

SAPHNELO CODING RESOURCE

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 is not recommended in these situations.

Physician Office Coding

It is important to note that the codes identified below are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of the following codes does not guarantee reimbursement.

National Drug Code (NDC)

10-digit NDC

Dosage	Code	Description
SAPHNELO 300 mg, administered as an IV infusion over a 30-minute period, every 4 weeks	0310-3040-00	One carton containing one single-dose vial

11-digit NDC

Dosage	Code	Description
SAPHNELO 300 mg, administered as an IV infusion over a 30-minute period, every 4 weeks	00310-3040-00	One carton containing one single-dose vial

Current Procedural Terminology® (CPT)

Submitting accurate codes and claims is important to ensure proper reimbursement of services. The chart below lists the POTENTIAL CPT code for your reference when submitting claims for SAPHNELO.

Intravenous infusion	Code	Description
	96XXX	Check payer's policy to obtain appropriate administration code

Place of Service Code¹

Code	Location	Description
11	Office	Office, other than a hospital, skilled nursing facility, military treatment facility, community health center, state or local public health clinic, or intermediate care facility, where the health care professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis

Healthcare Common Procedure Coding System (HCPCS)²

Please contact the payer or AstraZeneca Access 360™ at **1-866-SAPHNELO** (1-866-727-4635) for additional coding information.

Code	Description	Vial size	Billing Units	NDC
J0491	Injection, anifrolumab-fnia, 1 mg	300 mg/2 mL single-dose vial	300 units	0310-3040-00

HCPCS modifier used to report zero drug wastage^{3,4}

Modifiers provide a means to report or indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. The modifier below may be applicable in physician offices and hospital outpatient departments.

Modifier	Description	Indication and placement
JZ	Zero drug amount discarded/not administered to any patient	<p>Modifier used to report no wastage from single-use vials</p> <ul style="list-style-type: none"> • CMS claims should include the JZ modifier when no wastage has occurred; other payer requirements may vary • Typically, the modifier is appended to the drug HCPCS code on the same line

SAPHNELO CODING RESOURCE (Cont'd)

ICD-10-CM Diagnosis Codes⁵

Code	ICD-10-CM Description
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

Hospital Outpatient Department Coding

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Place of Service Code¹

Code	Location	Description
19	Off campus: outpatient hospital	A portion of an off-campus hospital provider-based department that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
22	On campus: outpatient hospital	A portion of a hospital's main campus that provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

SAPHNELO CODING RESOURCE (Cont'd)

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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
- **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
- **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

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 5\%$) 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.

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Please read [Prescribing Information](#), including [Patient Information](#).

You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling 1-800-236-9933. If you prefer to report these to the FDA, call 1-800-FDA-1088

The AstraZeneca Access 360[™] program provides personal support to connect patients to affordability programs and streamline access and reimbursement for **SAPHNELO**[®] (anifrolumab-fnia) injection, for intravenous use.

For more information, call Access 360 at **1-866-SAPHNELO (1-866-727-4635)**, Monday through Friday, 8 AM - 6 PM ET.



1-866-SAPHNELO (1-866-727-4635)



1-866-511-2360



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Please see Important Safety Information on page 4 and **Prescribing Information**, including **Patient Information**.

References: **1.** Centers for Medicare & Medicaid Services. Place of Service Code Set. Accessed May 19, 2023. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set **2.** Centers for Medicare & Medicaid Services (CMS) healthcare. Updated March 01, 2022. Accessed May 19, 2023. <https://www.cms.gov/files/document/2021-hcpcs-application-summary-quarter-4-2021-drugs-and-biologicals.pdf>. **3.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. Accessed May 19, 2023. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update> **4.** Centers for Medicare & Medicaid Services. JW modifier: drug/biological amount discarded/not administered to any patient frequently asked questions. Accessed May 19, 2023. <https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf>. **5.** Centers for Medicare & Medicaid Services. 2021 ICD-10-CM Codes. Accessed May 19, 2023. <https://www.cms.gov/medicare/icd-10/2021-icd-10-cm>.

