SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Saphnelo™ (anifrolumab) **for IV Infusion (J0491) (Medical)**

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

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: 300 mg every 4 weeks

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. **(Trials will be verified using pharmacy claims and/or submitted chart notes.)**

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❑ Diagnosis: Moderate-to-Severe Systemic Lupus Erythematosus (SLE)

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 ≥ 1:80
  - ❑ anti-double stranded DNA (anti-dsDNA) ≥ 30 IU/mL
  - ❑ anti-Smith (anti-SM) antibody levels elevated according to reference range
- ❑ 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 ≥ 1A or ≥ 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)

❑ Moderate-to-Severe Systemic Lupus Erythematosus (SLE)

Reauthorization Approval: 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.

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- ❑ 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

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy - PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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.****

***Approved by Pharmacy and Therapeutics Committee**: 11/12/2021
REVISED/UPDATED: ~~12/13/2021; 12/23/2021; 5/13/2022; 6/4/2022;~~ **6/17/2022**