

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Saphnelo[®] (anifrolumab)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosage: SUBQ: 120 mg once weekly

Quantity Limit: 4 injections (3.2 mL) per 28 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ☐ Prescribed by or in consultation with a rheumatologist or nephrologist
- ☐ Member is 18 years of age or older
- ☐ Member has a diagnosis of autoantibody-positive SLE confirmed by **ONE** of the following (**submit lab results for documentation**):
 - ☐ anti-nuclear antibody (ANA) titer $\geq$ 1:80
 - ☐ anti-double stranded DNA (anti-dsDNA) $\geq$ 30 IU/mL
 - ☐ anti-Smith (anti-SM) antibody levels elevated according to reference range

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- ☐ Member has active moderate to severe SLE activity as confirmed by **ONE** of the following (**submit results for documentation**):
- ☐ Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of ≥ 6
 - ☐ British Isles Lupus Assessment Group (BILAG) 2004 organ domain score of $\geq 1A$ or $\geq 2B$
- ☐ Member has tried **THREE** of the following (**verified by chart notes or pharmacy paid claims; check all that apply**):

☐ mycophenolate	☐ hydroxychloroquine	☐ azathioprine
☐ cyclophosphamide	☐ methotrexate	☐ cyclosporine
☐ corticosteroids	☐ Other: _____	

- ☐ Member is currently established on at least **ONE** of the following therapies taken for the last 90 days and will continue on current therapy if approved for Saphnelo™ (**verified by chart notes or pharmacy paid claims; check all that apply**):

☐ mycophenolate	☐ hydroxychloroquine	☐ azathioprine
☐ cyclophosphamide	☐ methotrexate	☐ cyclosporine
☐ corticosteroids	☐ Other: _____	

- ☐ Saphnelo™ will **NOT** be approved for members with any of the following:
- Severe active central nervous system lupus
 - Severe active lupus nephritis
 - Concurrent use with cyclophosphamide, voclosporin or other biologic therapies, including belimumab (Benlysta)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ☐ Member has experienced a positive clinical response to Saphnelo™ therapy as confirmed by **ONE** of the following (**submit results for documentation**):
- ☐ Reduction of all baseline BILAG A to B/C/D and baseline BILAG B to C/D, and no BILAG worsening in other organ systems, as defined by ≥ 1 new BILAG A or ≥ 2 new BILAG B
 - ☐ No worsening from baseline in SLEDAI-2K, where worsening is defined as an increase from baseline of > 0 points in SLEDAI-2K
- ☐ Member has an absence of intolerable side effects such as serious or recurrent infections, malignancy, severe hypersensitivity reactions/anaphylaxis or intolerable infusion reactions

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Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.