Saphnelo® (anifrolumab-fnia) (Intravenous)

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I. Length of Authorization

Coverage will be provided for 12 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Saphnelo 300 mg/2 mL (150 mg/mL) in a single-dose vial: 1 vial every 4 weeks

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

- 300 billable units (300 mg) every 4 weeks

III. Initial Approval Criteria [1]

- Patient is at least 18 years of age; **AND**
- Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria [1]

- Patient must not have a clinically significant active infection; **AND**
- Patient will not receive a live or live-attenuated vaccine concurrently with treatment; **AND**
- Will not be used in combination with other biologic therapies, including B-cell targeted therapies (e.g., belimumab), cyclophosphamide, or voclosporin; **AND**
- Will be used in combination with standard therapy (e.g., anti-malarials, corticosteroids, non-steroidal anti-inflammatory drugs, immunosuppressives); **AND**
- Patient does not have any of the following exclusion criteria:
  - Severe active central nervous system lupus
  - Severe active lupus nephritis; **AND**

Systemic Lupus Erythematosus (SLE) † [1,7,9,10,12,14,16-18]

- Patient has a confirmed diagnosis of SLE as evidenced by all of the following:
  - Confirmed SLE classification criteria score ≥ 10* (*Note: must include clinical and immunologic domains criteria)*
  - Anti-nuclear antibody (ANA) titer of ≥ 1:80 measured via indirect immunofluorescence (IIF) on human epithelial (HEp-2) cells (or an equivalent ANA positive test) at least once; **AND**
- Patient has failed to respond adequately to at least one (1) standard therapy such as anti-malarials, corticosteroids, or immunosuppressives; **AND**
- Patient has moderate to severe disease defined as a Physician's Global Assessment (PGA) score of > 1 **AND** one of the following:
  - Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K) score of ≥ 6
  - Disease activity with ≥ 2 systems with British Isles Lupus Assessment Group-2004 (BILAG) B scores
  - ≥ 1 system(s) with British Isles Lupus Assessment Group-2004 (BILAG) A score(s)

*Classification Criteria for Systemic Lupus Erythematosus (SLE) [14]	
Clinical Score Δ (range: 0-39)	**Clinical Domains and Criteria**
2	**Constitutional:** Unexplained fever > 101°F
	Hematologic:
3	White blood cell count < 4,000/mm3
4	Platelet count < 100,000/mm3 or Autoimmune hemolysis
	Neuropsychiatric:
2	Delirium
3	Psychosis
5	Primary generalized seizure or partial/focal seizure
	Mucocutaneous+:
2	Non-scarring alopecia or oral ulcers
4	Subacute cutaneous or discoid lupus
8	Acute cutaneous lupus
	Serosal:
5	Pleural or pericardial effusion
6	Acute pericarditis
	Musculoskeletal:
6	Joint involvement with either synovitis involving 2 or more joints with swelling or effusion OR tenderness in 2 or more joints with at least 30 minutes of morning stiffness
	Renal:
4	Proteinuria > 0.5g/24 hr by a 24-hour urine or equivalent spot urine protein-to-creatinine ratio
8	Renal biopsy class II or V lupus nephritis
10	Renal biopsy Class III or IV lupus nephritis
Immunologic Score Δ (range: 0-12)	**Immunologic Domains and Criteria**

2	**Presence of antiphospholipid antibodies** (i.e., positive lupus anticoagulant, positive anti-ß2GP1 antibodies, and/or anti-cardiolipin antibodies at medium or high titer)
3 4	**Presence of low complement proteins** (below lower limit of normal): Low C3 OR low C4 Low C3 AND C4
6	**Presence of anti-Sm and/or anti-dsDNA antibodies**
* A web-based scoring calculator as well as further definitions of each criterion are available at: https://rheumatology.org/criteria ᐞ Occurrence on at least one occasion is sufficient to count toward score when all other causes have been ruled out. Count only the highest weighted score within each of the 10 domains (7 clinical and 3 immunologic) and any additional criteria within the same domain will not count. + Observed by a physician via clinical exam or photograph review	

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,7]

Coverage can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious infections, malignancy, severe hypersensitivity reactions/anaphylaxis, etc.; **AND**
- Adequate documentation of disease stability and/or improvement as indicated by one or more of the following when compared to pre-treatment baseline:
  - Improvement in the SELENA-SLEDAI-2K; **OR**
  - Reduction of baseline BILAG-2004 from A to B or from B to C/D, and no BILAG-2004 worsening in other organ systems, as defined by ≥2 new BILAG-2004 B; **OR**
  - No worsening (<0.30 points increase) in Physician's Global Assessment (PGA) score; **OR**
  - Seroconverted (negative)

V. Dosage/Administration [1]

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 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)

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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	National Government Services, Inc. (NGS)
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC