Saphnelo® (anifrolumab-fnia) (Intravenous)

Document Number: IH-0614

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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 must have tried and failed to have an adequate response to or had an intolerance to Benlysta (belimumab); **AND**

- 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]

- Patient has a confirmed diagnosis of SLE with at least 4 diagnostic features (see list of diagnostic SLE criteria below)* one of which must include a positive autoantibody test (e.g., anti-nuclear antibody [ANA] greater than laboratory reference range and/or anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA); **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 as evidenced by BOTH of the following:
  - Physician's Global Assessment [PGA] score of ≥ 1; **AND**
  - Systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI 2K) score of ≥ 6 **OR** British Isles Lupus Assessment Group-2004 (BILAG) B organ domain score of ≥ 2

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

***Systemic Lupus Erythematosus Diagnostic Criteria [9,10]**

Patient must have at least 4 out of 11 diagnostic SLE features:

1. Malar rash
2. Discoid rash
3. Photosensitivity
4. Oral ulcers
5. Nonerosive arthritis (involving 2 or more peripheral joints)
6. Pleuritis/pericarditis
   - Pleuritis - history of pleuritic pain or rubbing heard by a physician or evidence of pleural effusion
   - Pericarditis - documented by electrocardiogram or rubbing heard by a physician or evidence of pericardial effusion
7. Renal disorder
   - Persistent proteinuria > 0.5 grams/day or > 3+ on urine dipstick
   - Cellular casts (red cell, hemoglobin, granular, tubular, or mixed)
8. Seizures/psychosis
9. Hematologic disorder
   - Hemolytic anemia with reticulocytosis
   - Leukopenia < 4,000/mm^3 on ≥ 2 occasions
   - Lymphopenia < 1,500/mm^3 on ≥ 2 occasions
   - Thrombocytopenia < 100,000/mm^3 in the absence of offending drugs
10. Immunologic disorder
    - Presence of anti-Sm or antiphospholipid antibodies
    - Presence of anti-double-stranded DNA [anti-dsDNA] greater than 2 fold the laboratory reference range if tested by ELISA
11. Positive anti-nuclear antibody [ANA] greater than laboratory reference range

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:
  - No worsening in the SLEDAI-2K score where worsening is defined as >0 point increase; **OR**
  - Reduction of baseline BILAG-2004 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-point 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

1. Saphnelo [package insert]. Wilmington, DE; AstraZeneca Pharm.; September 2022. Accessed March 2023.
2. Hannon CW, McCourt C, Lima HC, et al. Interventions for cutaneous disease in systemic lupus erythematosus. Cochrane Database Syst Rev. 2021 Mar 9;3:CD007478. doi: 10.1002/14651858.CD007478.pub2.
3. Furie R, Morand EF, Askanase AD, et al. Anifrolumab reduces flare rates in patients with moderate to severe systemic lupus erythematosus. Lupus. 2021 Jul;30(8):1254-1263. doi: 10.1177/09612033211014267. Epub 2021 May 12.
4. Morand EF, Furie R, Tanaka Y, et al; TULIP-2 Trial Investigators. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. N Engl J Med. 2020 Jan 16;382(3):211-221. doi: 10.1056/NEJMoa1912196. Epub 2019 Dec 18.

5. Petri M, Orbai AM, Alarcón GS, et al. Derivation and validation of the Systemic Lupus International Collaborating Clinics classification criteria for systemic lupus erythematosus. Arthritis Rheum. 2012 Aug;64(8):2677-86. doi: 10.1002/art.34473.
6. Calvo-Alén J1, Silva-Fernández L, Úcar-Angulo E, et al. SER consensus statement on the use of biologic therapy for systemic lupus erythematosus. Reumatol Clin. 2013 Sep-Oct;9(5):281-96.
7. Gordon C, Amissah-Arthur MB, Gayed M, et al. The British Society for Rheumatology guideline for the management of systemic lupus erythematosus in adults. Rheumatology (Oxford). 2018 Jan 1;57(1):e1-e45. doi: 10.1093/rheumatology/kex286.
8. NICE. Belimumab for treating active autoantibody-positive systemic lupus erythematosus: Technology Appraisal Guidance [TAG397]. https://www.nice.org.uk/guidance/ta397. Published: 22 June 2016. Accessed March 2021.
9. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus in adults. Arthritis Rheum. 1999;42(9):1785–1796.
10. Lam NC, Ghetu MV, Bieniek ML. Systemic Lupus Erythematosus: Primary Care Approach to Diagnosis and Management. Am Fam Physician. 2016 Aug 15;94(4):284-94.
11. NICE. Belimumab for treating active autoantibody-positive systemic lupus erythematosus: Technology appraisal guidance [TA752]. https://www.nice.org.uk/guidance/ta752. Published: 15 December 2021. Accessed March 2023.
12. Fanouriakis A, Kostopoulou M, Alunno A, et al. 2019 update of the EULAR recommendations for the management of systemic lupus erythematosus. Ann Rheum Dis 2019;78: 736–745.

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