Saphnelo® (anifrolumab-fnia) Intravenous Use 300 mg/vial

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) 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)

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.

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® (anifrolumab-fnia) injection, for intravenous use - 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

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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.

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

Healthcare Common Procedure Coding System (HCPCS)[1]

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	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

ICD-10-CM Diagnosis codes[2]

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
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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)

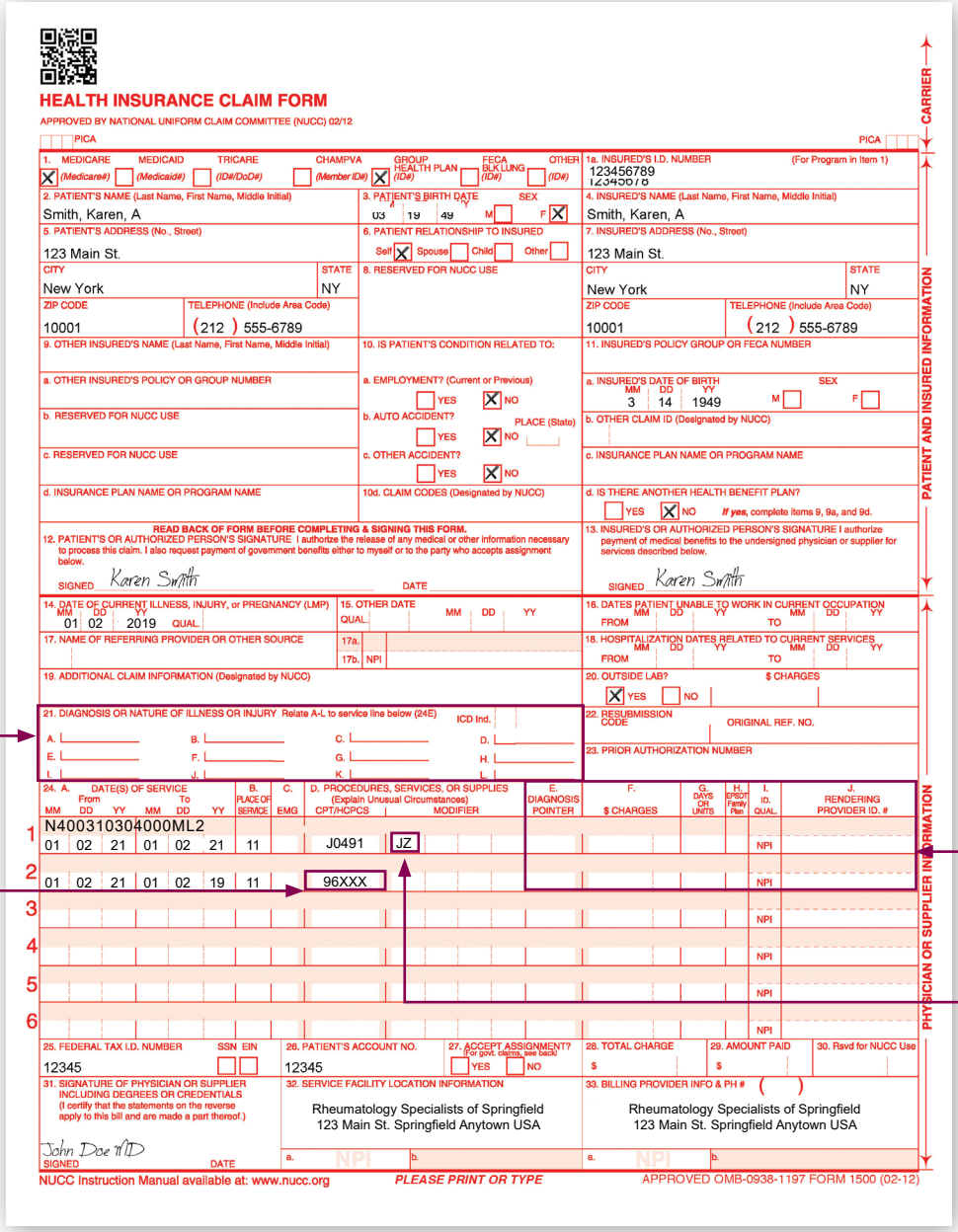
WARNINGS AND PRECAUTIONS (cont'd)

- **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

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

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#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) 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. #
1 N400310304000ML2 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

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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

Hospital Outpatient Department Coding

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10-digit NDC

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M32.9	Systemic lupus erythematosus, unspecified

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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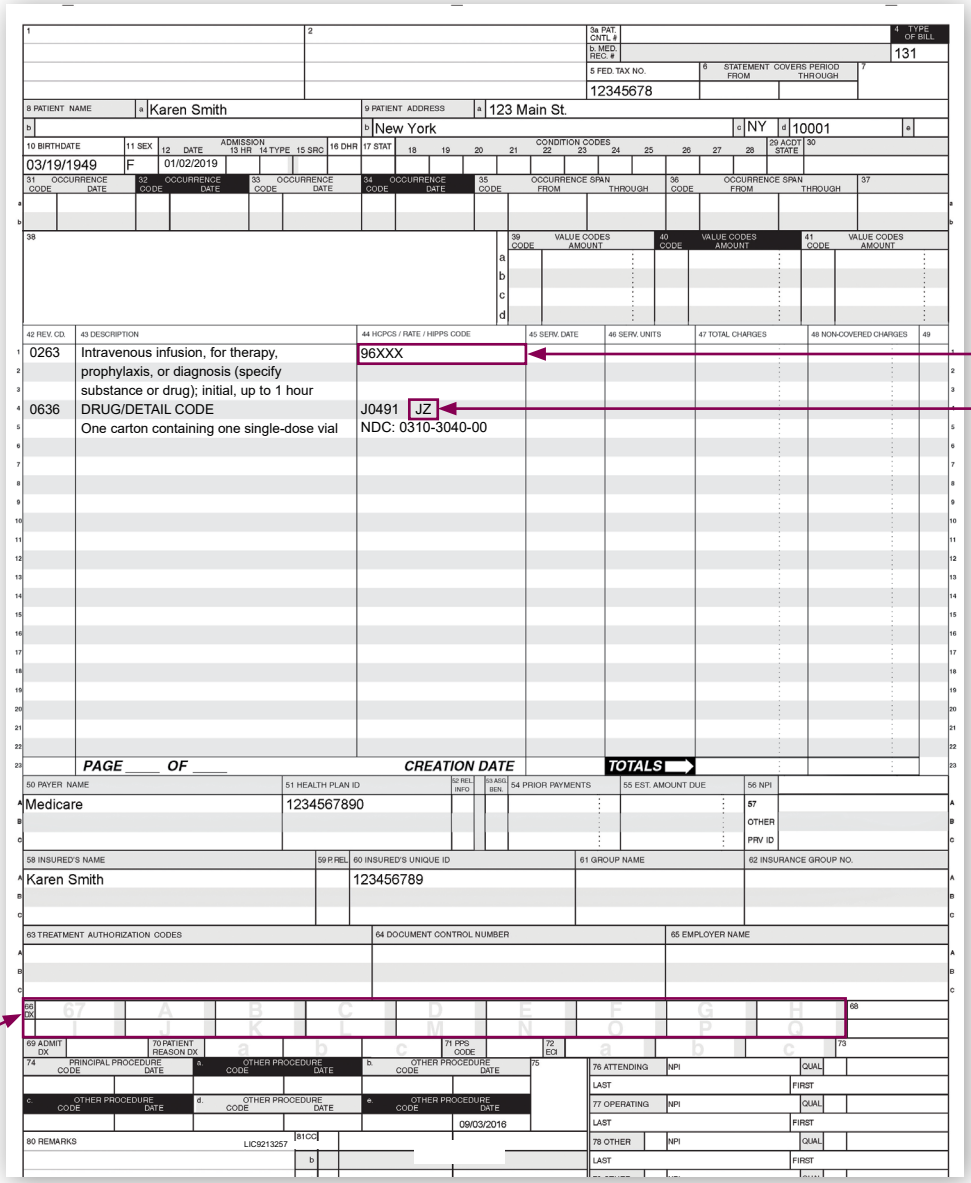
UB–04 Example Claim Form

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
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

3a PAT. CNTL #	4 TYPE OF BILL
b MED. REC. #	131
5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM / THROUGH
12345678	

8 PATIENT NAME	9 PATIENT ADDRESS			
a Karen Smith	a 123 Main St.			
b	b New York	c NY	d 10001	e

10 BIRTHDATE	11 SEX	12 ADMISSION DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	29 ACDT STATE
03/19/1949	F	01/02/2019						

50 PAYER NAME	51 HEALTH PLAN ID	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI
A Medicare	1234567890			57 OTHER PRV ID

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

74 PRINCIPAL PROCEDURE CODE / DATE	80 REMARKS	81CC
e. OTHER PROCEDURE CODE / DATE: 09/03/2016	LIC9213257	

76 ATTENDING	77 OPERATING	78 OTHER
NPI / QUAL / LAST / FIRST	NPI / QUAL / LAST / FIRST	NPI / QUAL / LAST / FIRST

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.

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.

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)

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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Saphnelo® (anifrolumab-fnia) Intravenous Use 300 mg/vial | AstraZeneca Access 360™

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CONTRAINDICATION

Known history of anaphylaxis with SAPHNELO.

WARNINGS AND PRECAUTIONS

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Please see full Prescribing Information, including Patient Information.

You may report side effects related to AstraZeneca products.

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www.MyAccess360.com

One MedImmune Way,
Gaithersburg, MD 20878

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References: 1. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations. Updated March 01, 2022. Accessed May 25, 2023. https://www.cms.gov/files/document/2021-hcpcs-application-summary-quarter-4-2021-drugs-and-biologicals.pdf **2.** Centers for Medicare & Medicaid Services. 2021 ICD-10-CM Codes. Accessed May 25, 2023. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm **3.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. Accessed May 25, 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 25, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf

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