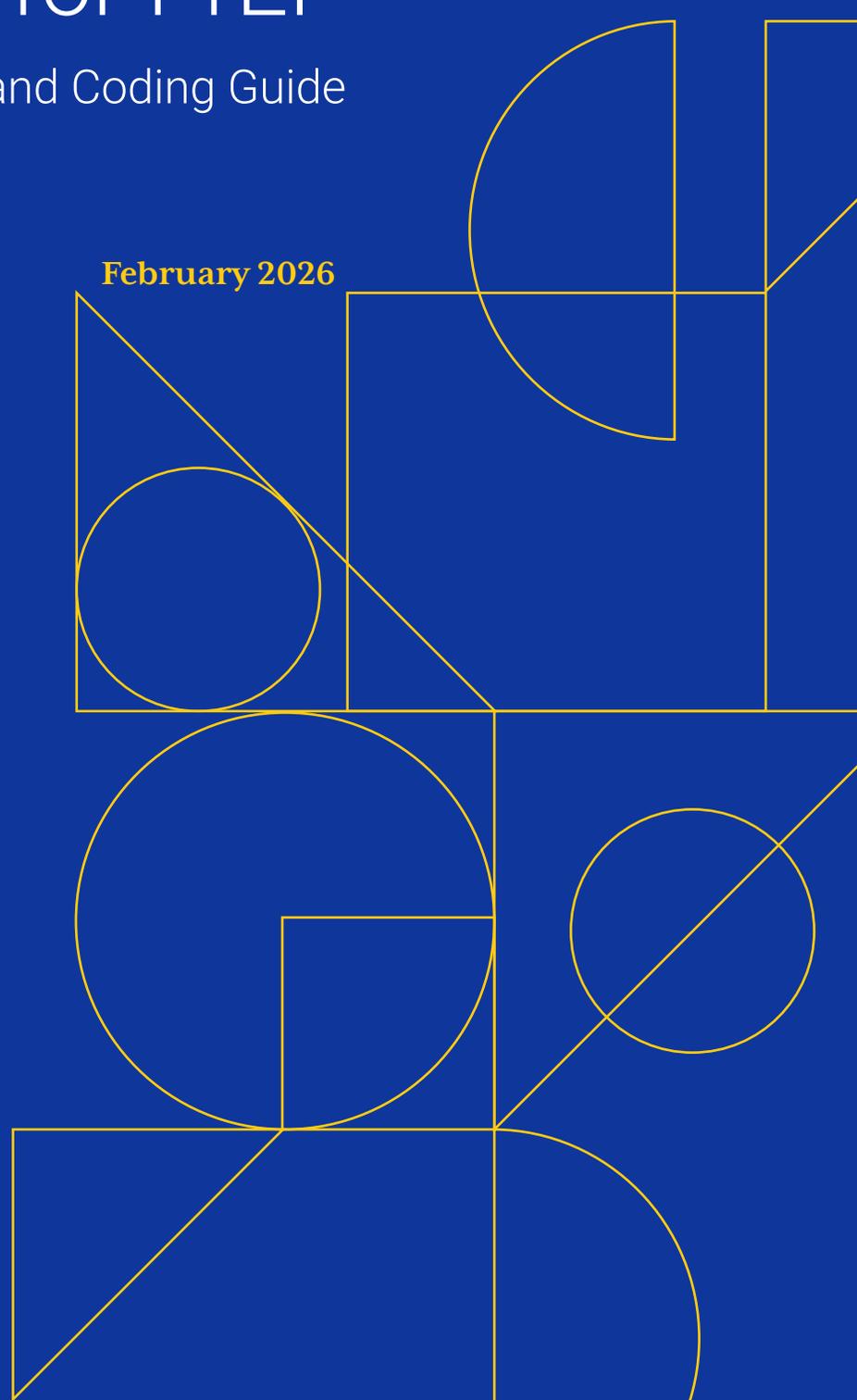


Lenacapavir for PrEP

A Supplemental Billing and Coding Guide

February 2026

An abstract geometric design composed of yellow lines on a blue background. The design features various shapes including squares, circles, and triangles, some of which are partially cut off by the edges of the page. The lines are thin and create a complex, layered pattern.

Disclaimer

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Acknowledgments

This document was developed by NASTAD (National Alliance of State and Territorial AIDS Directors) in collaboration with, Caroline Peucker, a billing and coding expert and this document's primary author. NASTAD would also like to thank the following individuals that shared their time and expertise during the development of this guide, including but not limited to:

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Nicole Elinoff	NASTAD
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Introduction

What's Changed? Integrating LEN for PrEP into PrEP Billing and Coding Guide

In June 2025, the U.S. Food and Drug Administration (FDA) approved Lenacapavir (LEN) for PrEP, making it the second long-acting injectable antiretroviral option available for PrEP.

The current list and timeline of FDA-approved PrEP medications:

- 2012 - TDF/FTC (Truvada®) was the first FDA-approved medication for use in HIV prevention.
- 2019 - The FDA approved the second drug, TAF/FTC (Descovy®), to prevent HIV transmission.
- 2020 - The FDA approved the generic version of TDF/FTC for commercialization.
- 2021 - The FDA approved the first injectable treatment for HIV prevention, Cabotegravir extended-release injectable suspension (Apretude®)
- 2025 - The FDA approved long-acting injectable LEN for PrEP (Yeztugo®).

Purpose and Scope

This supplement provides billing and coding guidance for LEN for PrEP oral and injectable components, as well as provider administration for injectable PrEP. It is designed for use alongside the [NASTAD Billing Coding Guide for HIV Prevention](#) by outpatient clinics, public health programs, Federally Qualified Health Centers (FQHCs)/Rural Health Centers (RHCs), hospital-based clinics, pharmacies, and payer billing teams. This supplement is designed to serve as a strategic tool for providers to develop a flexible plan for implementing LEN for PrEP within their organizations. The "Obstacles to Payments" in the 2023 Guide and the Billing Alerts in this supplement identify potential roadblocks to accurate claim processing and payment. Although some clinical documents¹ may be referenced in this billing and coding guide, it is not a clinical practice guide.

Billing Team Alert!

At the time of this publication, injectable LEN for PrEP has not received a Grade A or B recommendation from the U.S. Preventive Services Task Force (USPSTF). As a result, patients may still be responsible for copayments or coinsurance costs required by their insurance plans.

¹ Centers for Disease Control (CDC) - [Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis – United States, 2025](#)

HCPCS and ICD-10 Coding

Several sets of codes were developed to translate healthcare services, diagnoses, procedures, equipment, and supplies into a standard alphanumeric language used to communicate between providers and payers. For a complete description and explanation of these code sets, see Section II, Codes and Coding for Services, starting on page 10, in the [NASTAD Billing Coding Guide for HIV Prevention](#). The Centers for Medicare and Medicaid Services (CMS) maintains the HCPCS Level II code set, which is typically used to describe services and supplies not described by CPT® codes. For this PrEP supplement, HCPCS codes are used to describe drugs and drug administration.

Prior Authorization Alert!

Verify that the correct payer prior authorization guidelines are applied. Coverage requirements for LEN for PrEP do not apply to Len for PrEP. Providers and staff should be aware that indicating only **Lenacapavir** under a treatment authorization may result in the incorrect payer policy being applied.

HCPCS Coding for LEN for PrEP and Administration and Testing

The HCPCS code for LEN for PrEP has two possible codes depending on the date of service. The earliest date for coding is the date the FDA approved LEN for PrEP.

Effective Date	HCPCS Code	Description
6/18/2025–9/30/2025	J0799	PrEP, FDA-approved, not otherwise classified (NOC) ² (A temporary code for LEN for PrEP until a more specific code was created)
On/after 10/01/2025	J0738	Injection, Lenacapavir, 1 mg (PrEP)
On/after 10/01/2025	J0752	Oral, Lenacapavir, 300 mg (PrEP)

Billing Team Alert!

Payer formularies are lists of covered medications. Each payer—including commercial insurers, state Medicaid programs, and the federal Medicare program—maintains its own schedule and process for managing its formulary. **Establishing a systematic follow-up process for payer inquiries with inconclusive coverage determinations can greatly support both the billing team and the patient.**

² Billing and Coding: Additional Claim Documentation Requirements for Not Otherwise Classified (NOC) Drugs and Biological Products with Specific FDA Label Indications <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=54880the>

Injectable LEN for PrEP

LEN for PrEP is administered as two subcutaneous injections (1.5 mL) in the abdomen, once every six months, along with oral lead-in doses (two on the day of injection and two the following day).

For each injection encounter, the provider administering the LEN for PrEP will report:

1. An administration code:

- **96372** -Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)
OR
- **G0012** - Injection of pre-exposure prophylaxis (prep) drug for HIV prevention, under skin or into muscle

G0012 is a HCPCS code effective January 2, 2024, created by CMS specifically for Medicare use in the PrEP NCD. Other government and commercial payers may adopt this HCPCS code for PrEP injection. Always refer to the specific payer policy to determine the appropriate injection administration code.

Please refer to NASTAD's PrEP for HIV CMS National Coverage Determination (NCD) Supplement for Medicare-specific guidance.

2. A drug code:

For dates of service **6/18/2025–9/30/2025**

- J0799 - FDA-approved prescription drug, only for use as HIV pre-exposure prophylaxis (not for use as treatment of HIV), not otherwise classified **for the Lenacapavir**
J0799 is a "not otherwise classified" code. A NOC code is an HCPCS code that represents a medical service or supply for which a more specific code is not available. Because NOC codes may be used for more than one drug, additional information is needed on the claim to identify the drug clearly. Follow payer-specific guidelines for reporting in the proper fields.
 - Name of drug
 - Report only one unit of J0799
 - Dosage and strength
 - National Drug Code (NDC)³

For dates of service **10/1/2025 – present**

- **J0738** -Injection, Lenacapavir for PrEP 1 mg, FDA-approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV)
 - Report one unit per 1 mg administered
 - Report appropriate NDC if required by the payer

3. ICD-10 code

- Link ICD-10 code Z29.81 - Encounter for HIV pre-exposure prophylaxis should be linked to both the injection and the administration. **Z29.81 must always be reported in the primary position for PrEP injection visits.**
- Code in the second and subsequent ICD-10 positions screening codes for specific tests ordered, any applicable risk factors for HIV, and clinically relevant comorbidities for the service. Refer to the PrEP payer-specific policy for ICD-10 requirements.

³ The National Drug Code (NDC) is a universal 10-digit, 3-segment product identifier for human drugs in the United States, serving as a unique identifier for drugs and their packaging. It identifies the drug manufacturer, the specific drug product, and its package size and is found on prescription and non-prescription medication packages and their inserts. <https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information>

4. Screening Tests⁴

- HIV antigen/antibody testing
- STI Testing (vaginal, oral, rectal, urine, or blood as needed) per PrEP protocols

If other services are rendered on the same date by the same provider, refer to Page 19 of the [NASTAD Billing Coding Guide for HIV Prevention](#) for information on related services. For example, if a documented and separately identifiable visit is reported on the same day as the 96372 injection administration code, append modifier 25 to the visit code.

Oral Lenacapavir

The LEN for PrEP injection regimen is accompanied by oral loading doses at initiation and an oral bridging dose if the continuation visit is delayed beyond 28 weeks, plus 6 months and 2 weeks. The oral loading doses are self-administered. Self-administered drugs are medications that can be used on an outpatient basis and do not typically require clinical supervision or assistance to consume, apply, or inject. With limited exceptions, routes of administration, including but not limited to oral and topical routes, are frequently designated as self-administered. Most self-administered drugs are covered under a patient's pharmacy benefit, meaning they are dispensed by a retail or specialty pharmacy and billed via pharmacy claims (NDC-based).

However, **Lenacapavir tablets** may be covered under a patient's **medical benefit** instead. When this occurs, the provider can obtain the product through **buy-and-bill**, meaning the clinic purchases the drug in advance, keeps it in office stock, and dispenses it directly to the patient at the point of care. These National Drug Codes are universal product identifiers found on all non-prescription and prescription medication packages.

Billing Team Alert!

LEN for PrEP may be covered under a patient's medical benefit or pharmacy benefit. The most reliable way to confirm the appropriate coverage channel is to contact the payer directly—either online or by phone. The benefit category under which Len for PrEP is covered will determine the proper acquisition and billing process for the medication.

HCPCS

- J0752⁵ - Oral, Lenacapavir, 300 mg, FDA-approved prescription, only for use as HIV pre-exposure prophylaxis (not for use as treatment for HIV)

ICD-10 code

- Link ICD-10 code Z29.81 - Encounter for HIV pre-exposure prophylaxis should be linked to both the injection and the administration. Z29.81 must always be reported in the primary position for PrEP injection visits.
- Code in the second and subsequent ICD-10 places screening codes for specific tests ordered, any applicable risk factors for HIV, and clinically relevant comorbidities for the service. Refer to the PrEP payer-specific policy for ICD-10 requirements.

⁴ For coding descriptions and billing recommendations, see [NASTAD Billing Coding Guide for HIV Prevention](#), Section VII. Labs for PrEP Initiation and Supplemental Testing.

⁵ HCPCS code J0752 should be used by providers billing under the medical benefit, such as when dispensing the oral lead-in or bridging doses directly from clinic stock. Oral loading doses obtained by the patient from a specialty pharmacy are billed by the pharmacy using the drug's NDC.

For additional resources and information on Lenacapavir for PrEP, visit [NASTAD's long-acting injectable PrEP microsite](#).

Glossary

Entry	Definition & Links
Benefit Channel	A benefit channel in health insurance refers to the specific way health services are covered or managed. Examples include medical benefits for hospitals and providers, procedures, or Pharmacy benefits that cover prescription drugs.
Buy & Bill	A process by which a physician or practice can purchase medications, administer them in the office, and bill directly to the payer.
Cabotegravir	CAB is a single antiretroviral drug given as an intramuscular injection every two months to prevent HIV.
CDC	Centers for Disease Control and Prevention CDC is the nation's leading science-based, data-driven, service organization that protects the public's health. https://www.cdc.gov/
CMS	Center for Medicare and Medicaid Services: is the U.S. federal agency that works with state governments to manage the Medicare program, and administer Medicaid and the Children's Health Insurance program. https://www.cms.gov/
Cost Share	This term refers to the share of medical care costs covered by your insurance that the patient pays out of pocket. This term can include deductibles, co-insurance, or co-payments. It does not refer to balances due to services that are not covered.
CPT	Current Procedural Terminology (Level I codes) are codes created by the AMA that offer a uniform language for coding medical services. The US DHHS approves CPT codes as the US national coding set. This code set describes the services provided to a patient. https://www.ama-assn.org/practice-management/cpt
FDA Approval	FDA approval of a drug means that the Center has reviewed data on the drug's effects for Drug Evaluation and Research, and the drug is determined to provide benefits that outweigh its known and potential risks for the intended population. The drug approval process takes place within a structured framework.
Formulary	A drug formulary is a list of medications that are covered by a health insurance plan. It includes a list of medications, drug tiers based on cost and clinical value, and coverage rules.
FQHC	Federally Qualified Health Center
HCPCS	Healthcare Common Procedure Coding System: (say hick-picks). These are Level II HCPCS codes, which identify products, supplies, and services not included in CPT. HCPCS codes are 5 characters: one alpha followed by 4 numeric.

ICD-10	International Classification of Diseases, Tenth Revision. ICD-10 is the system of codes used by providers to classify signs, symptoms, illness, or injury. These codes support the medical necessity of the CPT codes, which describe the service.
Medical Policies (Payer Policy)	Plan/Payer documents that indicate clinical criteria used to support coverage determinations for specific medical, surgical, or dental procedures, devices, or medications. They may also indicate the billing format for claims to ensure that information for successful coverage is communicated, e.g., CPT, ICD, and Modifiers.
Modifier	Modifiers are two-digit codes appended to CPT or HCPCS codes to indicate that specific circumstances altered a service.
NASTAD	National Alliance of State and Territorial AIDS Directors. NASTAD is a leading, nonpartisan nonprofit association that represents public health officials who administer HIV and hepatitis programs in the U.S.
NCD	National Coverage Determination
NDC	National Drug Code (NDC) is a universal 10-digit, 3-segment product identifier for human drugs in the United States, serving as a unique identifier for drugs and their packaging. It identifies the drug manufacturer and the specific drug product, and its package size, and is typically found on the labels of prescription and non-prescription medication packages, as well as their inserts.
NOC	Not Otherwise Classified. NOC Codes are used when no specific Healthcare Common Procedure Coding System (HCPCS or CPT) code exists for a particular item, service, or drug.
Payer	A healthcare organization that provides health coverage to members. A payer will have many plans under which members are covered.
Plan	A specific menu of health benefits an employer, union, or other group sponsor provides to a particular group to pay for health care services.
Prior Authorization	Prior authorization is an insurance company's process of reviewing and approving a medical service, prescription, or procedure before it is provided to ensure it's medically necessary and to control costs.
RHC	Rural Health Center
Specialty Pharmacy	A pharmacy that focuses on high-cost, high-touch, or limited distribution medications. It typically manages rare, chronic, and often complex medical conditions that require an increased level of patient management or counseling.
TAF/FTC	emtricitabine coformulated with tenofovir alafenamide (trade name Descovy®)

TDF/FTC	emtricitabine coformulated with tenofovir disoproxil fumarate (trade name Truvada®)
USPSTF	The U.S. Preventive Services Task Force is an independent, volunteer panel of national experts in disease prevention and evidence-based medicine. The Task Force works to improve the health of people nationwide by making evidence-based recommendations about clinical preventive services
USPSTF Grade A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
USPSTF Grade B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.

This NASTAD Billing Supplement was developed with support from Gilead Sciences. The views expressed are solely those of NASTAD.