# Saphnelo® (anifrolumab-fnia) (Intravenous)

Document Number: IC-P0614

**Last Review Date: 10/01/2026**
**Date of Origin: 09/01/2021**
**Dates Reviewed: 09/2021, 04/2022, 04/2023, 09/2023, 04/2024, 04/2025, 10/2026**

## I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

## II. Dosing Limits

**Max Units (per dose and over time) [HCPCS Unit]:**

- 300 billable units (300 mg) every 4 weeks

## III. Initial Approval Criteria

Prior authorization validity is provided in the following conditions:

- If the member has an FDA labeled indication, then ONE of the following:
  - The member's age is within FDA labeling for the requested indication for the requested agent; **OR**
  - There is support for using the requested agent for the member's age for the requested indication; **AND**

**Universal Criteria**

- The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist, nephrologist), or the prescriber has consulted with a specialist in the area of the member's diagnosis; **AND**
- The member does NOT have severe active lupus nephritis (LN) or severe active central nervous system (CNS) lupus; **AND**
- The member does NOT have any FDA labeled contraindications to the requested agent; **AND**

**Indication Specific Criteria**

- The member has a diagnosis of active systemic lupus erythematosus (SLE) WITHOUT active lupus nephritis (LN); **AND**
  - The member has moderate to severe SLE; **AND**
  - The member has ONE of the following:

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    - Tried and had an inadequate response, intolerance, or hypersensitivity to hydroxychloroquine; **OR**
    - An FDA labeled contraindication to hydroxychloroquine; **AND**
  - The member has ONE of the following:
    - Tried and had an inadequate response, intolerance, or hypersensitivity to ONE corticosteroid OR immunosuppressive agent (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); **OR**
    - An FDA labeled contraindication to ALL corticosteroids AND immunosuppressive agents (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); **AND**
  - The member will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide) in combination with the requested agent; **AND**
- The member will NOT be using the requested agent in combination with Lupkynis; **AND**
- ONE of the following:
  - The member will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, etc.); **OR**
  - The member will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors, etc.) and BOTH of the following:
    - The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent; **AND**
    - There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required); **AND**

- ONE of the following:
  - The member has ONE of the following:
    - Has tried and had an inadequate response to Benlysta after at least a 6-month duration of therapy; **OR**
    - Has an intolerance or hypersensitivity to Benlysta; **OR**
  - The member has an FDA labeled contraindication to Benlysta; **OR**
  - There is support that the use of Benlysta is not clinically appropriate for the member

## IV. Renewal Criteria

Prior authorization validity may be renewed based upon the following criteria:

- The member continues to meet the universal criteria and indication specific concomitant therapy requirements (not including prerequisite therapy) identified in section III; **AND**
- The member has had clinical benefit with the requested agent; **AND**



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- ONE of the following:
  - The member has ONE of the following:
    - Has tried and had an inadequate response to Benlysta after at least a 6-month duration of therapy; **OR**
    - Has an intolerance or hypersensitivity to Benlysta; **OR**
  - The member has an FDA labeled contraindication to Benlysta; **OR**
  - There is support that the use of Benlysta is not clinically appropriate for the member

## V. Dosage/Administration

| Indication | Dose |
|---|---|
| Systemic Lupus Erythematosus (SLE) | Administer 300 mg every 4 weeks as an intravenous infusion |

## VI. Billing Code/Availability Information

HCPCS Code:

- J0491 – Injection, anifrolumab-fnia 1 mg; 1 billable unit = 1 mg

NDC:

- Saphnelo 300 mg/2 mL single-dose vial for injection: 00310-3040-xx

## VII. References


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## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

| Factor | Conclusion |
|---|---|
| Indication | Yes: Consider for PA |
| Safety and efficacy | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |
| Cost of drug | Yes: Consider for PA |

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| M32.10 | Systemic lupus erythematosus organ or system involvement unspecified |
| M32.11 | Endocarditis in systemic lupus erythematosus |
| M32.12 | Pericarditis in systemic lupus erythematosus |
| M32.13 | Lung involvement in systemic lupus erythematosus |
| M32.14 | Glomerular disease in systemic lupus erythematosus |
| M32.15 | Tubulo-interstitial nephropathy in systemic lupus erythematosus |
| M32.19 | Other organ or system involvement in systemic lupus erythematosus |
| M32.8 | Other forms of systemic lupus erythematosus |
| M32.9 | Systemic lupus erythematosus, unspecified |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter



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15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | Wellpoint Federal |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | Wellpoint Federal |
| 15 | KY, OH | CGS Administrators, LLC |



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