



(anifrolumab-fnia)

Intravenous Use 300 mg/vial
Subcutaneous Use 120 mg/0.8 mL

AstraZeneca is here to
help you and your patients

ACCESSING SAPHNELO

A GUIDE FOR HEALTHCARE PROFESSIONALS

IMPORTANT SAFETY INFORMATION AND INDICATION

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.

CONTACT ACCESS 360

AstraZeneca Access 360™ has Patient Access Navigators who can provide access support Monday through Friday, 8 AM - 6 PM ET.



1-866-SAPHNELO (1-866-727-4635)
Monday–Friday, 8 AM to 6 PM ET, excluding holidays



www.MyAccess360.com



Fax: 1-866-511-2360



Access360@AstraZeneca.com

Saphnelo
SUPPORTS



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

THESE FREQUENTLY USED TERMS CAN HELP YOU NAVIGATE THE ACCESS PROCESS

ALTERNATE SITE OF CARE (ASOC)

A location of care outside of a traditional doctor's office to receive medical treatment. These sites may include urgent care centers, retail clinics, and worksite clinics.

APPEAL

The process to challenge a health insurance carrier's denial or coverage based on determination of medical necessity or limitations of coverage in the patient's insurance plan.

IMMUNOLOGY SALES SPECIALIST (ISS)/SAPHNELO SALES REPRESENTATIVE

An AstraZeneca representative who provides clinical education and product marketing services.

SAPHNELO INTRAVENOUS (IV)

An intravenous formulation of SAPHNELO administered in a physician office or an on/off campus outpatient hospital.

SAPHNELO PEN

A device that allows patients or caregivers to administer SAPHNELO subcutaneously (SC) at home.

SAPHNELO PREFILLED SYRINGE (PFS)

A device that allows patients or caregivers to administer SAPHNELO subcutaneously (SC) at home.

FIELD REIMBURSEMENT MANAGER (FRM)

A non-sales professional who supports HCP offices as they navigate insurance coverage, patient assistance programs, and the local reimbursement landscape.

PHARMACY BENEFIT MANAGER (PBM)

Third-party intermediaries between health insurance providers and pharmaceutical manufacturers. PBMs create lists of medicines that may be prescribed (formularies), negotiate rebates with manufacturers, process claims, and review the use of medicines.

PRIOR AUTHORIZATION (PA)

The approval needed from health insurance carriers before patients receive coverage for a specific treatment.

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

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.

SAPHNELO is for adults with moderate to severe SLE receiving standard therapy.
Not for severe active lupus nephritis or severe active central nervous system lupus.

ADMINISTRATION AND COVERAGE OPTIONS FOR SAPHNELO¹

Once a clinical decision is made to prescribe SAPHNELO, it's time to determine how your patient will be receiving the medicine.

SAPHNELO is provided as a clear to opalescent, colorless to slightly yellow, solution of anifrolumab-fnia, and is available in single-dose units as:



HEALTHCARE
PROVIDER (HCP)
ADMINISTERED

SAPHNELO vial for intravenous (IV) infusion:

one 300 mg/2 mL (150 mg/mL) vial,
diluted and administered over a
30-minute period, **every 4 weeks**
(NDC-00310-3040-00)



SAPHNELO Pen for subcutaneous (SC) injection:

one 120 mg/0.8 mL autoinjector,
administered **once every week**
(NDC 00310-3080-01)



PATIENT/CAREGIVER
ADMINISTERED

SAPHNELO prefilled syringe for subcutaneous (SC) injection:

one 120 mg/0.8 mL prefilled syringe,
administered **once every week**
(NDC 00310-3080-02)

For the autoinjector and prefilled syringe, a 28-day supply requires prescribing 3.2 mL, equivalent to 4 pens/syringes. Both options will be assigned an NCPDP billing unit of milliliters, with each pen/syringe containing a quantity of 0.8 mL.



Helpful resources may be found at MyAccess360.com

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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

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.

INDICATION

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SAPHNELO SUPPORT CUSTOMIZED TO YOUR NEEDS

Once a clinical decision is made to prescribe SAPHNELO, it's time to determine how your patient will be receiving the medicine.

Multiple Options for Benefits Investigation and Prior Authorization Resources Are Available



HUB that provides personalized support to help streamline access and reimbursement



Non-dispensing pharmacy that provides personalized support from e-prescription to fulfillment



Electronic platform streamlining PAs for healthcare providers and their staff



Third party specializing in medical benefit verification and PAs for specialty meds (formerly known as eBlu Solutions)

Regardless of what level of support an HCP chooses, FRM support is available along the patient journey.

ACCESS 360 OFFERS PERSONALIZED SAVINGS, SUPPORT, AND RESOURCES FOR YOUR PATIENTS

Access 360 can help you and your patients find information about coverage, costs, and affordability programs. The program is dedicated to providing support throughout the process, from prescription through long-term follow-up.

SAPHNELO Supports is a part of the Access 360 dedicated patient support program created to help answer questions patients might have as they get started with their treatment. SAPHNELO Supports can help patients start—and stay—on treatment.

SUPPORT IS TAILORED TO HELP MEET THE NEEDS OF HCPs AND PATIENTS



Access and Reimbursement Support

Provides access and reimbursement support resources for SAPHNELO
(See [page 7](#) for details)



Affordability Programs For Patients

Including the SAPHNELO Savings Program; eligible patients could pay as little as \$0* for SAPHNELO



Nurse Support

Provides answers to patients' questions about SAPHNELO

Have your patient contact Access 360 to learn more, Monday to Friday, 8 AM to 6 PM ET, excluding holidays.



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



1-866-511-2360



Access360@AstraZeneca.com



www.SAPHNELO.com
www.MyAccess360.com



One MedImmune Way
Gaithersburg, MD 20878

IMPORTANT SAFETY INFORMATION (cont'd)

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.

*See full Program eligibility on page 12.

ACCESS 360 PROVIDES PERSONAL SUPPORT TO STREAMLINE SAPHNELO ACCESS AND REIMBURSEMENT



Get started by filling out a Patient Enrollment Form

Be sure to complete the Patient Enrollment Form in its entirety and sign where indicated, including all patient and healthcare provider authorizations. Tips for completing key sections are shown below to help indicate what needs to be completed.

Determine patient's medical and prescription benefits

Request patient's insurance cards: Medical (including Secondary and Supplemental coverage) and Pharmacy cards.

Submit Enrollment Form

Complete the Enrollment Form:

- Available accompanying this guide
- Available online at: www.myaccess360.com/saphnelo
- Available at: Access 360 Provider Portal

Review and obtain Patient Authorization (and authorization for SAPHNELO Supports patient support program, if the patient would like to opt in to the savings program and additional services).

Available options to obtain Patient Authorization so Access 360 can provide patient-specific support:

- Patient to sign Enrollment Form prior to submission
- Online at: www.myaccess360paf.com
- Call Access 360 and give verbal authorization at: 1-866-SAPHNELO (1-866-727-4635)
- Note: HCP office staff attestation is needed for Access 360 to conduct a benefit investigation but not the patient authorization. Patient authorization is required, however, for Access 360 to perform a follow-up service request with the payer and/or specialty pharmacy or for field reimbursement support with an individual patient case

Submit Enrollment Form to Access 360: fax to 1-866-511-2360

TIPS FOR COMPLETING THE FORM

In Section 1, choose the appropriate method of obtaining SAPHNELO, to the best of your ability, along with patient services your office would like help with; reach out to Access 360 with questions if you are unsure.

In Sections 6 or 7, make sure to identify how and where SAPHNELO will be administered; reach out to Access 360 as needed with any questions (complete section 6 if the place of administration differs from the prescribing office and section 7 if utilizing a specialty pharmacy).

If you will not be using Access 360, see the next page for information about ASPN Pharmacies, which is an alternative resource to help your patients access SAPHNELO.

ASPN PHARMACIES IS AVAILABLE WHEN ePRESCRIBING SAPHNELO TO HELP ENSURE A SEAMLESS PATIENT EXPERIENCE*

ASPN Pharmacies offers prescribers a streamlined way to digitally manage patient prescriptions. Office staff members can be authorized to handle prescription management for multiple prescribers within the same practice and enrollment into patient Savings Program(s).



ASPN provides services support HUB for electronic prescribing

Electronic Prescription to Fulfillment

A single digital flow streamlining your prescribing journey



Offers electronic tools to manage patient prescription journey

Digital Prescription Management

Streamlines the process allowing prescribers to digitally manage the patient prescription journey



Facilitates communication and coordination with specialty pharmacies

Specialty Pharmacy Triage

Ensures accurate fulfillment for SAPHNELO



Supports patients with financial resources and access assistance

Personalized Patient Services

Supports patients with clear communication and affordability options

If you will not be using Access 360 or ASPN Pharmacies, additional programs to help access SAPHNELO are available (see next page).

*ASPN Pharmacies is a non-commercial, non-dispensing pharmacy.

ePrescribing Details (either location may be utilized as ASPN will triage the prescription to appropriate Specialty Pharmacy for fulfillment):

LIVINGSTON

290 W Mount Pleasant Ave., Building 2, 4th Floor, Ste 4210
Livingston, NJ 07039
ZIP for ePrescriptions: 07039
NCPDP: 3147863 | NPI: 1538590690

SCOTTSDALE

8010 E McDowell Rd., Suite 204-206
Scottsdale, AZ 85257
ZIP for ePrescriptions: 85257
NCPDP: 0365115 | NPI: 1891451282



www.aspnpharmacies.com

If you have any questions, contact ASPN Pharmacies at 1-866-470-0120, 8:30 AM to 8 PM ET, Monday-Friday or reach out to your SAPHNELO Field Reimbursement Manager.

To sign up for the Prescriber Portal, visit ASPN's Training page at aspnpharmacies.com/ASP/Training
Find answers to questions about ASPN Pharmacies at aspnpharmacies.com/ASP/FAQ

COVERMYMEDS AND CARETRIA PROVIDER CONNECT: ALTERNATIVES TO ACCESS 360 AND ASPN PHARMACIES FOR PRIOR AUTHORIZATION SUPPORT OPTIONS:

CoverMyMeds: An electronic platform streamlining PAs for healthcare providers and their staff

CareTria Provider Connect (formerly eBlu): An electronic portal specializing in medical benefit verification and PA for specialty meds



Receive faster* PA
determinations, often in
real time and with live
monitoring



PA request monitoring
with alerts when
action is needed



Available at no
cost to providers
and staff

*Compared to phone and fax.

CoverMyMeds

Live Chat: covermymeds.health
Phone: 1-866-452-5017
Monday-Friday: 8 AM to 11 PM ET
Saturday: 8 AM to 6 PM ET
go.covermymeds.health/provider

CareTria, formerly eBlu (Medical Benefit Support)

Phone: 502-373-3258
Monday-Friday: 8:30 AM to 5:30 PM ET
providerconnect@caretria.com
info.caretria.com/provider-connect-saphnelo
providerconnect.caretria.com

Policy Acumen Portal

The Policy Acumen Portal provides up-to-date resources for billing, coding, and coverage policies specific to SAPHNELO for preselected payers. To learn more about SAPHNELO state-by-state coverage, go to:

www.saphnelo.policyacumen.health

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.

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

HOW YOUR PATIENTS ACCESS SAPHNELO INTRAVENOUS, FROM PRESCRIPTION TO ADMINISTRATION

At each step along the way, AstraZeneca is dedicated to helping patients with resources available through Access 360.

1



PRESCRIPTION/ENROLLMENT

Healthcare Provider (HCP) and Biologics Coordinator:

- HCP prescribes **SAPHNELO**
 - HCP can request services and enroll patient in A360
 - Determine if patient will receive SAPHNELO via Buy & Bill or a Specialty Pharmacy Provider (SPP)

2



BENEFITS INVESTIGATION

Access 360:

- Conducts Benefits Investigation and completes Prior Authorization (PA) research
- Researches patient's pharmacy and medical benefit
- Submits prescription to SPP, if requested

CareTria Provider Connect and CoverMyMeds® (see page 7):

- Alternative Benefits Investigation and PA support options
- Completes real-time benefit verification

3



PRIOR AUTHORIZATION

Your Office:

- Submits PA to major medical and/or pharmacy benefit

Access 360, CareTria Provider Connect, or CoverMyMeds:

- Tracks status of submitted PA, if requested
- Communicates outcome of PA
- Assists with appeals support if PA is denied

4



AUTHORIZATION/DELIVERY

Office/Alternative Site of Care (ASOC) Administered

If your office uses Buy & Bill:

- Your office orders SAPHNELO through approved Specialty Distributor

If your patient uses an SPP:

- SPP contacts patient to discuss co-pay (if applicable)
- SPP authorizes payment and schedules delivery
- SPP delivers SAPHNELO to HCP/ASOC

5



ADMINISTRATION/REIMBURSEMENT

Office Administered:

If your office uses Buy & Bill:

- HCP administers SAPHNELO
- Your office submits claim*
- Access 360 assists with appeal support if claim is denied or underpaid
- Your office orders refill through approved Specialty Distributor

*Commercially insured patients may be eligible for additional savings. HCPs/SPPs can enroll patients at SAPHNELOsavings.com (with valid log-in) or SAPHNELOsupport.com.

**HEALTHCARE
PROVIDER (HCP)
ADMINISTERED:**
VIAL FOR INTRAVENOUS
(IV) INFUSION



10

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

HOW YOUR PATIENTS ACCESS SAPHNELO PEN OR SAPHNELO PREFILLED SYRINGE (PFS), FROM PRESCRIPTION TO ADMINISTRATION

At each step along the way, AstraZeneca is dedicated to helping patients with resources available through ASPN Pharmacies or Access 360.

1



PRESCRIPTION/ENROLLMENT

HCP and Biologics Coordinator:

- HCP prescribes **SAPHNELO**
 - HCP can submit e-prescription to ASPN Pharmacies via Electronic Medical Record (EMR)
 - Alternatively, HCP can request services and enroll patient in A360 or HCP can obtain product directly from a Specialty Pharmacy Provider (SPP)
 - Patient will receive SAPHNELO via an SPP

2



BENEFITS INVESTIGATION

Access 360 or ASPN:

- Conducts thorough Benefits Investigation and completes Prior Authorization (PA) research
- Researches your patient's pharmacy and medical benefit
- Submits prescription to SPP, if requested

3



PRIOR AUTHORIZATION

Your Office:

- Submits PA to pharmacy and/or major medical benefit

ASPN or Access 360:

- Tracks status of submitted PA, if requested
- Communicates outcome of PA
- Assists with appeals support if PA is denied

CoverMyMeds® (see page 9):

- Provides PA support

4



AUTHORIZATION/DELIVERY

Patient/Caregiver Administration (Pen or PFS):

Patient process (via an SPP):

- SPP contacts patient to discuss co-pay (if applicable)
- If your patient has trouble with their co-pay, they may reach out to the Co-pay Savings Program, if applicable
- SPP authorizes payment and schedules delivery
- SPP delivers SAPHNELO to patient's home

5



ADMINISTRATION/REIMBURSEMENT

Patient/Caregiver Administration (Pen or PFS):

- Patient/Caregiver injects SAPHNELO Pen or PFS
- SPP Submits claim*
- Patient/SPP manages refill

*Commercially insured patients may be eligible for additional savings. HCPs/SPPs can enroll patients at SAPHNELOSavings.com (with valid log-in) or SAPHNELOSupport.com.

PATIENT/CAREGIVER ADMINISTERED:



SAPHNELO PEN
FOR SUBCUTANEOUS (SC) INJECTION



SAPHNELO PREFILLED SYRINGE
FOR SUBCUTANEOUS (SC) INJECTION

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OVER 95% OF COMMERCIAL PATIENTS ENROLLED IN THE CO-PAY SAVINGS PROGRAM PAY \$0* FOR SAPHNELO²

✓ IF SAPHNELO IS APPROVED

Eligible patients may pay as little as \$0* for SAPHNELO and its infusion administration or injection training up to \$16,500 per calendar year^{†‡}

To be eligible, patients must:

- Have commercial insurance
- Have SAPHNELO approved by their insurance plan

NOTE: Offer is invalid for claims and transactions more than 365 days from the date of service

Specialty Pharmacy Acquisition

Out-of-pocket costs for SAPHNELO:

For help with out-of-pocket costs for SAPHNELO, patients can sign up for the SAPHNELO Savings Program by signing the support program section of the AstraZeneca Access 360™ Enrollment Form.

Out-of-pocket costs for SAPHNELO infusion administration or injection training:

Patient or HCP is responsible for requesting reimbursement for out-of-pocket costs for infusion administration or injection training. Reimbursement forms are available by contacting Access 360 at 1-866-SAPHNELO (1-866-727-4635).

Specialty Distributor Acquisition: Buy & Bill

To set up an account, please contact Access 360 at 1-866-SAPHNELO (1-866-727-4635).

When purchasing SAPHNELO to administer to your patients:

Existing provider account? Log into SAPHNELOSavings.com to access the portal and enroll your patients.

To set up an account: Please contact Access 360 at 1-866-SAPHNELO (1-866-727-4635).

No provider account? Go to SAPHNELOSupport.com to enroll patients.

- Upon enrollment completion, your patient's co-pay details will be provided and will also be automatically emailed to your patient
- After administering SAPHNELO, submit a claim to patient's insurance. You will receive an Explanation of Benefits (EOB) to determine the patient's amount owed for SAPHNELO, including the injection administration
- To request reimbursement for patient's SAPHNELO out-of-pocket costs, including infusion administration or injection training, submit copies of the EOB form and the CMS-1500 or UB-04 form to SAPHNELOSavings.com (log-in required) or SAPHNELOSupport.com. Out-of-pocket patient costs vary; most eligible patients may pay as little as \$0 per injection of SAPHNELO
- After the SAPHNELO Savings Program claim is reviewed and approved, you will be notified that the patient-specific Virtual Debit Card has been loaded with the approved amount. Process card funds as a debit card transaction.

✓ ELIGIBILITY

Patients may be eligible for this offer with the following criteria:

- Insured by Commercial insurance with a valid prescription for SAPHNELO, AND
- Are a resident of the United States or US Territories AND
- Are not enrolled in a government-funded program

Patients who are enrolled in a state- or federally funded prescription insurance program are not eligible for this offer. This includes patients who are enrolled in Medicare Part B, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), Department of Defense (DoD) programs or TriCare, and patients who are Medicare eligible and enrolled in an employer-sponsored group waiver health plan or government-subsidized prescription drug benefit program for retirees. Patients who are enrolled in a state or federally funded prescription program may not use this program even if they elect to be processed as uninsured (cash-paying). This offer is not insurance.

*For eligible commercially insured patients only. Subject to applicable insurance plan's eligibility rules and requirements; restrictions may apply.

[†]Patients are responsible for any cost associated with the infusion administration or injection training above the \$150 per infusion administration or injection training provided by the program.

[‡]Patients who are residents of Massachusetts and Rhode Island are not eligible for infusion administration or injection training assistance.

[§]Patients who enroll receive support for up to 24 months from the date of initial prescription.

TERMS OF USE

Eligible commercially insured patients with a valid prescription for SAPHNELO who enroll in this program may pay as little as \$0 per administration of SAPHNELO dependent upon patient's prescription coverage of SAPHNELO.

SAPHNELO Savings Program – If SAPHNELO is covered by the health plan:

- Up to \$16,500 per calendar year in assistance for out-of-pocket expenses
- The out-of-pocket costs covered by the program can include the cost of the product itself, the cost of injection administration, and injection training of the product (program maximum of \$150 per infusion administration or injection training)^{†‡}
- Other restrictions may apply. Patient must be enrolled in the program before use. If you have any questions regarding the offer, please call **1-866-SAPHNELO** (1-866-727-4635)
- Offer is invalid for claims or transactions more than 365 days from the date of service

Other restrictions apply. Patient is responsible for applicable taxes, if any. Non-transferable, limited to one per person, cannot be combined with any other offer. Void where prohibited by law, taxed, or restricted. Patients, pharmacists, and prescribers cannot seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this offer. AstraZeneca reserves the right to rescind, revoke, or amend this offer, eligibility, and terms of use at any time without notice. This offer is not conditioned on any past, present, or future purchase, including refills. Offer must be presented along with a valid prescription for SAPHNELO at the time of purchase. Program covers the cost of the drug, infusion administration, or injection training,^{†‡} and does not cover the costs for office visits or any other associated costs.

THE DENIED PATIENT SAVINGS PROGRAM IS HERE TO HELP

If a patient with commercial insurance has a SAPHNELO prescription for on-label use and their PA appeal has been denied by their insurance plan, SAPHNELO may be available at no cost through the Denied Patient Savings Program.

X IF SAPHNELO IS DENIED

If SAPHNELO is denied by insurance for on-label use, submit an appeal. If the appeal is denied, patients pay \$0 for SAPHNELO and its infusion administration or injection training for up to 24 months.[§]

To be eligible, patients must:

- Have commercial insurance
- Have had PA and PA appeal denied by insurance company
- Have SAPHNELO prescribed for on-label use

TERMS OF USE

Denied Patient Savings Program – If SAPHNELO is NOT covered by the health plan for on-label use:

- Prescription fills for up to 24 months from the date of the initial prescription
- This program is only administered by approved specialty pharmacies
- Program support includes periodic Benefits Investigation to identify potential changes in patient coverage. If a change in coverage is identified, the prescriber will be contacted to initiate a new Prior Authorization for the patient. If the Prior Authorization is approved, the patient will transition to coverage via their insurance benefits
- Patients denied coverage for SAPHNELO subcutaneous and currently receiving approved SAPHNELO intravenous therapy are not eligible for Denied Patient Savings Program

BY USING THIS PROGRAM, PATIENTS AND THEIR PHARMACIST AND/OR PHYSICIAN UNDERSTAND AND AGREE TO COMPLY WITH THESE ELIGIBILITY REQUIREMENTS AND TERMS OF USE.

**For more information on the Denied Patient Savings Program,
please contact your local Field Reimbursement Manager.**

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Subcutaneous Use 120 mg/0.8 mL

SAPHNELO IS AVAILABLE THROUGH THE FOLLOWING

Specialty Pharmacy Providers (SPPs):

Accredo Specialty Pharmacy
p: 866-759-1557 • f: 888-302-1028
www.accredo.com
8 AM–8 PM ET, Monday–Friday

Alivia Specialty Pharmacy
p: 787-925-1989 • f: 787-925-1015
www.aliviahealth.com
7 AM–6 PM, Monday–Friday
Saturday, Sunday, and Outside Office
Hours: On call Personnel

Amber Specialty Pharmacy
p: 888-370-1724 • f: 877-645-7514
www.amberpharmacy.com
24 hours a day, Monday–Sunday

Axiom Healthcare
(Puerto Rico only)
p: 787-780-7200 • f: 787-779-1430
www.axiumpri.com
8 AM–6 PM ET Non DST, Monday–Friday

CVS Specialty
p: 866-526-4984 • f: 855-592-6890
www.cvsspecialty.com
8:30 AM–8:30 PM ET, Monday–Friday

Optum Specialty Pharmacy
p: 855-427-4682 • f: 877-342-4596
<https://specialty.optumrx.com>
8:30 AM–8 PM ET, Monday–Friday

Pharmacare Specialty Pharmacy
(Hawaii only)
p: 808-840-5600 • f: 808-840-5678
www.pharmacarehawaii.com
8:30 AM–5:00 PM HST, Monday–Friday

Walgreens Specialty Pharmacy
p: 800-445-3674 • f: 866-773-0143
www.WalgreensSpecialtyRx.com
8 AM–8 PM ET, Monday–Friday
8 AM–5 PM ET, Saturday

Specialty Distributors:

AmerisourceBergen Besse Medical
p: 800-543-2111 • f: 800-543-8695
www.besse.com
7 AM–11 PM ET, Monday–Friday
8:30 AM–8 PM ET, Saturday–Sunday

Cardinal Health Specialty Distribution
p: 855-740-1871 • f: 888-345-4916
<http://specialtyonline.cardinalhealth.com>
8 AM–8 PM ET, Monday–Friday

Cencora ASD Healthcare
p: 800-746-6273 • f: 800-547-9413
www.asdhealthcare.com
8 am–7:30 pm ET, Monday–Thursday
8 am–7 pm ET, Friday

CuraScript SD
p: 877-599-7748 • f: 800-862-6208
www.curascripstd.com
8 AM–7 PM ET, Monday–Friday

Dakota Drug Inc.
p: 866-210-5887 • f: 763-421-0661
www.dakdrug.com

DMS Pharmaceutical Group, Inc.
p: 877-788-1100 • f: 847-518-1105
www.dmspharma.com

McKesson Plasma and Biologics
(Hospitals, IDNs, VA)
p: 877-625-2566 • f: 888-752-7626
mpborders@mckesson.com
9 AM–7:30 PM ET, Monday–Friday

McKesson Specialty Health
(MD Offices)
p: 855-477-9800 • f: 800-289-9285
www.mckessonspecialtyhealth.com
8 AM–8 pm ET, Monday–Friday

Metro Medical
p: 800-768-2002 • f: 615-256-4194
www.metromedicalorder.com
7 AM–7 PM CT, Monday–Friday

Oncology Supply
p: 800-633-7555 • f: 800-248-8205
www.oncologysupply.com
7 AM–11 pm ET, Monday–Friday
8:30 AM–8 pm ET, Saturday–Sunday

Your patient's insurance may dictate which pharmacies they can use to get their medicine.

This list reflects SPPs available as of April 2026.

QUICK TIP

When you decide on a Specialty Pharmacy, share the pharmacy's contact information with your patient and let them know the pharmacy will reach out to them for next steps. The patient will need to answer or call back.

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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/overtake 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).**

SAPHNELO REIMBURSEMENT CODES: FOR INTRAVENOUS OR SUBCUTANEOUS UTILIZATION

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)¹

ADMINISTRATION	ADMINISTRATION METHOD	DESCRIPTION	10-DIGIT NDC	11-DIGIT NDC
Physician Administered	SAPHNELO 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)³

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.

ADMINISTRATION METHOD	CODE	DESCRIPTION
Physician Administered Intravenous Infusion	96XXX	Check payer's policy to obtain appropriate administration code
Patient/Caregiver Administered 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

Diagnosis Codes⁴

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

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.

1		2		3a PAT. CMT. # b. MED. REC. #		4 TYPE OF BILL 131	
5 FED. TAX NO. 12345678		6 STATEMENT COVERS PERIOD FROM		7 THROUGH			
8 PATIENT NAME Karen Smith		9 PATIENT ADDRESS 123 Main St.		c NY		d 10001	
10 BIRTHDATE 03/19/1949		11 SEX F		12 DATE 01/02/2019		13 ADMISSION 13 HR 14 TYPE 15 SRG	
16 DMR		17 STAT		18 19 20 21		22 23 24 25 26 27 28	
29 ACCT STATE		30		31		32	
33 OCCURRENCE DATE		34 OCCURRENCE DATE		35 OCCURRENCE DATE		36 OCCURRENCE DATE	
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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

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

SAPHNELO REIMBURSEMENT CODES: FOR INTRAVENOUS UTILIZATION ONLY

Please note that the codes identified below are also provided as 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.

Healthcare Common Procedure Coding System (HCPCS)⁵

CODE	DESCRIPTION	VIAL SIZE	BILLING UNITS
J0491	Injection, anifrolumab-fnia, 1 mg	300 mg/2 mL single-dose vial	300 units

HCPCS Modifier Used to Report Zero Drug Wastage^{6,7}

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

Place of Service Code⁸

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

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

1. MEDICARE ☒ MEDICAID ☐ TRICARE ☐ CHAMPVA ☐ GROUP HEALTH PLAN ☒ FECA (LUNG) ☐ OTHER ☐

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

3. PATIENT'S BIRTH DATE
MM DD YY 03 19 49 SEX F ☒

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 ☒ Spouse ☐ Child ☐ Other ☐

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

8. RESERVED FOR NUCC USE

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

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 DATE

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
FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE
17a. NAME 17b. NPI

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☒ YES ☐ NO \$ CHARGES

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

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. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DATES OF UNITS H. PRIOR Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. #

1 N400310304000ML2 J0491 JZ

2 01 02 21 01 02 19 11 96XXX

3

4

5

6

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

26. PATIENT'S ACCOUNT NO. 12345

27. ACCEPT ASSIGNMENT? (If print, select one box) 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

33. BILLING PROVIDER INFO & PH # ()

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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References: **1.** SAPHNELO [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2026. **2.** Data on File, US-75701, AstraZeneca Pharmaceuticals LP. **3.** American Medical Association. CPT® 2024 Professional Edition. Chicago, IL: American Medical Association; 2024. Accessed August 4, 2025. <https://www.ama-assn.org/practice-management/cpt> **4.** Centers for Medicare & Medicaid Services. 2021 ICD-10-CM Codes. Accessed August 11, 2025. <https://www.cms.gov/medicare/coding-billing/icd-10-codes> **5.** 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> **6.** Centers for Medicare & Medicaid Services. HCPCS Quarterly Update. Accessed August 11, 2025. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update> **7.** 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> **8.** 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>

