Important considerations when developing a Tiering Exception Request Letter for ARCALYST® (rilonacept)

A tiering exception can be requested when a medication is on a health insurance plan's formulary but is placed in a nonpreferred tier that has a higher co-pay or co-insurance. However, plans may make a tiering exception when the drug demonstrates medical necessity. Physicians have the option to request a tiering exception so their patient can obtain the nonpreferred medication at a lower out-of-pocket cost. Plans often have specific Tiering Request Forms that must be used. Please follow the plan's requirements when requesting an exception; otherwise, treatment may be delayed.

HERE ARE SOME HELPFUL TIPS FOR DRAFTING A TIERING EXCEPTION REQUEST 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 exception is requested, 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/submitting 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**

☐ **A Letter of Medical Necessity**

☐ **A statement of financial hardship, written by the patient**

☐ **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.

Sample Tiering Exception Request 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 tiering 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]	Patient: [Patient's First and Last Name]
Attn: [Department]	Date of Birth: [Patient's Date of Birth]
[Health Plan Contact]	Member ID #: [Patient's Member ID #]
[Health Plan Address]	Member Group #: [Patient's Group ID #]
[Health Plan City, State ZIP]	Claim #: [Claim #]

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

Dear [Health Plan Contact],

I an writing to request a tiering exception for ARCALYST on behalf of my patient, [Patient Name], who is currently a member of [Health Plan Name]. This request is for ARCALYST, which is medically appropriate and necessary for this patient diagnosed with [diagnosis] ([ICD-10 code(s)]), to be made available as a preferred medication.

Other treatments that [Patient Name] is taking or has taken for [diagnosis] ([ICD-10 code(s)]) have not demonstrated adequate efficacy or have led to tolerability issues.

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]

I have enclosed a copy of the patient's medical records along with a Letter of Medical Necessity. The letter details the reasons why ARCALYST is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary.

I am requesting a tiering exception because the cost associated with the assigned tier for ARCALYST would present a financial hardship for [Patient Name] and prevent [him/her] from being able to access a medication that will help manage [his/her] [diagnosis] ([ICD-10 code(s)]).

Considering the patient's diagnosis, medical history, and the clinical evidence supporting the efficacy of ARCALYST® (rilonacept) in treating **[diagnosis]** (**[ICD-10 code(s)]**). I believe treatment with ARCALYST is warranted, appropriate, and medically necessary. 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 **[Patient Name]** would benefit from a tiering exception.

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) Indication and Important Safety Information

Indication

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- 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 <u>full Prescribing Information</u>.