Saphnelo (anifrolumab-fnia)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

Saphnelo (anifrolumab-fnia) is a human IgG1k monoclonal antibody that binds to subunit 1 of the type 1 interferon receptor (IFNAR1) and blocks type 1 interferon signaling, resulting in inhibition of interferon responsive gene expression and downstream inflammatory and immunological process, including plasma cell differentiation and normalization of T-cell subsets.

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Saphnelo is indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

Limitations of Use
The efficacy of Saphnelo has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. The use of Saphnelo is not recommended in those situations.

POLICY

Required Documentation
Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests: Medical records (e.g., chart notes, lab reports) documenting the presence of autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins).
B. Continuation requests: Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

A. Severe active lupus nephritis in a member initiating therapy with Saphnelo.
B. Severe active central nervous system (CNS) lupus (including seizures that are attributed to CNS lupus, psychosis, organic brain syndrome, cerebrovascular accident, cerebritis, or CNS vasculitis requiring therapeutic intervention within 60 days before initiation of anifrolumab) in a member initiating therapy with Saphnelo.
C. Member is using Saphnelo in combination with other biologics.

Criteria for Initial Approval

A. Systemic lupus erythematosus (SLE)
   Authorization of 12 months may be granted for treatment of active SLE when all of the following criteria are met:
   1. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm, antiphospholipid antibodies, complement proteins)
   2. The member is receiving a stable standard treatment for SLE with any of the following (alone or in combination):
      i. Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone)
      ii. Antimalarials (e.g., hydroxychloroquine)
      iii. Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate, cyclosporine, cyclophosphamide)

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of systemic lupus erythematous who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

1 vial (300 mg) per 28 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- C9086 – Injection, anifrolumab-fnia, 1 mg (cancelled 4/1/2022)
- J0491 – Injection, anifrolumab-fnia, 1 mg (effective 4/1/2022)

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POLICY HISTORY

Policy #: 05.04.43
Original Effective Date: November 16, 2021
Reviewed: June 2022
Revised: June 2022
Current Effective Date: June 27, 2022