# US-113085

# SAPHNELO Sample Letter of Appeal_ May 2026

**Dimensions - 8.5 inches high x 11 inches wide**

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**AstraZeneca**

# SAPHNELO Sample Appeal Letter

When a payer denies a prior authorization (PA), precertification, or reauthorization request for SAPHNELO® (anifrolumab-fnia), patients have the right to appeal the decision. If a patient chooses to pursue an appeal, you may support the process by submitting an appeal letter with supporting documentation.

As part of the appeal, payers may request additional information to support coverage for SAPHNELO following a denial. The appeal letter should describe why SAPHNELO is medically necessary for the patient and may include supporting documentation. The letter may be submitted either in response to the initial denial or following a payer's request for additional information. It should contain patient-specific details, address the reason for denial, be written on the prescriber's letterhead, and be signed by the prescriber.

This Sample Appeal Letter is provided for informational purposes only and does not constitute legal advice or official guidance from payers. The template is offered as a general framework to assist in preparing an appeal. As you review the template below, please note that you will need to populate or provide the information in bracketed red font ([xxx]).

**It is not intended to influence reimbursement decisions or replace the independent medical judgment of a healthcare provider.**

**AstraZeneca makes no representations or guarantees that use of this information will result in coverage or payment for SAPHNELO, or that any payment received will fully offset provider costs. Attachments to be included with the letter of appeal are original claim form, copy of denial or explanation of benefits, and any other supporting documents. If you need additional references, please contact our information center at 1-800-236-9933.**

[Date]
[Contact Name], [Title] [Name of Health Insurance Plan or Pharmacy Benefit Manager]
[Address]
[City, State ZIP Code]

**Re:** [First/Second]-Level Appeal for Coverage Denial of SAPHNELO
[Request for Expedited Review Due to Medical Urgency]

**Denial Letter Date:** [MM/DD/YYYY]
**Denial Reference #:** [Denial Reference #]

**Patient:** [Name]
**Date of Birth:** [MM/DD/YYYY]
**Member ID Number:** [Insurance ID Number] **Group Number:** [Insurance Group Number]
**Rx Bin:** [Rx Bin Number] **Rx PCN:** [Rx PCN Number] **Rx Group:** [Rx Group Number]

Dear [Contact Name],

I am a [medical specialty] and am writing on behalf of my patient, [Patient name], to formally appeal [payer name]'s decision to deny coverage for SAPHNELO® (anifrolumab-fnia), which has been prescribed for [patient-specific diagnosis].

It is my understanding based on your letter of denial dated, [MM/DD/YYYY], that coverage has been denied for the following reason(s), [List the specific reason(s) for the denial stated in the denial letter]. This appeal provides patient-specific clinical information and medical rationale demonstrating that SAPHNELO is medically necessary and appropriate for this patient.

## REASON(S) FOR DENIAL AND TREATMENT RATIONALE (refer to page 3 for additional information)

[In the appeal letter, you will likely want to address the denial reason stated in the denial letter from the insurance plan. Clearly explain why the reason(s) stated in the insurance plan as a cost for denial of coverage, do not preclude use of SAPHNELO. During the appeal process, it is generally not helpful to provide additional information beyond the specific denial reasons.]

In my medical opinion, SAPHNELO is the most appropriate treatment for [Name of Patient], a[n] [age]-year-old [gender] who requires treatment with SAPHNELO after being diagnosed with [patient-specific diagnosis] on [MM-DD-YYYY]. The stated reason(s) for denial include, [insert each and all reasons and address each reason point by point and provide any supporting documentation, if applicable, for why denial is not appropriate].

## SUMMARY AND OPTIONAL MEDICAL HISTORY (see page 4 for additional information)

As stated in my initial authorization request, [Name of Patient] presented with [insert specific clinical presentations and previous treatments, including any relevant patient – specific clinical scenarios demonstrating serious medical need]. For the above reasons, I request that you reverse the coverage determination. Delayed or denied access to SAPHNELO places [Name of Patient] at risk of [include potential medical implications due to lack of treatment as deemed appropriate].

For your additional information, I am enclosing [list enclosures, such as copy of denial letter, supporting clinical documentation, etc.]. If you have any questions, please feel free to call me at [physician's telephone number] to discuss.

Thank you in advance for your immediate attention to this request.

Sincerely,

[Provider Name]
[Provider Identification Number]
[Provider Practice Name]
[Provider Phone Number]
[Provider Fax Number]
[Provider Email]

Enclosures
[At the bottom of your letter, list the items you have enclosed, which may include things such as the original denial letter, confirmatory laboratory testing results, clinical scoring sheets and other patient chart notes, progress notes, clinical trials, guidelines or consensus statements, FDA approval letter, other relevant references, and publications regarding prescribed medicine etc.]
[Include Indication and Important Safety Information]
[Include full Prescribing Information, including Patient Information]

## TREATMENT RATIONALE TO SUPPORT APPEAL

Below are some of the common reasons your patient's PA, precertification, or reauthorization request may be denied. In your appeal letter, ensure that each reason for denial is addressed by sharing your medical expertise on why the requirement is satisfied or should not apply in your patient's individual case. Be sure to attach the supporting references and any additional documentation in your reply.

1. **Denial due to indication:** Consider including information regarding this patient's current diagnosis and information regarding any confirmation of the stated diagnosis.

   Consider documentation if the patient's diagnosis aligns to the FDA-approved indication and if standard diagnostic requirements have been met.

2. **Denial due to required use of standard of care:** List treatments with the respective clinical responses here including trial/failure dates, steroid taper attempts, current SOC regimen and list clinical rationale.
3. **Denial due to lack of documented disease activity:** Include information such as SLEDAI-2K score, BILAG score, Physician Global Assessment (PGA), organ involvement, and flare history, if applicable.
4. **Denial due to vaccination status:** Document completion of relevant immunizations prior to initiating SAPHNELO.
5. **Denial due to safety concerns or comorbidities:** Address infection risk, hypersensitivity, or contraindications and provide monitoring strategies.
6. **Denial due to requirement for other biologic therapy first:** You may want to provide evidence to support a professional judgment that the indicated therapy is not appropriate for your patient.

- If the patient has tried and failed the preferred/required alternative, consider including dates of the previous treatment regimen, a description of the treatment outcome(s) including any negative or ineffective results, and rationale for treatment with SAPHNELO. You may want to include description of treatment outcome or worsening symptoms as evidenced clinical scoring indices (eg, SLEDAI, PGA, BILAG)
- Consider whether the patient's therapy response, disease activity, or quality of life may be impacted by the use of the preferred/required alternative due to patient's disease biology or phenotype, lack of anticipated clinical benefit based on disease features, weight-based dosing concerns, comorbidities such as history of depression/suicidality, ethnicity/race considerations, risk of worsening of disease due to delayed onset of action (if applicable).
- If applicable, also document why SAPHNELO would be your preferred therapy for this patient in your professional opinion (eg, treatment burden, long-term disease management, shared decision-making, prior treatment fatigue or adherence concerns)

# INFORMATION PAYERS COMMONLY REQUEST

**☐ Confirmed diagnosis of Systemic Lupus Erythematosus (SLE) based on established classification criteria (ACR, SLICC, or EULAR/ACR Guidelines)**

**☐ Laboratory evidence of immunologic activity such as ANA, anti–dsDNA, anti-Smith, complement (C3/C4) levels, antiphospholipid antibodies**

**☐ Baseline and ongoing disease activity scores: SLEDAI-2K, BILAG, Physician Global Assessment, Lupus QoL (include historical tracking, if possible)**

**☐ Documentation of prior and current SLE-directed therapies including steroids, antimalarials, immunosuppressants, and current biologics, with treatment response and rationale for changes.**

**☐ Evidence supporting moderate to severe disease activity or inadequate disease control such as:**

- ☐ Note steroid burden or difficulty tapering
- ☐ Identify ongoing organ involvement or serologic activity
- ☐ Include functional/QoL impairment
- ☐ Recent disease progression (flares, hospitalizations, worsening symptoms)

**☐ Clinical manifestations consistent with moderate to severe SLE, including:**

- ☐ Musculoskeletal (such as arthritis, arthralgia, osteonecrosis, myopathy)
- ☐ Mucocutaneous (such as rash, photosensitivity, alopecia)
- ☐ Renal
- ☐ Hematologic (such as anemia, leukopenia, thrombocytopenia)
- ☐ Cardiopulmonary (such as pericarditis, myocarditis, pleuritis, pleural effusion, pneumonitis, ILD)
- ☐ Neurologic (headaches, cognitive dysfunction, neuropathies)
- ☐ Constitutional symptoms (fatigue, fever, loss of appetite, headache)
- ☐ Vascular (such as vasculitis, thromboembolic disease)

**☐ Assessment of functional limitations affecting daily functioning (eg, fatigue, joint pain, cognitive symptoms)**

**☐ Relevant comorbid conditions influencing disease management (eg, renal impairment, metabolic, cardiovascular, BMI,* infections, osteoporosis, psychiatric conditions).**
*** BMI-SAPHNELO is not weight-based dosing**

**☐ Racial/Ethnicity Efficacy Considerations**

**☐ Contraindications, hypersensitivities, precautions, or clinical considerations related to payer mandated biologic therapy.**

**☐ No exclusions prior to initiating proposed biologic therapy**

- ☐ Document no active severe infection
- ☐ Include TB/HIV/Hep screening, if required
- ☐ Review vaccination status
    - ☐ Note absence of contraindications

## GENERAL TIPS FOR COMPLETING AN APPEAL LETTER

**Familiarize yourself with the payer's appeals process.** Each payer has specific requirements for submitting an appeal, so it is important to follow their guidelines when submitting an appeal. Many payers require the use of their own appeal request forms, which are typically available on their websites. If a payer-specific form is required, submit it along with your appeal letter. Contact the payer directly with any questions and request written instructions to ensure you are following the correct appeals process.

**Timing is critical when submitting an appeal.** Review the denial letter carefully to identify submission deadlines and any payer-specific timelines or requirements for appeals.

**Expedited reviews may be available in urgent situations.** If the situation is medically urgent, the patient may request an expedited appeal, with a decision generally issued within 72 hours. For more information, please visit HealthCare.gov.

**Understand the reason for the denial.** Carefully review the denial letter to determine the payer's stated reason(s). You may also contact the payer to discuss the denial, which can help identify potential pathways for timely resolution:

- **Denials due to inaccurate or incomplete information:** Review the PA or reauthorization request to identify any missing or incorrect information. Once all required information is accurate and complete, resubmit the PA or reauthorization request.
- **Denials based on medical rationale:** Ensure the appeal letter includes clear, specific, and relevant medical information that supports the use of SAPHNELO in accordance with the payer's criteria. The letter should clearly explain why SAPHNELO is the most appropriate treatment option for the patient.

**Submit all required documentation together and in the specified order.** Follow the payer's appeal instructions carefully and include all requested materials at the same time. Documentation may include:

- The payer's appeal form (if required)
- Your appeal letter
- A copy of the payer's denial letter
- Supporting materials such as clinical notes, genetic testing results, or other relevant documentation

**Leverage support from Field Reimbursement Managers (FRMs).** Dedicated FRMs are available to support healthcare provider offices following a PA denial and can help facilitate patient access to prescribed AstraZeneca therapies. FRMs can assist with:

- Education on payer options for PA resubmission, including peer-to-peer reviews, appeal processes, and applicable timelines
- Review of redacted denial letters or Explanation of Benefits (EOB) statements to provide tailored guidance on next steps and best practices

## KEY RESOURCES AVAILABLE TO YOU

- The **Access and Reimbursement Guide** is a resource that provides education and support about the access and reimbursement process.
- The SAPHNELO **Full Prescribing Information** provides details and directions on how to prescribe SAPHNELO and pertinent efficacy and safety data.
- The **FDA Approval Letter** provides information on the response from the FDA in reference to the application filed SAPHNELO.
- The **Free Limited Supply (FLS) Request** provides a free, short-term supply of SAPHNELO for eligible patients who are denied immediate access or are awaiting insurance coverage determination.
- *Please note that FLS is a temporary program and does not replace existing affordability programs that may be more appropriate for long-term access barriers.*

**For additional access resources, please see AstraZeneca Access 360™ Forms and Resources or scan the QR code to find the right access and support options for you and your SAPHNELO patients.**