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

AstraZeneca Access 360™

Access and Reimbursement Guide

The AstraZeneca Access 360™ program provides personal support to connect patients to affordability programs and streamline access and reimbursement for SAPHNELO® (anifrolumab-fnia)

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)

Access360@AstraZeneca.com

www.MyAccess360.com

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.

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

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

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)

Administration	Administration Method	Description	10-digit NDC	11-digit NDC
Physician Administered	SAPHNELO® (anifrolumab-fnia) injection, for intravenous use administered as an IV infusion	300 mg/vial	**0310-3040-00**	**00310-3040-00**
Patient/Caregiver Administered	SAPHNELO single-dose autoinjector pen-subcutaneous injection	120 mg/0.8 mL	**0310-3080-01**	**00310-3080-01**
	SAPHNELO single-dose prefilled syringe-subcutaneous injection	120 mg/0.8 mL	**0310-3080-02**	**00310-3080-02**

Current Procedural Terminology® (CPT)[1]

Physician Administered	Code	Description
Intravenous infusion	**96XXX**	Check payer's policy to obtain appropriate administration code
Patient/Caregiver Administered	**Code**	**Description**
Injection Education	**99211**	Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified healthcare professional

Healthcare Common Procedure Coding System (HCPCS)[2]

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	Modifier used to report no wastage from single-use vials • 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

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

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Place of Service Codes[5]

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
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

ICD-10-CM Diagnosis codes[6]

Code	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

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

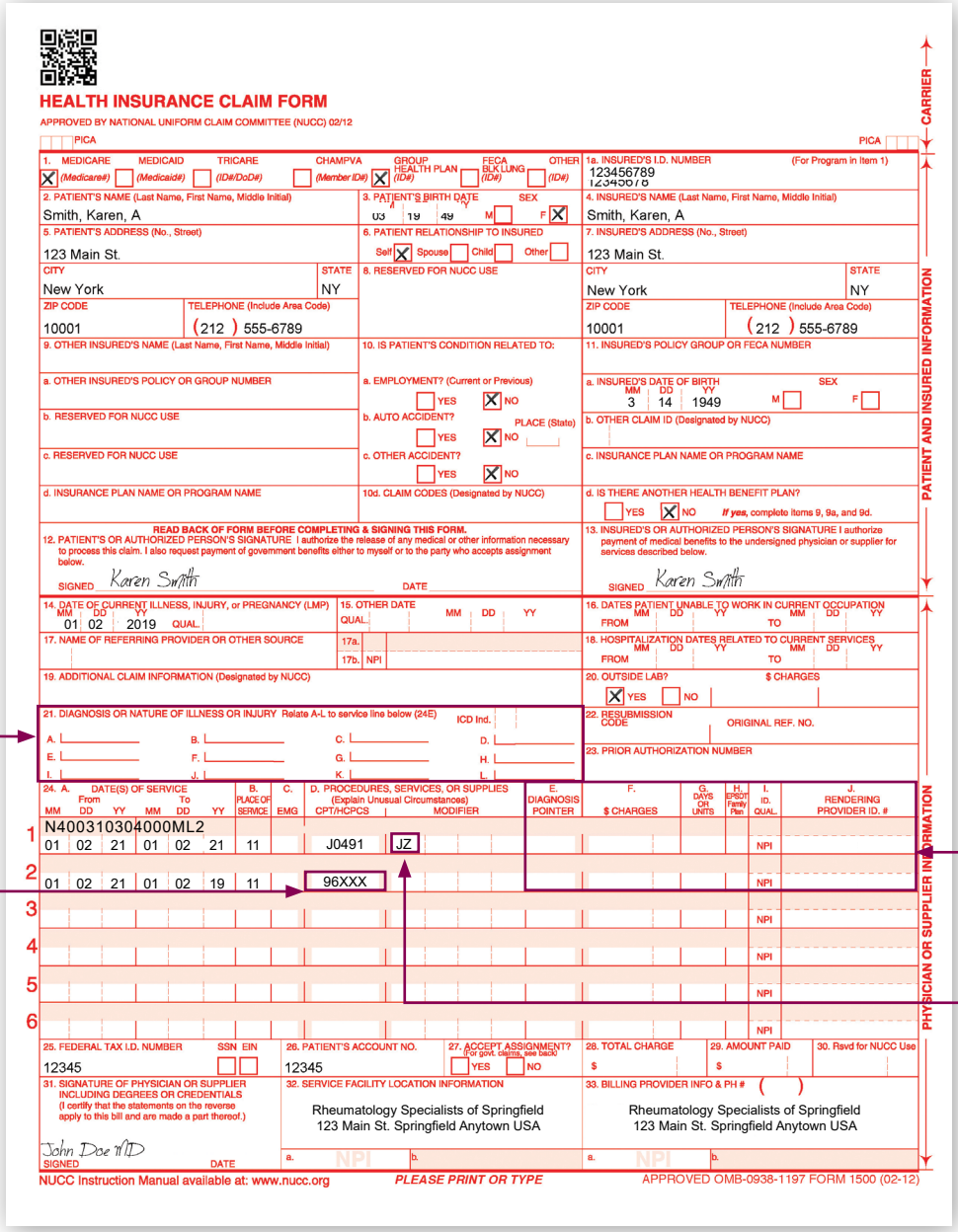
- **Immunization:** Avoid the use of live or live-attenuated vaccines in patients treated with SAPHNELO
- **Use With Biologic Therapies:** SAPHNELO is not recommended for use in combination with other biologic therapies, including B-cell targeted therapies

ADVERSE REACTIONS

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

CMS–1500 Example Claim Form

Prescribers use this form when billing insurers for medication administered in the physician's office and for their professional services.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) X | MEDICAID (Medicaid#) | TRICARE (ID#/DoD#) | CHAMPVA (Member ID#) | GROUP HEALTH PLAN (ID#) X | FECA BLK LUNG (ID#) | OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 123456789

2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Smith, Karen, A

3. PATIENT'S BIRTH DATE: 03 19 49 SEX: M | F X

4. INSURED'S NAME (Last Name, First Name, Middle Initial): Smith, Karen, A

5. PATIENT'S ADDRESS (No., Street): 123 Main St.

6. PATIENT RELATIONSHIP TO INSURED: Self X | Spouse | Child | Other

7. INSURED'S ADDRESS (No., Street): 123 Main St.

CITY: New York | STATE: NY

8. RESERVED FOR NUCC USE

CITY: New York | STATE: NY

ZIP CODE: 10001 | TELEPHONE (Include Area Code): (212) 555-6789

ZIP CODE: 10001 | TELEPHONE (Include Area Code): (212) 555-6789

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous): YES | NO X

a. INSURED'S DATE OF BIRTH: MM DD YY 3 14 1949 SEX: M | F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES | NO X PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES | NO X

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES | NO X — If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED Karen Smith DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED Karen Smith

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY: 01 02 2019 QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES X | NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N400310304000ML2											
1 01 02 21	01 02 21	11		J0491	JZ					NPI	
2 01 02 21	01 02 19	11		96XXX						NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN: 12345

26. PATIENT'S ACCOUNT NO.: 12345

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES | NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

John Doe MD SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

Rheumatology Specialists of Springfield
123 Main St. Springfield Anytown USA

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

Rheumatology Specialists of Springfield
123 Main St. Springfield Anytown USA

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Input Diagnosis Code(s) here

Check payer policy to obtain appropriate administration code and input here

Complete Sections E-J

Input JZ modifier to indicate no drug was wasted

The suggestions contained on this form are for example only, and AstraZeneca makes no representation that the information is accurate or that it will comply with the requirements of any particular payer/insurer. Providers are solely responsible for determining the billing and coding requirements applicable to any payer/insurer. The information provided here is not intended to be conclusive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. AstraZeneca makes no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use. The use of this information does not guarantee payment or that any payment received will cover your costs.

IMPORTANT SAFETY INFORMATION (cont'd)

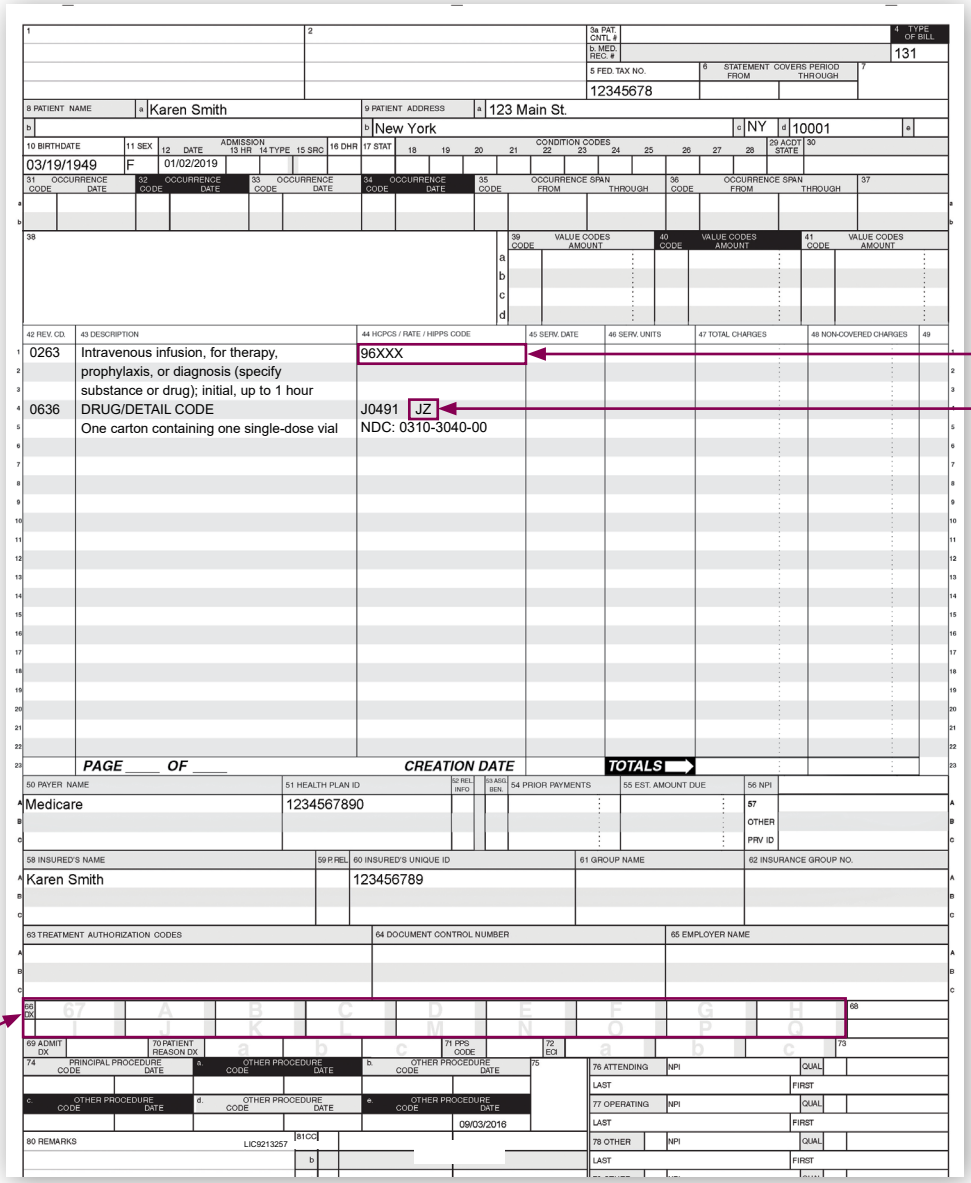
ADVERSE REACTIONS (cont'd)

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.

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

UB–04 Example Claim Form

Hospitals use this form when billing insurers for medication administered in the inpatient or outpatient setting. Outpatient hospitals should bill with the appropriate revenue code.



42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0263	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour	96XXX				
0636	DRUG/DETAIL CODE One carton containing one single-dose vial	J0491 JZ NDC: 0310-3040-00				

50 PAYER NAME	51 HEALTH PLAN ID	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
Medicare	1234567890			

58 INSURED'S NAME	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
Karen Smith	123456789		

Check payer policy to obtain appropriate administration code and input here

Input JZ modifier after HCPCS code to report no product wastage

Input Diagnosis Code(s) here

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IMPORTANT SAFETY INFORMATION (cont'd)

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.

Prior Authorization and Appeal Checklists

These checklists are intended to simplify the prior authorization (PA) and denial/appeal process for SAPHNELO® (anifrolumab-fnia) injection, for intravenous use.*

PRIOR AUTHORIZATION (PA) CHECKLIST

The items below may be necessary to obtain a PA decision from a health plan. Please ensure you have all information below prior to submitting the PA.

☐ **Completed PA request form (some health plans require specific forms)** including the following:

- ☐ Patient name, insurance policy number, and date of birth
- ☐ Physician name and NPI number
- ☐ Facility name and NPI number
- ☐ Date of service
- ☐ Patient diagnosis (ICD-10 code[s])
- ☐ Relevant procedure and HCPCS codes for services/products to be performed/provided
- ☐ Product NDC
- ☐ Setting of care

☐ **Letter of medical necessity and relevant clinical support**

- ☐ Include the Provider ID number in the letter

☐ **Documentation that supports the treatment decision, such as:**

- ☐ Previous given treatments/therapies
- ☐ Patient-specific clinical notes detailing the relevant diagnosis
- ☐ Relevant laboratory results
- ☐ Product Prescribing Information

Prior authorization requirements vary by health plan and may require pre-approval. Please contact the patient's health plan for specific PA requirements to ensure efficient and timely review. Failure to obtain prior authorization can result in non-payment by the plan.

Prior to submission, please keep track of dates and methods of correspondence (phone, email, and written); record the names of insurance contacts and reviewers with whom you speak; and summarize conversations and written documents issued by the insurer.

DENIAL AND APPEAL CHECKLIST

If the health plan denied a PA for an AstraZeneca medicine:

☐ **Review the denial notification** to understand the reason and circumstances that need to be addressed and explained in the appeal letter.

☐ **Understand the plan's most recent explanation of benefits** or contact a representative at the insurer to verify where the appeal should be sent and any deadlines.

☐ **Write an appeal letter.** If you need additional information regarding this process, please contact Access 360 for examples.

If you or your patient have not received a decision within 30 days:

☐ **Follow up with the health plan.** Confirm that the appeal letter was received and ask about its status. If the coverage denial was upheld, you could resubmit another appeal with new information or ask for a Supervisor or Manager to assist.

If the denial is upheld again:

☐ **Ask for a one-time exception or consider filing a complaint** with the state's insurance commissioner.

☐ **If the insurer continues to deny the claim:** Your patient may request an external appeal (the process varies by state law), in which an independent third party will review the claim and make a final, binding decision.

☐ Please contact your Field Reimbursement Manager (FRM) or Access 360 if you need additional support.

***Providers and patients are encouraged to contact the patient's insurer for detailed instructions on completing a PA or how to appeal/overturn a denial. If you have any questions, or need guidance, please contact AstraZeneca Access 360™ or your Field Reimbursement Manager at 1-866-SAPHNELO (1-866-727-4635).**

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS (cont'd)

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.

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

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
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- **Use With Biologic Therapies:** SAPHNELO is not recommended for use in combination with other biologic therapies, including B-cell targeted therapies

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You may report side effects related to AstraZeneca products.

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Access360@AstraZeneca.com

www.MyAccess360.com

One MedImmune Way,
Gaithersburg, MD 20878

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References: 1. American Medical Association. CPT® 2024 Professional Edition. Chicago, IL: American Medical Association; 2024. https://www.ama-assn.org/practice-management/cpt. Accessed August 4, 2025. **2.** Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations. Updated March 01, 2022. Accessed August 11, 2025. 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 August 11, 2025. 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 August 11, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **5.** Centers for Medicare & Medicaid Services. Place of Service Code Set. Accessed August 20, 2025. https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets. **6.** Centers for Medicare & Medicaid Services. ICD-10-CM Codes. Accessed August 11, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes

AstraZeneca

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