STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

RILONACEPT

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
RILONACEPT	ARCALYST	35438		GPI-10 (6645006000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
   - The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   - Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g., Ilaris [canakinumab], Kineret [anakinra])

   If yes, **enter TWO approvals by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL:**
     - **Approve for 1 month with a quantity limit of #5 per 28 days.**
   - **SECOND APPROVAL:**
     - **Approve for lifetime with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).**

   If no, continue to #2.

2. Does the patient have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and meet **ALL** of the following criteria?
   - The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   - The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   - Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g., Ilaris [canakinumab], Kineret [anakinra])

   If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #3.

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GUIDELINES FOR USE (CONTINUED)

3. Is the request for the treatment or reduction in risk of recurrent pericarditis (RP) and the patient meets **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had an episode of acute pericarditis
   - The patient has been symptom-free for an interval of 4 to 6 weeks
   - The patient has TWO of the following: chest pain consistent with pericarditis, pericardial friction rub, ECG showing diffuse ST-segment elevation or PR-segment depression, and new or worsening pericardial effusion
   - The patient had a trial of or contraindication to two NSAIDs (e.g., ibuprofen, indomethacin) AND colchicine
   - Arcalyst will NOT be used concurrently with other IL-1 inhibitors (e.g., Ilaris [canakinumab], Kineret [anakinra])

   If yes, **approve for 12 months by HICL or GPI-10 as follows:**
   INITIAL REQUESTS:
   - **FIRST APPROVAL:**
     - **Approve for 1 month with a quantity limit of #5 per 28 days.**
   - **SECOND APPROVAL:**
     - **Approve for 11 months with a quantity limit of #4 per 28 days (enter a start date of 3 days BEFORE the END of the first approval).**

   SUBSEQUENT REQUESTS:
   - **Approve for 12 months with a quantity limit of #4 per 28 days.**

   If no, do not approve.

   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **RILONACEPT (Arcalyst)** requires the following rule(s) be met for approval:
   A. You meet ONE of the following:
      1. You have Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS: an inherited inflammatory disorder that is triggered with cold) or Muckle-Wells Syndrome (MWS: a disorder characterized by periodic episodes of skin rash, fever, and joint pain)
      2. You have Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a type of immune system disorder)
      3. Arcalyst will be used for the treatment or reduction in risk of recurrent pericarditis (RP: a type of heart condition that returns)

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GUIDELINE FOR USE (CONTINUED)

B **If you have Cryopyrin-Associated Periodic Syndromes including Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome, approval also requires:**
1. You are 12 years of age or older
2. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
3. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
4. Arcalyst will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

C. **If you have Deficiency of Interleukin-1 Receptor Antagonist, approval also requires:**
1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: fungal infection of toenail)
3. Arcalyst will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

D. **If the request is for the treatment or reduction in risk of recurrent pericarditis, approval also requires:**
1. You are 12 years of age or older
2. You had an episode of acute pericarditis (a type of short-term heart condition)
3. You have been symptom-free for 4 to 6 weeks
4. You have TWO of the following: chest pain consistent with pericarditis, pericardial friction rub (a type of heart condition), electrocardiogram (ECG: a type of lab test) showing diffuse ST-segment elevation or PR-segment depression (an abnormal heart test), and new or worsening pericardial effusion (a type of heart condition)
5. You had a trial of or contraindication to (harmful for) two NSAIDS (non-steroidal anti-inflammatory drugs such as ibuprofen, indomethacin) AND colchicine
6. Arcalyst will NOT be used concurrently with other IL-1 inhibitors (such as Ilaris [canakinumab], Kineret [anakinra])

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GUIDELINE FOR USE (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Arcalyst.

REFERENCES

- Arcalyst [Prescribing Information]. London, UK: Kiniksa Pharmaceuticals; May 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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