**Sample Letter of Medical Necessity 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]** 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: Authorization for treatment with 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 coverage for ARCALYST for the treatment of **[diagnosis]** (**[ICD-10 code(s)]**) on behalf of my patient, **[Patient Name]**, who is currently a member of **[Health Plan Name]**.

I have reviewed your drug coverage policy and believe that ARCALYST is medically appropriate and necessary for this patient who has been diagnosed with **[diagnosis]** (**[ICD-10 code(s)]**). 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 (i.e., 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 treatments, and responses to those treatments (see sample table below)]**

|  |  |  |
| --- | --- | --- |
| **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)**

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.]**