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

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

- 300 billable units (300 mg) every 4 weeks

III. Initial Approval Criteria

- Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to Benlysta (belimumab) prior to initiating therapy with Saphnelo (anifrolumab-fnia); **AND**

Target Agent(s) will be approved when ALL of the following are met:

- ONE of the following:

  The requested agent is eligible for continuation of therapy AND ONE of the following:

Agent(s) Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

  - The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days; **OR**
  - The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed; **OR**

  – BOTH of the following:

  - ONE of the following:

- The patient has a diagnosis of active systemic lupus erythematosus (SLE) WITHOUT active lupus nephritis (LN) AND ALL of the following:
  - The requested agent is FDA labeled or compendia** supported for SLE; **AND**
  - BOTH of the following:
    - The patient has moderate to severe SLE; **AND**
    - ONE of the following:
      - The patient 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 patient has an FDA labeled contraindication to Benlysta; **OR**
      - There is support that the use of Benlysta is not clinically appropriate for the patient; **AND**
  - BOTH of the following:
    - ONE of the following:
      - The patient has ONE of the following:
        - Has tried and had an inadequate response to hydroxychloroquine; **OR**
        - Has an intolerance or hypersensitivity to hydroxychloroquine; **OR**
      - The patient has an FDA labeled contraindication to hydroxychloroquine; **AND**
    - ONE of the following:
      - The patient has ONE of the following:
        - Has tried and had an inadequate response to ONE corticosteroid OR immunosuppressive agent (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); **OR**
        - Has an intolerance or hypersensitivity to ONE corticosteroid OR immunosuppressive agent (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); **OR**
      - The patient has an FDA labeled contraindication to ALL corticosteroids AND immunosuppressive agents (i.e., azathioprine, methotrexate, mycophenolate, cyclophosphamide); **OR**
- The patient has another FDA labeled indication for the requested agent and route of administration; **AND**

o If the patient has an FDA labeled indication, then ONE of the following:

        - The patient'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 patient's age for the requested indication; **OR**
    - The patient has another indication that is supported in compendia** for the requested agent and route of administration; **AND**
- If the patient has a diagnosis of active systemic lupus erythematosus (SLE) WITHOUT active LN, then BOTH of the following:
    - The patient is currently treated with standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide); **AND**
    - The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide) in combination with the requested agent; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient does NOT have severe active central nervous system (CNS) lupus; **AND**
- BOTH of the following:
    - The patient does NOT have severe active LN; **AND**
    - The patient will NOT be using the requested agent in combination with Lupkynis; **AND**
- ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table§):
    - The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**
    - The patient will be using the requested agent in combination with another immunomodulatory agent 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**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing (or supported in compendia**) for the requested indication

***Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence*

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

- The patient has been previously approved for the requested agent through the plan's Medical Drug Review process [Note: patients not previously approved for the requested agent will require initial evaluation review]; **AND**
- The patient has had clinical benefit with the requested agent; **AND**
- ONE of the following:

  The patient has a diagnosis of active systemic lupus erythematosus (SLE) WITHOUT active lupus nephritis (LN) AND BOTH of the following:

  The patient is currently treated with standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide); **AND**

  The patient will continue standard SLE therapy (i.e., corticosteroids, hydroxychloroquine, azathioprine, methotrexate, mycophenolate, cyclophosphamide) in combination with the requested agent; **OR**

  The patient has a diagnosis other than active SLE OR active LN; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist, nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient does NOT have severe active central nervous system (CNS) lupus; **AND**
- BOTH of the following:

  The patient does NOT have severe active LN; **AND**

  The patient will NOT be using the requested agent in combination with Lupkynis; **AND**
- ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table**§**):

  The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors); **OR**

  The patient will be using the requested agent in combination with another immunomodulatory agent 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**
- The patient does NOT have any FDA labeled contraindications to the requested agent; **AND**
- The requested quantity (dose) is within FDA labeled dosing (or supported in compendia******) for the requested indication

***Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence*

§Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Leqselvi (deuruxolitinib) Litfulo (ritlecitinib) Nemluvio (nemolizumab-ilto) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Otulfi (ustekinumab-aauz) Pyzchiva (ustekinumab-ttwe) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab)

§Contraindicated as Concomitant Therapy
Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Saphnelo (anifrolumab-fnia) Selarsdi (ustekinumab-aekn) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) subcutaneous injection Stelara (ustekinumab) Steqeyma (ustekinumab-stba) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Ustekinumab Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yesintek (ustekinumab-kfce) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

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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9. 2024 American College of Rheumatology (ACR) Guideline for the Screening, Treatment, and Management of Lupus Nephritis: Guideline Summary. American College of Rheumatology. Published online November 18, 2024. https://rheumatology.org/lupus-guideline

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 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	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
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	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC