

# STANDARD MEDICARE PART B MANAGEMENT

## SAPHNELO (anifrolumab-fnia)

### POLICY

#### I. INDICATIONS

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. Use of Saphnelo is not recommended in these situations.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- 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).
- B. Continuation requests: Medical records (e.g., chart notes, lab reports) documenting disease stability or improvement.

#### III. 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.

#### IV. CRITERIA FOR INITIAL APPROVAL

##### Systemic lupus erythematosus (SLE)

Authorization of 12 months may be granted for treatment of active SLE when all of the following criteria are met:

- A. Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm)
- B. The member meets either of the following criteria:
  - 1. 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)
  - 2. The member has a clinical reason to avoid treatment with a standard treatment regimen.

#### V. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Saphnelo
- B. Saphnelo is being used to treat an indication enumerated in Section IV
- C. The member is receiving benefit from therapy. Benefit is defined as disease stability or improvement.

#### VI. REFERENCES

1. Saphnelo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.
2. 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.
3. Aringer M, Costenbader K, Daikh D, et al. 2019 European League Against Rheumatism/American College of Rheumatology classification criteria for systemic lupus erythematosus. *Ann Rheum Dis*. 2019;78:1151-1159.