MEDICAL REVIEW GUIDELINE

Saphnelo Criteria for Coverage

COMMUNITY HEALTH CHOICE

Saphnelo® (anifrolumab-fnia)

Effective Date: 10/1/2024

Medical Care Management Committee Approval: 8/15/2024

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Saphnelo® (anifrolumab-fnia) product:

HCPCS Code	Description
J0491	Injection, anifrolumab-fnia, 1 mg

Coverage Criteria

Saphnelo® (anifrolumab-fnia) will be considered medically necessary for members meeting ALL of the following criteria:

1. Member is ≥18 years of age; AND
2. Diagnosis of systemic lupus erythematous (SLE) confirmed by a specialist; AND
3. Member has moderate to severe, active disease; AND
4. Member is on a stable standard therapy regimen which includes hydroxychloroquine with or without systemic corticosteroid (e.g., prednisone) or immunosuppressant (e.g., azathioprine, methotrexate, mycophenolate mofetil) and will continue using concomitantly with Saphnelo®, unless documented contraindication to all; AND
5. Saphnelo® is prescribed by or in consultation with a rheumatologist, nephrologist, or dermatologist; AND
6. History of inadequate response, adverse event or contraindication to preferred product Benlysta®

(belimumab) (may require prior authorization); AND
7. Saphnelo® will not be used in combination with other biologics (e.g., Benlysta®); AND
8. Member does not have severe active lupus nephritis or severe active central nervous system lupus.

Criteria for Continuation of Coverage

1. Saphnelo® is and will continue to be used in combination with at least one standard therapy (systemic corticosteroid, antimalarial, or immunosuppressant) unless contraindicated; AND
2. Documentation of beneficial response to Saphnelo®; AND
3. Medication is prescribed by or in consultation with a rheumatologist, nephrologist, or dermatologist

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J0491	Injection, anifrolumab-fnia, 1 mg

Diagnosis Code	Description
M32.0	Drug-induced systemic lupus erythematosus
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

Policy Revision History

Status	Effective Date	Description
Baseline	10/1/24	Initial version of Saphnelo (anifrolumab-fnia) Review Guideline