Medical Policy

Saphnelo™ (anifrolumab-fnia)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_091
CURRENT VERSION EFFECTIVE DATE	1/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Saphnelo™ (anifrolumab-fnia) therapy.

POLICY

Prior Authorization and Medical Review is required.

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

A. Patient has a documented diagnosis of moderate to severe systemic lupus erythematosus (SLE); **AND**
B. Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; **AND**
C. Patient is currently receiving **at least one** standard of care treatment for active systemic lupus erythematosus (e.g., corticosteroids, or immunosuppressants); **AND**

D. Patient will not be using Saphnelo in combination with a biologic agent or Benlysta.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Patients with severe active lupus nephritis or severe active central nervous system lupus

BACKGROUND

Saphnelo is a human IgG1κ monoclonal antibody that binds to subunit 1 of the type I interferon receptor (IFNAR) with high specificity and affinity. This binding inhibits type I IFN signaling, thereby blocking the biologic activity of type I IFNs. Saphnelo also induces the internalization of IFNAR1, thereby reducing the levels of cell surface IFNAR1 available for receptor assembly. Blockade of receptor mediated type I IFN signaling inhibits IFN responsive gene expression as well as downstream inflammatory and immunological processes. Inhibition of type I IFN blocks plasma cell differentiation and normalizes peripheral T-cell subsets. Type I IFNs play a role in the pathogenesis of SLE. Approximately 60-80% of adult patients with active SLE express elevated levels of type I IFN inducible genes.

DEFINITIONS

1. SAPHNELO (anifrolumab-fnia) injection, for intravenous use. Initial U.S. Approval: 2021
    a. SAPHNELO (anifrolumab-fnia) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution for intravenous infusion. It is packaged in a 2 mL clear glass vial containing 300 mg/2 mL (150 mg/mL) of anifrolumab-fnia.

CODING

Applicable NDC Codes	
00310-3040-00	SAPHNELO, anifrolumab-fnia 150 mg/1 ml, 2 ml

Applicable Procedure Code	
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

Applicable ICD-10 Codes	
J0491	Injection, anifrolumab-fnia, 1 mg

EVIDENCE BASED REFERENCES

1. Product Information: SAPHNELO(TM) intravenous injection, anifrolumab-fnia intravenous injection. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2021.

POLICY HISTORY

Original Effective Date	11/1/2021
Revised Date	July, 2022 – Added J code J0491: Injection, anifrolumab-fnia, 1 mg Effective 4/1/2022 March 1, 2023 - Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	November 1, 2021 July 26, 2022