Sunlenca®
(lenacapavir) injection
463.5 mg/1.5 mL

SUNLENCA® INITIATION GUIDE

Acquisition, Access, and Reimbursement for SUNLENCA

INDICATION

SUNLENCA, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 whose current antiretroviral regimen is failing due to resistance, intolerance, or safety considerations.

IMPORTANT SAFETY INFORMATION

Contraindications

- **Coadministration:** Concomitant administration of SUNLENCA is contraindicated with strong CYP3A inducers.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

SUNLENCA® OVERVIEW

Sunlenca® (lenacapavir) injection 463.5 mg/1.5 mL

SUNLENCA is a long-acting injectable administered twice a year, which provides a complete HIV-1 treatment regimen when used in combination with an optimized background regimen[1]

Your office can acquire SUNLENCA in two ways: through a specialty pharmacy or through a specialty distributor (buy-and-bill). Your patient's insurer may dictate how SUNLENCA is acquired.

Acquiring SUNLENCA via specialty pharmacy

- Send SUNLENCA prescription to specialty pharmacy
- Specialty pharmacy conducts benefits investigation
- Specialty pharmacy sends summary of benefits to you and patient and coordinates any prior authorization requirements
- Specialty pharmacy contacts patient to provide counseling and collect co-pay
- Specialty pharmacy contacts you to coordinate shipment with patient appointment
- Initiate SUNLENCA and coordinate every-6-month maintenance subcutaneous (SC) injections[1]

We are here to help! Go to the last page for information on how to connect with a Reimbursement Manager and the Advancing Access® team for additional support.

Acquiring SUNLENCA via buy-and-bill

- Office conducts benefits investigation
- Order SUNLENCA from specialty distributor
- Store and track supply of SUNLENCA
- Initiate SUNLENCA and collect co-pay
- Coordinate every-6-month maintenance SC injections[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported in patients treated with combination antiretroviral (ARV) therapy.
- **Long-acting properties and potential associated risks with SUNLENCA:** Residual concentrations of SUNLENCA may remain in the systemic circulation of patients for up to 12 months or longer. SUNLENCA may increase exposure, and potential risk of adverse reactions, to drugs primarily metabolized by CYP3A initiated within 9 months after last injection. Counsel patients regarding the dosing schedule because nonadherence could lead to loss of virologic response and development of resistance. If virologic failure occurs, switch to an alternative regimen if possible. If discontinuing SUNLENCA, begin alternate suppressive ARV regimen within 28 weeks from last injection.
- **Injection site reactions** may occur, and nodules and indurations may be persistent. Improper administration (intradermal injection) has been associated with serious injection site reactions.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

ADMINISTRATION

Initiation

SUNLENCA® initiation includes oral tablets and the first set of SC injections.[1]

- A treatment regimen incorporating SUNLENCA begins with 1 of 2 initiation options. Providers should determine the appropriate initiation option for the patient. See diagrams to the right for additional details[1]
  - Patients must maintain an optimized background regimen (OBR) while taking SUNLENCA[1]

Turn the page to see guidance for maintenance dosing with SUNLENCA.

Dosing instructions

Initiation[1]

Option 1:

Lenacapavir 300-mg tablets (4-tablet blister pack or bottle):
Take 2 tablets (600 mg) by mouth on both Day 1 and Day 2.

Lenacapavir injection (309 mg/mL):
Inject 927 mg (two 1.5-mL injections) subcutaneously into the abdomen on Day 1 and then every 6 months (26 weeks).

Option 2:

Lenacapavir 300-mg tablets (5-tablet blister pack):
Take 2 tablets (600 mg) by mouth on both Day 1 and Day 2 and 1 tablet (300 mg) on Day 8.

Lenacapavir injection (309 mg/mL):
Inject 927 mg (two 1.5-mL injections) subcutaneously into the abdomen on Day 15 and then every 6 months (26 weeks).

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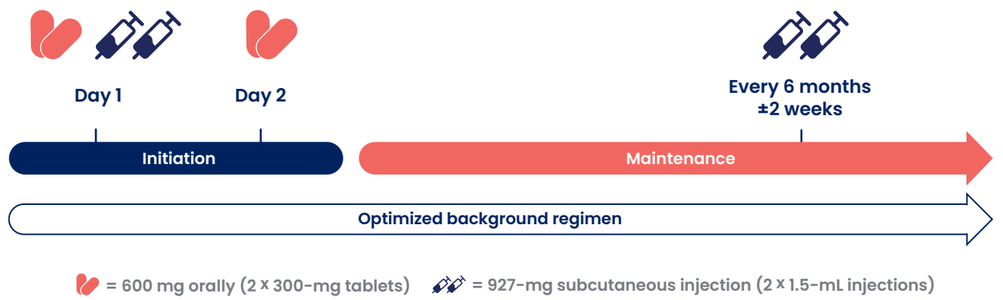
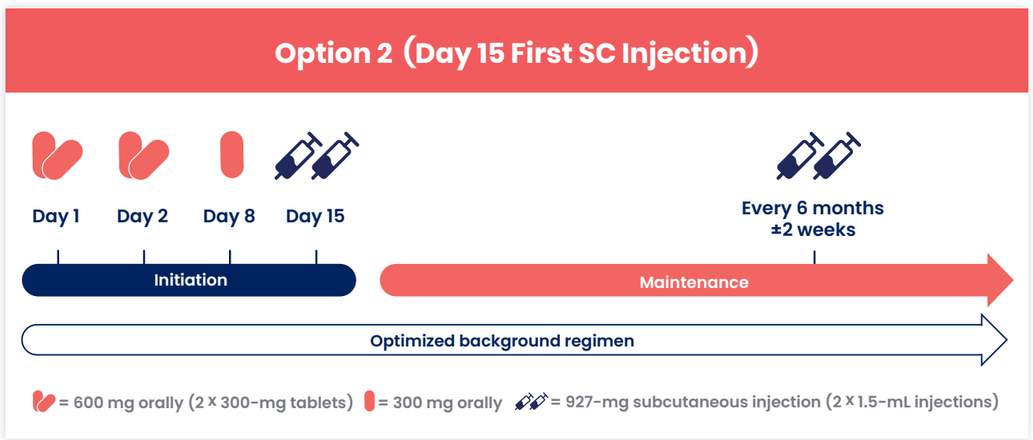
Two ways to start SUNLENCA prior to maintenance injections[1]:

Option 1 (Day 1 First SC Injection)



Option 2 (Day 15 First SC Injection)



For more information about SUNLENCA dosing and administration, visit SunlencaHCP.com.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- **Most common adverse reactions** (incidence ≥3%, all grades) are injection site reactions (65%) and nausea (4%).

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

ADMINISTRATION (cont'd)

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Maintenance

SUNLENCA® maintenance involves SC injections administered by a healthcare professional every 6 months, in addition to an ongoing OBR.[1]

- Maintenance injections are given every 26 weeks (±2 weeks) from the date of the previous injection[1]

Dosing instructions

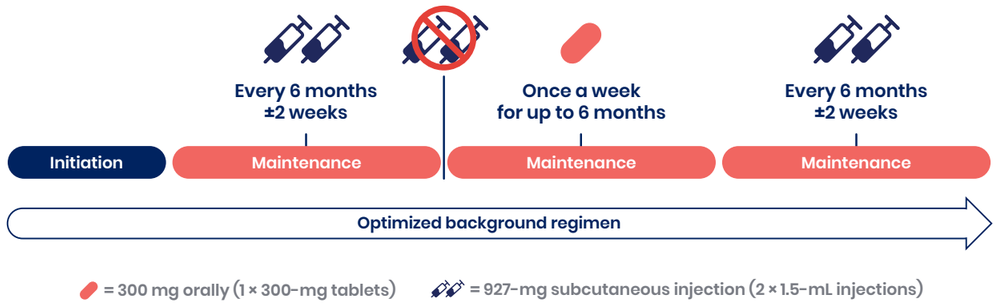
Maintenance[1]

Lenacapavir injection (309 mg/mL):
Inject 927 mg (two 1.5-mL injections) subcutaneously into the abdomen every 6 months (26 weeks).

For planned missed injections

Lenacapavir 300-mg tablets (4-tablet bottle):
At 26 to 28 weeks since the last injection, take 1 tablet (300 mg) by mouth once every 7 days for up to 6 months. Resume maintenance injections within 7 days of the last oral dose.

Planned Missed Injections[1]



During the maintenance period, if a patient plans to miss a scheduled 6-month injection visit by more than 2 weeks, SUNLENCA tablets may be taken for up to 6 months until injections resume.

If a patient plans to miss their injections, beginning between 26 and 28 weeks since the last injection, patients should begin taking the maintenance oral dosage of 300 mg, taken once every 7 days for up to 6 months. Maintenance injections should resume within 7 days of the last oral dose.

Unplanned Missed Injections[1]

Patients who miss a scheduled injection visit should be clinically reassessed, including consideration of lenacapavir resistance testing, to ensure resumption of therapy remains appropriate.

During the maintenance period, if more than 28 weeks have passed since the last injection and if clinically appropriate to continue SUNLENCA, restart the initiation dosage regimen from Day 1, using either initiation option.

For more information about SUNLENCA dosing and administration, visit SunlencaHCP.com.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions

- **Prescribing information:** Consult the full prescribing information for SUNLENCA for more information on Contraindications, Warnings, and potentially significant drug interactions, including clinical comments.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

ACCESS AND REIMBURSEMENT

Sunlenca® (lenacapavir) injection 463.5 mg/1.5 mL

Main factors that will affect coverage and reimbursement for prescribed SUNLENCA®

1. Type of Payer

Different insurance statuses and coverage details will impact how a patient accesses SUNLENCA.

Understanding details of a patient's coverage is critical when coordinating procurement of SUNLENCA.

2. Benefit Category

SUNLENCA may be covered under the medical benefit, the pharmacy benefit, or both. The Gilead Advancing Access® program can perform a benefits investigation for enrolled patients to confirm coverage. Visit the last page for more information about Advancing Access.

3. Coverage Requirements

Plans may require prior authorization(s) (PA) or other supporting documentation to confirm patient eligibility.

Some plans may allow one PA to cover the course of therapy, while others may require separate PAs for the oral and injectable components.

A specialty pharmacy can support the PA process.[2]

SUNLENCA must be acquired 1 of 2 ways: through a specialty pharmacy or directly from a specialty distributor

Oral component is likely to be covered under the pharmacy benefit. Exceptions are possible.

SC injectable component may be covered under the medical benefit and/or the pharmacy benefit.

The benefit category (ie, pharmacy benefit or medical benefit) under which SUNLENCA is covered by the patient's insurer will dictate how you acquire the medication.

- **Components covered under the pharmacy benefit** can generally be acquired via the designated specialty pharmacy. If the SC injection is covered under the medical benefit, the medication may be acquired directly from a specialty distributor via the buy-and-bill process
- **Assignment of Benefit (AOB)** may be permitted by some payers. AOB allows the designated specialty pharmacy to acquire and bill for reimbursement for SUNLENCA, even when it is covered under the medical benefit
  - The specialty pharmacy can verify if this option is available for your patient

Go to the **Specialty Contacts** tab for information on the in-network specialty pharmacy and specialty distributors.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions (cont'd)

- **Enzymes/transporters:** Drugs that are strong or moderate inducers of CYP3A may significantly decrease the concentration of SUNLENCA. Drugs that strongly inhibit CYP3A, P-gp, and UGT1A1 together may significantly increase the concentration of SUNLENCA. SUNLENCA may increase the exposure of drugs primarily metabolized by CYP3A, when initiated within 9 months after the last injection of SUNLENCA, which may increase the potential risk of adverse reactions.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

SPECIALTY PHARMACY ACQUISITION

Sunlenca® (lenacapavir) injection 463.5 mg/1.5 mL

Key things to know about SUNLENCA® specialty pharmacy acquisition

Benefits Investigation

- The specialty pharmacy can conduct a benefits investigation to confirm coverage for your patient
- The Gilead Advancing Access® program can also run a benefits investigation and offer reimbursement support to patients who enroll in the program

Medication Shipment

- The specialty pharmacy will deliver the medication directly to your office (rather than to the patient) unless directed otherwise
- Refrigeration is not required

Appointment Coordination

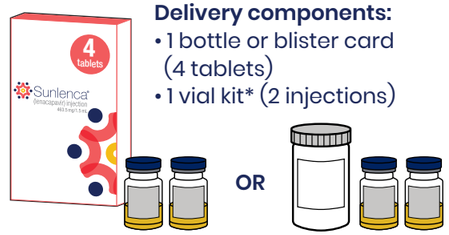
- Your office and the specialty pharmacy will coordinate the timing of product shipment according to the patient's injection appointment schedule

Patient Out-of-Pocket (OOP) Responsibilities

- The patient may be required to pay any drug-related co-pays or coinsurance directly to the specialty pharmacy
- Commercially insured patients who are prescribed SUNLENCA may be eligible to enroll in the Gilead Advancing Access co-pay coupon program. Please see the last page for Advancing Access contact information

Please see the Specialty Contacts tab for more information about ordering from the specialty pharmacy.

Initiation Option 1 (Day 1 First Injection)



Delivery components:
- 1 bottle or blister card (4 tablets)
- 1 vial kit* (2 injections)

Initiation Option 2 (Day 15 First Injection)

Delivery components:
- 1 blister card (5 tablets)
- 1 welcome card
- 1 vial kit* (2 injections)

Maintenance

Delivery components:
- 1 vial kit* (2 injections) per maintenance dose

Images for illustrative purposes only. Actual packaging may differ.

Please see the Additional Information tab for a list of the contents provided in the injection vial kit.

*Vials contain a yellow solution.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration

- **Dosage:** Initiation with 1 of 2 options, followed by maintenance injection dosing once every 6 months. Tablets may be taken with or without food.
  - **Initiation Option 1:** Day 1: 927 mg by subcutaneous injection and 600 mg orally (2 x 300-mg tablets). Day 2: 600 mg orally (2 x 300-mg tablets).
  - **Initiation Option 2:** Day 1: 600 mg orally (2 x 300-mg tablets). Day 2: 600 mg orally (2 x 300-mg tablets). Day 8: 300 mg orally (1 x 300-mg tablet). Day 15: 927 mg by subcutaneous injection.
  - **Maintenance:** 927 mg by subcutaneous injection every 26 weeks +/- 2 weeks from date of last injection.
- **Planned missed injections:** If scheduled injection is to be missed by more than 2 weeks, SUNLENCA tablets may be used for oral bridging for up to 6 months until injections resume. Dosage is 300 mg orally (1 x 300-mg tablet) every 7 days.
- **Unplanned missed injections:** During the maintenance period, if more than 28 weeks have elapsed since the last injection and tablets have not been taken for oral bridging, restart the initiation dosage regimen from Day 1, using Option 1 or Option 2, if clinically appropriate.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

BUY-AND-BILL ACQUISITION

With buy-and-bill, your practice will order and purchase SUNLENCA® directly from a specialty distributor within the network.

When covered under the medical benefit, the buy-and-bill process may be preferred or required by the patient's health insurance.

- In many cases, only the injectable component of SUNLENCA will be covered under the medical benefit, while the oral component will be covered under the pharmacy benefit and acquired from the designated specialty pharmacy

Key things to know about SUNLENCA buy-and-bill acquisition

Injectable Component

- Your office will need to plan ahead and coordinate the shipment to arrive prior to the patient's scheduled injection appointment
- The specialty distributor will supply the medication to your office
- Your office will collect any co-pays or coinsurance for the injectable component from the patient
- If your office prefers not to buy-and-bill, and the patient's insurance plan does not allow SUNLENCA to be obtained through the specialty pharmacy, you may consider referring a patient to an alternative provider for the injection

Oral Component

- If the oral component is covered under the pharmacy benefit, it must be ordered from the specialty pharmacy; this is not subject to buy-and-bill reimbursement
- The specialty pharmacy will work with your office to coordinate shipment of the oral component around scheduled injection appointments

Please see the Specialty Contacts tab of this document for more information about ordering from a specialty distributor authorized by Gilead.

MEDICARE BUY-AND-BILL REIMBURSEMENT

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J codes are used to buy-and-bill for Medicare reimbursement

- The HCPCS (Healthcare Common Procedure Coding System) billing J-code for SUNLENCA is J1961
- This code should be used for all billing related to SUNLENCA injections
- Until the average sale price (ASP) is calculated, reimbursement will be set at 103% of wholesale acquisition cost (WAC)*

Healthcare providers and facilities can also bill Medicare for professional services associated with drug administration.

Medicare typically pays 80% of the allowed charges for most covered Part B drugs and the associated drug administration, and the remaining 20% is typically paid by the beneficiary as coinsurance. Medicare-eligible patients are also responsible for paying a deductible amount, which may be covered by supplemental insurance.

*Medicare allowable will be 106% of ASP once the ASP is established.

For more information, see Sample Claim Forms for Buy-and-Bill Acquisition on the following pages.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

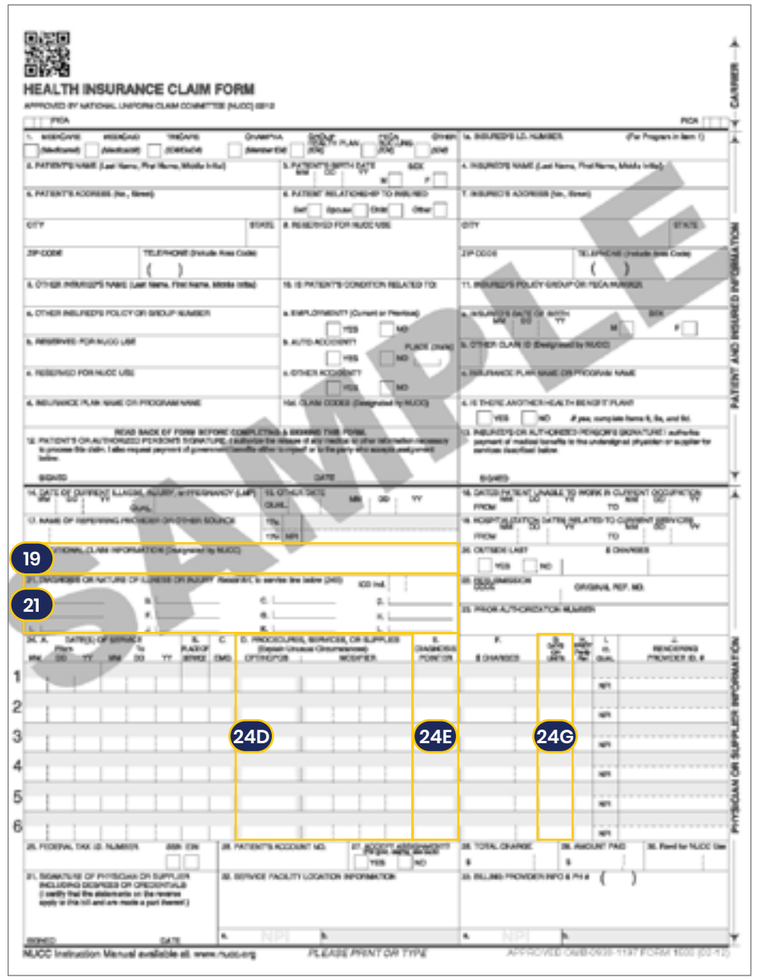
- **Pregnancy:** There is insufficient human data on the use of SUNLENCA during pregnancy. An Antiretroviral Pregnancy Registry (APR) has been established.
- **Lactation:** Individuals with HIV-1 infection should be informed of the potential risks of breastfeeding.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

SAMPLE CLAIM FORMS

The sample claim forms are for reference only and relevant to the Medicare SUNLENCA® buy-and-bill process. Commercial claim forms may look different.

CMS 1500: HCP Office



Box 19
SUNLENCA, route of administration, NDC, dosage (guidelines will vary by payer)

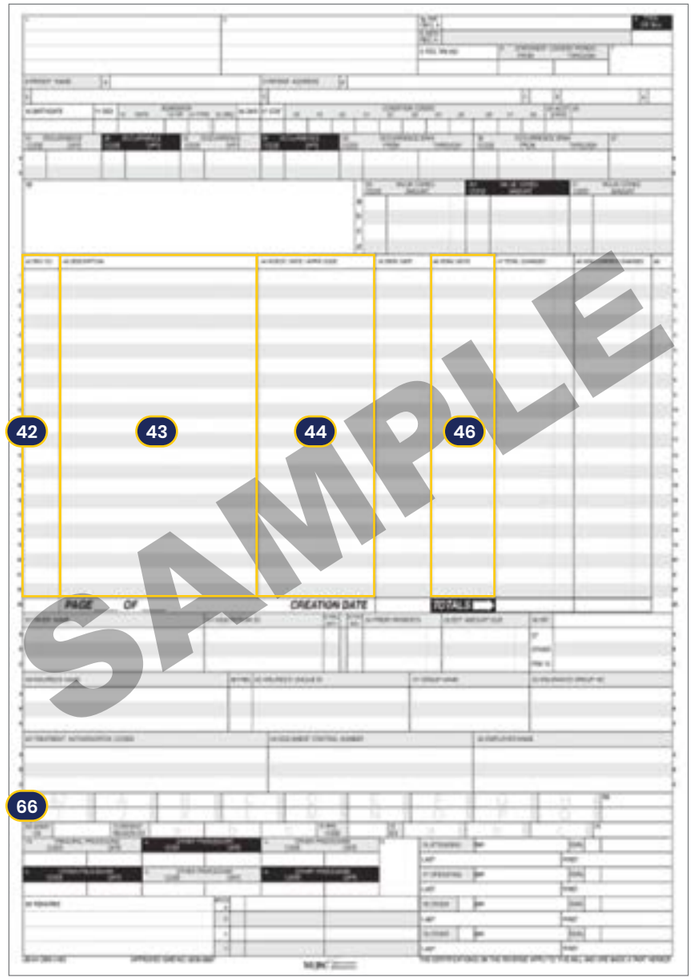
Box 21
Applicable diagnosis codes

Box 24D
Approved product and administrator coding

Box 24E
Record ICD-10-CM code from Box 21

Box 24G
Appropriate units used
- On a separate line, enter units of waste (if applicable) and any associated modifier (indicate unit to mg conversion for SUNLENCA)

CMS 1450: Hospital Outpatient



Locator 42
Suggested revenue coding for each line item billed

Locator 43
Descriptor for each line item
- Provide brand and generic names

Locator 44
Appropriate HCPCS code and CPT code

Locator 46
Appropriate units used
- On a separate line, enter units of waste (if applicable) and any associated modifier (indicate unit to mg conversion for SUNLENCA) and include in Locator 44

Locator 66
Applicable diagnosis codes

Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. This resource is not intended to be legal advice or substitute for a provider's independent judgment.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- **Coadministration:** Concomitant administration of SUNLENCA is contraindicated with strong CYP3A inducers.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

COMMONLY USED BILLING CODES

Quick reference of commonly used codes for SUNLENCA®	
Current Procedural Terminology (CPT®) code for reporting the injection of a provider-administered prescription drug	**96372** Therapeutic, prophylactic, or diagnostic injection (specify SUNLENCA); subcutaneous or intramuscular
Healthcare Common Procedure Coding System (HCPCS) code for reporting a provider-administered prescription drug	**J1961** Injection, lenacapavir, 1 mg
National Drug Code (NDC) Codes (10-digit)	**SUNLENCA Tablets (4-count blister pack) 61958-3001-1** **SUNLENCA Tablets (4-count bottle) 61958-3001-3** **SUNLENCA Tablets (5-count blister pack) 61958-3001-2** **SUNLENCA Withdrawal Needle Injection Kit 61958-3005-1** **SUNLENCA Vial Access Device Injection Kit 61958-3002-1** **SUNLENCA Vial 61958-3004-1**
NDC (11-digit)	**SUNLENCA Tablets (4-count blister pack) 61958-3001-01** **SUNLENCA Tablets (4-count bottle) 61958-3001-03** **SUNLENCA Tablets (5-count blister pack) 61958-3001-02** **SUNLENCA Withdrawal Needle Injection Kit 61958-3005-01** **SUNLENCA Vial Access Device Injection Kit 61958-3002-01** **SUNLENCA Vial 61958-3004-01**
International Classification of Disease ICD-10 diagnosis codes	**Z21** Asymptomatic HIV infection status **B20** Human immunodeficiency virus disease (HIV)

Place of service codes	
Office	**11**
Independent clinic	**49**
Off-campus outpatient hospital	**19**
On-campus outpatient hospital	**22**

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PRODUCT PACKAGING

Sunlenca® (lenacapavir) injection 463.5 mg/1.5 mL

The injection vial kit includes:

- 2 vials
- 2 withdrawal needles OR 2 vial access devices*
- 2 syringes and injection needles
- Instructions for use

*The injection kit you receive will contain either withdrawal needles OR vial access devices. Instructions for preparing the injections differ between the two kit versions. Please refer to the included Instructions for Use for the proper preparation and administration steps applicable to your kit.

The oral initiation kit includes:

- 4-tablet bottle, 4-tablet blister pack, or 5-tablet blister pack
- Welcome card (5-tablet blister packs only)

Only one initiation kit will be provided based on which initiation option you've chosen for the patient.

Store tablets and injections at a controlled room temperature (20 °C-25 °C, 68 °F-77 °F). Keep the vials in the original carton until just prior to preparation in order to protect from light. Dispense and store tablets only in original bottle or blister pack.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Immune reconstitution syndrome,** including the occurrence of autoimmune disorders with variable time to onset, has been reported in patients treated with combination antiretroviral (ARV) therapy.
- **Long-acting properties and potential associated risks with SUNLENCA:** Residual concentrations of SUNLENCA may remain in the systemic circulation of patients for up to 12 months or longer. SUNLENCA may increase exposure, and potential risk of adverse reactions, to drugs primarily metabolized by CYP3A initiated within 9 months after last injection. Counsel patients regarding the dosing schedule because nonadherence could lead to loss of virologic response and development of resistance. If virologic failure occurs, switch to an alternative regimen if possible. If discontinuing SUNLENCA, begin alternate suppressive ARV regimen within 28 weeks from last injection.
- **Injection site reactions** may occur, and nodules and indurations may be persistent. Improper administration (intradermal injection) has been associated with serious injection site reactions.

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

SUNLENCA® SPECIALTY PHARMACY

SUNLENCA can be ordered through the following designated specialty pharmacy:

CVS specialty

Phone: 1-877-602-5889
Fax: 1-877-733-3199
Website: www.cvsspecialty.com

SUNLENCA can also be ordered through the following authorized Specialty Distributors (buy-and-bill). These authorized distributors include:

CardinalHealth

Phone: 1-866-677-4844
Website: specialtyonline.cardinalhealth.com

ASD Healthcare
AmerisourceBergen

Phone: 1-800-746-6273
Website: asdorder.amerisourcebergen.com

The list of authorized distributors is updated periodically and subject to change. Please visit gilead.com/purpose/medication-access/authorized-distributors for updates.

ADDITIONAL SUPPORT FOR ACQUIRING SUNLENCA

Sunlenca® (lenacapavir) injection 463.5 mg/1.5 mL

Reimbursement Managers

For additional support with understanding general access and acquisition topics, please call 877-290-6025 to schedule an appointment with a Reimbursement Manager.

Gilead Advancing Access® Program

For information on patient support offerings, visit GileadAdvancingAccess.com/hcp or call 1-800-226-2056, Monday through Friday, 9 AM to 8 PM ET.

Advancing Access can address patient-specific questions for patients enrolled in the Advancing Access program.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- **Most common adverse reactions** (incidence ≥3%, all grades) are injection site reactions (65%) and nausea (4%).

Please see additional Important Safety Information throughout and click for full Prescribing Information for SUNLENCA.

References

1. SUNLENCA. Prescribing information. Gilead Sciences, Inc.; 2024.
2. DeMarzo A. Pharmacy's role in the prior authorization process. PriorAuthTraining.org. Published December 28, 2020. Accessed November 22, 2024. https://www.priorauthtraining.org/pharmacys-role-in-the-prior-authorization-process/

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