# US-113084

# SAPHNELO Letter of Medical Necessity_May 2026

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

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**AstraZeneca**

# SAMPLE SAPHNELO LETTER OF MEDICAL NECESSITY

## Template Instructions:

This template is offered as a resource a healthcare provider may use when responding to the patient's health benefits company request for a letter of medical necessity for SAPHNELO® (anifrolumab-fnia). As you review the template below, please note that you will need to populate or provide the information in bracketed red font ([xxx]).
Documents typically included with the letter of medical necessity are a copy of the denial or explanation of benefits, any supporting documents, and Prescribing Information. If you have questions, please contact our Information Center at 1-800-236-9933.

**This letter 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]
Insured: [Name]; Policy Number: [Number]; Group Number: [Number]

Request Type: ☐ New Start ☐ Continuation ☐ Appeal ☐ Expedited Review

Dear [Medical Director/Reviewer],

I am writing on behalf of my patient, [Patient Name], to request authorization for SAPHNELO® (anifrolumab-fnia) as medically necessary for the treatment and management of [diagnosis + ICD-10 Code]. This document summarizes the patient's clinical history, prior therapies, and the medical rationale supporting this request.

## PATIENT MEDICAL AND TREATMENT HISTORY (see page 3)

[Patient Name] is a/an [age]-year-old [gender] who has been treated for [diagnosis + ICD-10 Code] since [MM/DD/YYYY] supported by: [consider providing relevant SLE clinical signs and symptoms and describe the severity of disease, including:

- ☐ **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)**
- ☐ **Clinical manifestations consistent with moderate to severe SLE, including:**
  - ☐ Musculoskeletal (such as arthritis, arthralgia, osteonecrosis, myopathy)
  - ☐ Mucocutaneous (such as rash, photosensitivity, alopecia)
  - ☐ Lupus nephritis (Class [#]) if biopsy-proven
  - ☐ Hematologic abnormalities (such as anemia, leukopenia, thrombocytopenia)
  - ☐ CNS
  - ☐ Other: [specify]
- ☐ **Inadequate response, intolerance, or contraindication to the following standard therapies:**
  - ☐ Hydroxychloroquine – [duration, response]
  - ☐ Corticosteroids – [dose, duration, adverse effects]
  - ☐ Immunosuppressants:
    - ☐ Azathioprine – [outcome]
    - ☐ Mycophenolate mofetil – [outcome]
    - ☐ Methotrexate – [outcome]
    - ☐ Cyclophosphamide – [outcome]
    - ☐ Other: [specify]

## PAYER STEP THERAPY REQUIREMENT THROUGH OTHER BIOLOGIC (If Applicable)

Your policy requires trial or failure of [recommended biologic therapy] prior to approval. Based on the patient's clinical profile, the alternative therapy is not clinically appropriate due to:
[If appropriate, consider documenting the following:

- ☐ Inadequate response to payer-mandated biologic therapy
- ☐ Intolerance or adverse effects
- ☐ Contraindications or elevated clinical risk
- ☐ Patient-specific factors that limit appropriateness of the payer mandated biologic therapy]

## REQUESTED THERAPY & RATIONALE

**Requested Medication:**

[Biologic Name] – [Dose/Strength]

Administration: [IV/SC, frequency]

**Clinical Rationale**

[Consider providing a clear justification for the medical necessity of SAPHNELO for this patient. Describe the proposed SAPHNELO treatment plan, including dosage, administration frequency, and the anticipated clinical benefits for the patient. For example:

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
- Functional/QoL impairment
- Recent disease progression (flares, hospitalizations, worsening symptoms)
- Assessment of functional limitations affecting daily functioning (eg, fatigue, joint pain, cognitive symptoms)
- Relevant comorbid conditions influencing disease management (eg, renal impairment, metabolic, cardiovascular, infections, osteoporosis, psychiatric conditions)

Given this patient's ongoing disease activity, prior treatment failures, and risk or organ damage, initiation of SAPHNELO is medically necessary and appropriate. Denial of this therapy would significantly compromise the patient's health outcomes.

## SUMMARY

Enclosed are all relevant records and documentation supporting the medical necessity of SAPHNELO for this patient. I respectfully request prompt review and approval. Should additional information be required, please contact me at [Physician Phone Number].

Thank you for your timely consideration of this request.

Sincerely,

[Physician's Name]
[Physician's Practice Name]

**References**
[Include SAPHNELO PI]
[Include Indication and Important Safety Information]
[Include other relevant references and publications regarding SAPHNELO]
[Clinical/ progress notes, lab results, imaging, disease score documentation]
[List of medications provided including, dosages, dates used, and if samples were given]

## 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 (include lab results and dates)**

**☐ 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 biologics (include reasons for failure/intolerance)**

**☐ 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, worsening symptoms, hospitalizations, ER visits)

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

- ☐ Musculoskeletal (such as arthritis, arthralgia, osteonecrosis, myopathy)
- ☐ Mucocutaneous (such as rash, photosensitivity, alopecia)
- ☐ Renal (such as proteinuria)
- ☐ 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).**

**☐ Contraindications, hypersensitivities, precautions, adherence issues, 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