Syndrome
MWS shares many of the same inflammatory signs and symptoms of FCAS, but they are often more chronic, and patients have multiple unknown triggers for symptoms onset. Cold exposure may, however, exacerbate inflammation. In addition to episodes of rash, fever/chills, joint pain, fatigue, and eye pain/redness, which can last from 2 to 3 days, MWS also is associated with synovitis and sensorineural deafness. Secondary amyloidosis may occur in as many as 25 percent of patients with MWS, often resulting in renal failure.

Chronic Infantile Neurological Cutaneous Articular Syndrome (CINCA) or Neonatal-Onset Multisystem Inflammatory Disorder (NOMID)
NOMID/CINCA is the most severe and debilitating form of CAPS with symptoms manifesting shortly after birth. Beyond those symptoms manifested in FCAS and MWS, NOMID patients also present with significant disabilities, including optic nerve abnormalities (papilledema), chronic aseptic meningitis, mental retardation, facial malformation, and arthropathy with aberrant ossification (especially in the knees and elbows). Anakinra is the only IL-1 receptor antagonist approved for used for NOMID.

Rilonacept is a targeted inhibitor of interleukin-1 (IL-1), the key driver of inflammation in cryopyrin-associated periodic syndromes (CAPS). Rilonacept acts as a decoy receptor that binds IL-1 beta and the blocks IL-1 beta signaling, thereby preventing its interaction with cell surface receptors. It also binds IL-1 alpha and IL-1 receptor antagonist with reduced affinity.

The FDA's approval of Arcalyst was based on a phase III clinical trial by Hoffman et al. (2008)

One randomized, controlled study compared rilonacept to placebo in 47 patients randomized to receive either rilonacept (n=23) or placebo (n=24) in a blinded fashion for six weeks. Of 47 patients who enrolled in the 24-week, multiphase, sequential, Phase III pivotal trials of rilonacept, 44 entered into the open- label treatment phase in 22 centers in the United States. All patients were tested and found to be positive for theCIAS1 mutation. At the end of six weeks, patients receiving placebo received active drug, while patients randomized to rilonacept continued with treatment in a single blinded fashion and were enrolled in 2 consecutive studies.

A two-part double-blind, placebo-controlled, randomized trial was conducted to determine the efficacy of rilonacept in patients with FCAS and MWS.

Study 1 entailed a 6-week randomized double-blind comparison of weekly subcutaneous injections of rilonacept (160 mg) versus placebo. Study 2 consisted of a 9-week single-blind treatment with rilonacept (part A), followed by a 9-week, randomized, double-blind, placebo-controlled withdrawal procedure (part B). Primary effectiveness was evaluated using a validated composite key symptom score. A total of 44

patients completed both studies.

In Study 1, rilonacept therapy reduced the group mean composite symptom score by 84%, compared with 13% with placebo therapy (primary end point; $p < 0.0001$ versus placebo). Rilonacept also significantly improved all other effectiveness end points in Study 1 (numbers of multi-symptom and single-symptom disease flare days, single-symptom scores, physician's and patient's global assessments of disease activity, limitations in daily activities, as well as hsCRP and SAA levels). In Study 2-part B, rilonacept was superior to placebo for maintaining the improvements seen with rilonacept therapy, as shown by all effectiveness parameters (primary end point; $p < 0.0001$ versus placebo). Rilonacept was generally well-tolerated. The authors concluded that treatment with weekly rilonacept provided marked and lasting improvement in the clinical signs and symptoms of CAPS and normalized the levels of SAA from those associated with risk of developing amyloidosis. Rilonacept exhibited a generally favorable safety and tolerability profile.
The main outcome measure was the change from baseline in patient-rated mean symptom scores. Symptoms assessed were joint pain, fatigue, rash, eye redness/pain, and fever or chills. The rilonacept group reported a statistically greater decrease in symptom score from baseline (-2.4) compared to placebo (-0.5, $p < 0.0001$) during the first part of the trial. In the second part (n = 45), all patients were treated with rilonacept for 9 weeks, followed by 9 more weeks of rilonacept or withdrawal with placebo. Mean symptom scores increased more in patients who were switched to placebo from rilonacept (0.9) compared to those who remained on rilonacept (0.1, 95% CI -1.3 to - 0.4).
Conclusion:

- The results of 2 pivotal, sequential, placebo-controlled, Phase III studies have shown that subcutaneous rilonacept 160 mg weekly provides marked and lasting improvement in the clinical signs and symptoms associated with CAPS, with a generally favorable safety and tolerability profile.
- Treatment of patients with FCAS or MWS with rilonacept resulted in a significant (84%) improvement in a composite symptom score and normalized elevated SAA and hs-CRP levels. Unlike previous studies of therapies for CAPS, these 2 studies were multicenter, large (n=47) relative to the total population of patients with CAPS in North America and used a validated instrument for CAPS symptom self-assessment to demonstrate the efficacy of rilonacept in adults.1

72-week open-label extension: Case series of 101 patients with familial cold autoinflammatory syndrome or Muckle-Wells syndrome treated with rilonacept 160 mg subcutaneously weekly

- 44 adults from the above study received 72 additional weeks of treatment and 57 newly enrolled patients aged 12-80 years received treatment for 72-96 weeks
- among all 101 patients, rilonacept associated with significant reductions in physician assessed disease activity score, mean serum amyloid A, and mean C-reactive protein at 24 weeks compared to baseline
- Reference: Clinical Therapeutics, Volume 34, Issue 10, 2091 – 2103

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Arcalyst (rilonacept) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Arcalyst (rilonacept) include: administration of live vaccines, active or chronic infections.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
N/A	

AVAILABLE DOSAGE FORMS:
Arcalyst SOLR 220MG single-dose vial

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treatment response. Curr Allergy Asthma Rep. 2011;11(1):12-20
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Kinase Deficiency, and Deficiency of the Interleukin-1 Receptor Antagonist. Arthritis & Rheumatology, 74(7), 1102–1121. https://doi.org/10.1002/art.42139

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Quantity Place of Administration Background References	Q4 2023
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Age Restrictions Quantity Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file