Mass General Brigham
Health Plan

Targeted Immunomodulators
Arcalyst (rilonacept)
Effective 06/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Notes	Arcalyst is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview
Arcalyst (rilonacept) is an interleukin-1β (IL-1β) blocker that is indicated for Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and for treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and children 12 years and older.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Cryopyrin-Associated Periodic Syndromes, including: Familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)
ALL of the following:
1. Diagnosis of one of the following:
    a. Familial cold autoinflammatory syndrome (FCAS)
    b. Muckle-Wells syndrome (MWS)
2. Member is ≥ 12 years of age
3. ONE of the following:
    a. Evidence of symptoms indicative of the disease (see appendix for examples)

    b. Confirmation of diagnosis through genetic testing
4. Appropriate dosing
5. Inadequate response, adverse reaction, or contraindication to Ilaris

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
ALL of the following:
1. Diagnosis of deficiency of interleukin-1 receptor antagonist
2. Confirmation of diagnosis through genetic testing
3. Inadequate response, adverse reaction, or contraindication to Kineret (anakinra)
4. Appropriate dosing

Recurrent pericarditis
ALL of the following:
1. Diagnosis of recurrent pericarditis
2. Member is ≥ 12 years of age
3. Inadequate response or adverse reaction to ONE or contraindication to BOTH of the following:
    a. aspirin
    b. Nonsteroidal anti-inflammatory drugs (NSAID)
4. Inadequate response or adverse reaction to ONE or a contraindication to ALL corticosteroids
5. Inadequate response, adverse reaction or contraindication to BOTH of the following:
    a. Colchicine
    b. Kineret (anakinra)
6. Appropriate dosing

Continuation of Therapy
Reauthorization by prescriber will infer a positive response to therapy and dosing is appropriate.

Limitations
1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

Appendix
Disease Symptoms
- **Tumor necrosis factor receptor associated periodic syndrome (TRAPS):**
    - Characterized by recurrent fevers over months or years every five to six weeks, focal myalgias, conjunctivitis, periorbital edema, abdominal pain, monoarticular arthritis, and rash.

- **Recurrent pericarditis:**
    - The predominant feature of recurrent pericarditis is usually pleuritic chest pain (often sharp, worse when lying flat, and alleviated when leaning forward), which may follow exertion. Some members may also report dyspnea or malaise.

- **Familial cold autoinflammatory syndrome (FCAS):**
    - Mildest phenotype; characterized by intermittent cold-induced rash with fever and arthralgia.

- **Muckle-Wells syndrome (MWS):**
    - Characterized by recurrent episodes of fever and urticaria associated with joint and ocular manifestations, deafness and reactive amyloid A amyloidosis.

- **Neonatal onset multisystem inflammatory disease (NOMID):**
    - Most severe spectrum of the disease; characterized by erythematous rash resembling urticaria, fever, impaired growth, chronic meningitis, hearing loss, uveitis, lymphadenopathy and hepatosplenomegaly. Limb and joint pain are common.

- **Hyperimmunoglobulin D syndrome (HIDS)/Mevalonate kinase deficiency (MKD):**
    - Characterized by episodic attacks of fever lasting three to seven days are accompanied, in most cases, by chills, cervical lymphadenopathy, abdominal pain, vomiting, and/or diarrhea. Other symptoms include headache, arthralgias/arthritis, aphthous ulceration, a pleomorphic rash, and splenomegaly. Elevated levels of immunoglobulin D (IgD) are often present.

References

1. Arcalyst [package insert]. Tarrytown (NY): Regeneron Pharmaceuticals, Inc; 2025 Mar.

Review History

06/14/2023 - Created for P&T in order to match MH UPPL. Effective 7/1/23.
05/15/2025 – Reviewed and updated for P&T. Performed annual medical criteria review. Policy has been updated to better reflect agents with prior authorization on medical benefit. Updated formatting and references. For FCAS and MWS indication, step-through requirement to Ilaris was added. Effective 6/1/25