Arcalyst® (rilonacept) For Injection

Important considerations when developing an Appeals Letter for ARCALYST® (rilonacept)

An Appeals Letter submitted to a health insurance plan can often prove beneficial if your patient has been denied use of a specific therapy that you feel is necessary for their treatment. It is essential to provide a complete package of supporting documents and information, as outlined below, when appealing a decision.

HERE ARE SOME HELPFUL TIPS FOR DRAFTING AN APPEALS LETTER:

Be Prepared
Know the insurance plan's specific guidelines and policies, such as when a referral is required, or if the patient meets the criteria stated in the plan's policy for the medication.

Be Timely
Be aware of and meet all deadlines. Once an appeal is submitted, be sure to check with the payer as the duration for authorizations can vary.

Be Detailed
This includes being as thorough as possible when completing the following:

- ☐ **Patient information:**
  - Full name
  - Member ID and group numbers
  - Date of birth
  - Claim ID number (if available)
- ☐ **Diagnosis indicating recurrence of pericarditis** along with specific ICD-10 code(s)
- ☐ **Frequency of recurrence** of pericarditis episodes
- ☐ **Severity of the patient's condition**
- ☐ **Summary of the patient's previous treatments,** including the duration of each and the rationale for discontinuation. Be sure to include coding information for prior treatments and services; this will help the insurance plan conduct their research in a more timely manner
- ☐ **Clinical rationale for treatment,** including trial data supporting FDA approval. Also include the appropriate dosing and administration information
- ☐ **Summary of your recommendation**
- ☐ **Acknowledgment of your familiarity with the health plan's claims and denials policy,** including the reason(s) for the denial
- ☐ **A Letter of Medical Necessity**
- ☐ **Additional supporting documents,** such as relevant medical records, clinical notes/diagnostic reports, medication records, ARCALYST Prescribing Information, relevant peer-reviewed journal articles, and the FDA Approval Letter for ARCALYST

Indication

ARCALYST is indicated for the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

Important Safety Information

Warnings and Precautions

- Interleukin-1 (IL-1) blockade may interfere with the immune response to infections. Treatment with another medication that works through inhibition of IL-1 has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking ARCALYST. ARCALYST is not recommended for use with tumor necrosis factor (TNF) inhibitors because this may increase risk of serious infections. ARCALYST should be discontinued if a patient develops a serious infection. Treatment with ARCALYST should not be initiated in patients with an active or chronic infection.

Please see additional Important Safety Information at the end of this document.
For more information about ARCALYST, see full Prescribing Information.

We have included a sample letter on the next page in the form of a template that aligns to these tips and guidelines for your use now and in the future.

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Sample Appeals Letter for ARCALYST® (rilonacept)

This sample letter is for demonstration purposes only. It provides an example of the type of information that may be required when requesting a formulary exception for ARCALYST from a patient's insurance company. Use of this template or the information in this template does not guarantee reimbursement or coverage. It is not intended to be a substitute for, or to influence, the independent clinical decision of the prescribing healthcare professional.

[Physician or Practice Letterhead]

[Date]

[Health Plan Name]
Attn: [Department]
[Health Plan Contact]
[Health Plan Address]
[Health Plan City, State ZIP]

Patient: [Patient's First and Last Name]
Date of Birth: [Patient's Date of Birth]
Member ID #: [Patient's Member ID #]
Member Group #: [Patient's Group ID #]
Claim #: [Claim #]

Request: Letter of appeal for ARCALYST® (rilonacept) injection for subcutaneous use
Diagnosis: [Diagnosis] ([ICD-10 code(s)])
Dosage: [Dose and frequency]

Dear [Health Plan Contact],

I am writing to request reconsideration of your denial of coverage for ARCALYST, which I have prescribed for the patient referenced above.

In brief, the [diagnosis] ([ICD-10 code(s)]) treatment regimen with ARCALYST is medically appropriate and necessary for [Patient Name] and should be covered and reimbursed. ARCALYST was denied for [Patient Name] because [reason(s) for denial]. Below I have listed relevant information about the patient's medical history and treatment as well as the clinical rationale for ARCALYST.

Summary of Patient's Diagnosis and Medical History

[Patient Name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [diagnosis] ([ICD-10 code(s)]) as of [date of diagnosis]. [He/She] has been in my care since [date].

[Additional information that may be relevant here includes:

- Qualitative assessment of the severity of the patient's pericarditis
- Frequency of the recurrence of pericarditis episodes
- Pericarditis symptoms experienced by the patient
- Impact of pericarditis recurrence on the patient's health-related quality of life and activities of daily living
- Related comorbidities or contraindications (ie, medical history, comorbidities, adverse events, and/or drug interactions) with formulary-preferred agents
- Acute and chronic complications associated with the patient's recurrent pericarditis or complications associated with pericarditis treatment
- Previous treatments for pericarditis including drug names, duration of treatment(s), and responses to those treatments (see sample table below)]

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Treatment	Start/Stop Dates	Responses to Treatment (eg, lack of efficacy, intolerability)
[Drug name]	[MM/YY] – [MM/YY]	[Please list reasons]
[Drug name]	[MM/YY] – [MM/YY]	[Please list reasons]

Clinical Rationale for ARCALYST® (rilonacept)

[Include a summary of reasons the preferred drugs on formulary are not appropriate and why ARCALYST is clinically indicated for the patient based on the Full Prescribing Information and other relevant supporting materials.]

Considering the patient's diagnosis, medical history, and the clinical evidence supporting the efficacy of ARCALYST in treating [diagnosis] ([ICD-10-code(s)]), I believe treatment with ARCALYST is warranted, appropriate, and medically necessary.

The accompanying materials support my recommendation for ARCALYST for [Patient Name].

I am requesting an expedited review of this request by a board-certified and specialty-matched physician who can render a decision based upon the rationale outlined above. If you have any questions, please contact me at [physician phone number and/or email]. I would be pleased to speak to you in more detail about why I consider ARCALYST to be medically necessary for [Patient Name]'s treatment of [diagnosis] ([ICD-10-code(s)]).

I look forward to receiving your timely response.

Sincerely,
[Physician Name]
[Physician signature]

[Physician address]
[Physician phone number]

Enclosures
[Include supporting evidence, such as relevant medical records, clinical notes/diagnostic reports, medication records, ARCALYST Prescribing Information, relevant peer-reviewed journal articles, and the FDA Approval Letter for ARCALYST.]

For more information about ARCALYST, see full Prescribing Information.

Arcalyst® (rilonacept) For Injection

ARCALYST® (rilonacept) Indication and Important Safety Information

Indication

ARCALYST is indicated for the treatment of recurrent pericarditis (RP) and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

Important Safety Information

Warnings and Precautions

- Interleukin-1 (IL-1) blockade may interfere with the immune response to infections. Treatment with another medication that works through inhibition of IL-1 has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking ARCALYST. ARCALYST is not recommended for use with tumor necrosis factor (TNF) inhibitors because this may increase risk of serious infections. ARCALYST should be discontinued if a patient develops a serious infection. Treatment with ARCALYST should not be initiated in patients with an active or chronic infection.
- It is possible that taking drugs that block IL-1 increase the risk of tuberculosis (TB) or other atypical or opportunistic infections. Refer to current practice guidelines to evaluate and to treat possible latent TB infections before initiating therapy.
- The impact of ARCALYST on infections and the development of malignancies is not known. However, treatment with immunosuppressants may result in an increase in the risk of malignancies.
- Hypersensitivity reactions occurred in clinical trials. If a hypersensitivity reaction occurs, discontinue ARCALYST and initiate appropriate therapy.
- Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted.
- Since no data are available, avoid administration of live vaccines while patients are receiving ARCALYST. Because IL-1 blockade may interfere with immune response to infections, it is recommended that, prior to initiation of therapy with ARCALYST, patients receive all recommended vaccinations, as appropriate.

Adverse Reactions

- The most common adverse reactions (≥10%) include injection-site reactions, upper respiratory tract infections, arthralgia, and myalgia.

Drug Interactions

- Concomitant administration of ARCALYST with TNF-blocking agents or other agents that block IL-1 or its receptor is not recommended, as this may increase the risk of serious infections.
- In patients being treated with CYP450 substrates with narrow therapeutic indices, therapeutic monitoring of the effect or drug concentration should be performed, and the individual dose of the medicinal product may need to be adjusted as needed.

Use in Specific Populations

- Pregnancy outcomes reported post marketing and during clinical trials were rare, therefore, the effect of using ARCALYST during pregnancy is not known.
- There is no information on the presence of ARCALYST in either human or animal milk, the effects on the breastfed infant, or the effects on milk production.

For more information about ARCALYST, see full Prescribing Information.