Saphnelo™ (anifrolumab-fnia)

Humana

Pharmacy Coverage Policy

Effective Date: December 15, 2021
Revision Date: November 22, 2023
Review Date: November 15, 2023
Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Saphnelo intravenous solution

Listed Indications

Systemic Lupus Erythematosus (SLE)

Systemic Lupus Erythematosus (SLE)

Does the member meet all of the following criteria?	
Criteria #1	Has a diagnosis of moderate to severe systemic lupus erythematosus
Criteria #2	Prior to initiating therapy, the member is positive for autoantibodies relevant to SLE (e.g., ANA, anti-ds DNA, anti-Sm)
Criteria #3	Will be using in combination with standard treatment regimens (e.g. combination of prednisone, hydroxychloroquine, and/or azathioprine)
Criteria #4	Does not have severe active lupus nephritis or severe active nervous system lupus
Criteria #5	Prescribed by or in consultation with a provider who has expertise in treating systemic lupus erythematosus
For continuation of therapy requests, does the member meet all of the following renewal criteria?	
Renewal Criteria #1	Member meets the initial treatment criteria
Renewal Criteria #2	Has demonstrated a response to Saphnelo (e.g. achieved low disease activity or improvement in signs and symptoms of the condition)
Approval Duration	
Initial	Saphnelo (anifrolumab-fnia) will be approved in plan year durations or as determined through clinical review.

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Background

This is a prior authorization policy about Saphnelo (anifrolumab-fnia).

- Systemic lupus erythematosus (SLE) is a complex, chronic, potentially life-threatening, autoimmune disease that is characterized by immunologic abnormalities resulting in systemic inflammation affecting multiple organs such as the skin, joints, kidney, lungs and central nervous system.
- SLE is difficult to diagnose because the symptoms are often mistaken for those of other diseases. The 2019 European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR) include classification criteria for SLE which requires the presence of a positive antinuclear antibodies (ANA) as an entry criterion. Additive criteria consist of seven clinical (ie, constitutional, hematologic, neuropsychiatric, mucocutaneous, serosal, musculoskeletal, renal) and three immunologic (ie, antiphospholipid antibodies, complement proteins, SLE-specific antibodies) domains, each of which are weighted from 2 to 10. Patients accumulating 10 or more points are classified as having SLE.
- Warnings and Precautions:
  - Serious infections: serious and sometimes fatal infections have occurred in patients receiving Saphnelo. Saphnelo increases the risk of respiratory infections and herpes zoster. Avoid initiating treatment during an active infection. Consider benefit-risk if using in patients with severe or chronic infections. Consider interrupting therapy if patients develop a new infection.
  - Malignancy: consider the individual benefit-risk in patients with known risk factors for malignancy prior to prescribing Saphnelo.
  - Immunization: avoid use of live or live-attenuated vaccines in patients receiving Saphnelo.

- Not recommended for use with other biologic therapies.

- For complete list of warnings, precautions and monitoring recommendations, see the product label.

Saphnelo (anifrolumab-fnia) is a type I interferon receptor antagonist.

Anifrolumab-fnia is a human monoclonal antibody that binds to subunit 1 of the type I interferon receptor with high specificity and affinity. This binding inhibits type I IFN signaling, thereby blocking the biologic activity of type I IFNs and inhibiting downstream inflammatory and immunological processes.

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

Saphnelo (anifrolumab-fnia) s available as 300 mg/2mL single dose vials.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Saphnelo; anifrolumab-fnia; systemic lupus erythematosus; intravenous; pharmacy

References

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