Saphnelo® (anifrolumab-fnia)
Intravenous Use 300 mg/vial
Subcutaneous Use 120 mg/0.8 mL

AstraZeneca Access 360™

Prior Authorization (PA) Considerations for SAPHNELO

Although coverage criteria for SAPHNELO differs across insurance payers, providing accurate and complete clinical documentation with current labs in support of the provider's treatment decision is key to timely review of PA requests and appeals.

Pharmacy and medical insurance payers may require submission of clinical documentation when requesting a Prior Authorization.

For more information, call Access 360 at **1-833-360-4357**, Monday through Friday, 8 AM to 6 PM ET.

1-833-360-HELP (1-833-360-4357)

www.MyAccess360.com

1-833-FAX-A360 (1-833-329-2360)

Access360@AstraZeneca.com

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 (CNS) lupus. Use is not recommended in these situations.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

Known history of anaphylaxis with SAPHNELO.

WARNINGS AND PRECAUTIONS

- **Serious Infections:** Serious and sometimes fatal infections have occurred in patients receiving immunosuppressive agents, including SAPHNELO. SAPHNELO increases the risk of respiratory infections and herpes zoster. Use caution in patients with severe or chronic infections. Avoid initiating treatment during an active infection and consider interrupting therapy in patients who develop a new infection during treatment

Please see additional Important Safety Information throughout and full Prescribing Information, including Patient Information.

Diagnosis

1. Was SAPHNELO prescribed in accordance with the FDA-approved labeling?

- ☐ Please refer to the **SAPHNELO Prescribing Information**
- ☐ Is the patient 18 years of age or older?
- ☐ Does the patient have a diagnosis of moderate or severe systemic lupus erythematous (SLE) and is receiving standard therapy?

2. Does the payer require submission of test results such as anti-nuclear antibody (ANA) titer or anti-double stranded DNA (anti-dsDNA)?

- ☐ Payers may require documentation of a positive autoantibody test; anti-Smith (anti-Sm) antibodies; antiphospholipid antibodies; complement proteins

Click **here** to download the SAPHNELO Access and Reimbursement Guide or visit **www.MyAccess360.com**.

Visit the SAPHNELO Policy Acumen Portal to access Payer billing, coding, and coverage policy resources. **https://saphnelo.policyacumen.health/**

Disease History

3. Does the payer require documentation of active disease?

- ☐ Some payers may require documentation of active disease evidenced by one or more of the following:
  - — SLEDAI-2K score ≥6 while on current SLE treatment
  - — Physician Global Assessment (PGA) score of ≥1
  - — Documentation of moderate to severe disease as evidenced by British Isles Lupus Assessment Group-2004 (BILAG-2004)

4. Does the patient have severe active central nervous system (CNS) lupus or severe active lupus nephritis?

- ☐ The efficacy of SAPHNELO has not been evaluated in patients with severe active lupus nephritis or severe active CNS lupus. Use of SAPHNELO is not recommended in these situations

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

- **Hypersensitivity Reaction Including Anaphylaxis:** Serious hypersensitivity reactions (including anaphylaxis) have been reported following SAPHNELO administration. Events of angioedema have also been reported. Other hypersensitivity reactions and infusion-related reactions have occurred following administration of SAPHNELO. SAPHNELO should be administered by healthcare providers prepared to manage hypersensitivity reactions, including anaphylaxis and infusion-related reactions, if they occur. Immediately interrupt administration and initiate appropriate therapy if a serious infusion-related or hypersensitivity reaction (eg, anaphylaxis) occurs

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Treatment Factors

5. Does the payer require submission of patient's current SLE treatment?

- ☐ Payers may require documentation of at least one standard-of-care treatment for systemic lupus erythematosus, including:
  - — Glucocorticoids (e.g., prednisone, methylprednisolone, dexamethasone), or
  - — Antimalarials (e.g., hydroxychloroquine), or
  - — Immunosuppressants (e.g., azathioprine, methotrexate, mycophenolate)

6. Does the payer require documentation of previous SLE treatments or co-morbid conditions?

- ☐ Payers may require documentation of trial/failure to previous treatments, or
- ☐ Intolerance to standard therapy, as determined by the prescriber, or
- ☐ Documentation individual has depression or suicidality, according to the prescriber

7. Was SAPHNELO prescribed by or in consultation with a Specialist?

- ☐ Payers may require SAPHNELO coordination with a Specialist, such as Rheumatologist, Clinical Immunologist, Nephrologist, Neurologist, or Dermatologist

8. Does the patient have an acute or chronic infection?

- ☐ Payers may require the patient to be free of any clinically significant active infection
- — Avoid initiating treatment with SAPHNELO in patients with any clinically significant active infection until the infection resolves or is adequately treated

9. Will the patient receive live vaccines?

- ☐ Payers may require vaccine records
- — Update immunizations, according to current immunization guidelines, prior to initiating SAPHNELO therapy. Avoid concurrent use of live or live-attenuated vaccines in patients treated with SAPHNELO

Continuation of Treatment/Reauthorization Criteria

10. For continuation of therapy/reauthorization, payers may require the following:

- ☐ Documentation of patient previously receiving SAPHNELO
- ☐ Documentation of a positive clinical response (e.g., reduction in flares, reduction in corticosteroid dose, etc.)
- ☐ Documentation that patient is currently receiving at least one standard-of-care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic
- ☐ Confirmation SAPHNELO is prescribed and dosed per the approved US Prescribing Information

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

- **Malignancy:** There is an increased risk of malignancies with the use of immunosuppressants. The impact of SAPHNELO on the potential development of malignancies is not known
- **Immunization:** Avoid the use of live or live-attenuated vaccines in patients treated with SAPHNELO
- **Use With Biologic Therapies:** SAPHNELO is not recommended for use in combination with other biologic therapies, including B-cell targeted therapies

Please see additional Important Safety Information throughout and full Prescribing Information, including Patient Information.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

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ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5%) are nasopharyngitis, upper respiratory tract infections, bronchitis, infusion-related reactions, herpes zoster and cough.

In the controlled clinical trials, the incidence of infusion-related reactions was 9.4% in patients while on treatment with SAPHNELO and 7.1% in patients on placebo. Infusion-related reactions were mild to moderate in intensity; the most common symptoms were headache, nausea, vomiting, fatigue, and dizziness.

USE IN SPECIFIC POPULATIONS

Pregnancy: A pregnancy exposure registry monitors pregnancy outcomes in women exposed to SAPHNELO during pregnancy. For more information about the registry or to report a pregnancy while on SAPHNELO, contact AstraZeneca at 1-877-693-9268.

There are insufficient data on the use of SAPHNELO in pregnant women to establish whether there is drug-associated risk for major birth defects or miscarriage. Advise female patients to inform their healthcare provider if they intend to become pregnant during therapy, suspect they are pregnant or become pregnant while receiving SAPHNELO.

Lactation: No data are available regarding the presence of SAPHNELO in human milk, the effects on the breastfed child, or the effects on milk production.

Pediatric Use: The safety and efficacy of SAPHNELO in pediatric patients less than 18 years of age has not been established.

INDICATION

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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 is not recommended in these situations.

Please read full Prescribing Information, including Patient Information.

You may report side effects related to AstraZeneca products.

Reference: SAPHNELO [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026.

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