NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Alister F. Martin, MD, MPP
Commissioner

Twice-Yearly Injectable Lenacapavir for HIV Pre-Exposure Prophylaxis (PrEP)

- Twice-yearly injectable lenacapavir is now recommended as a pre-exposure prophylaxis (PrEP) option for people at risk of HIV acquisition who meet eligibility criteria.
- Lenacapavir is administered as a subcutaneous injection every six months, expanding PrEP options with a twice-yearly dosing schedule compared to daily oral medication or bimonthly intramuscular injections.
- As lenacapavir for HIV PrEP is a newly approved medication, insurance policies are still evolving and coverage will vary.

February 23, 2026

Dear Colleague:

In June 2025, the U.S. Food and Drug Administration (FDA) approved lenacapavir, branded as Yeztugo, a twice-yearly injectable medication for use as HIV PrEP. Lenacapavir was previously approved for HIV treatment under the brand name Sunleca. Lenacapavir is the first ultra long-acting injectable medication approved for PrEP, with a dosing schedule of every six months. Lenacapavir is approved for use in adolescents and adults, regardless of sex assigned at birth or gender identity. Lenacapavir is administered as a subcutaneous injection, allowing for less frequent dosing than other available PrEP options (daily oral medication and bimonthly intramuscular injectable medication). This addition expands choice and flexibility within the HIV prevention toolkit—whether lenacapavir is a preferred method or an alternative for those who face challenges taking other PrEP regimens—and will help increase PrEP access and uptake across communities at increased risk of HIV acquisition.

Clinical Recommendation and Eligibility
In September 2025, the CDC issued a strong recommendation, based on high certainty of evidence, for lenacapavir as an HIV PrEP option. The assessment was based on the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) framework applied to two large randomized controlled trials demonstrating lenacapavir's efficacy and safety over 52 weeks of follow-up. The CDC applied the GRADE framework to evaluate critical outcomes, including HIV incidence, adverse events, and injection site reactions, and found lenacapavir to be highly effective with no significant safety concerns beyond mild-to-moderate injection site reactions that rarely led to discontinuation.

Lenacapavir is indicated for adults and adolescents who:

- Weigh ≥35 kg (≥77 lbs)
- Have risk factors for HIV acquisition, including but not limited to: recent diagnosis of a bacterial STI; are a man who reports sex with men (MSM); have a sexual partner with

HIV who is not virally suppressed; exchange of sex for money or other goods; history of incarceration; inconsistent condom use with a sexual partner with an unknown HIV status; or shared injection drug use equipment

Note: The NYC Health Department is committed to ensuring equitable access to biomedical HIV prevention interventions for all communities at risk of HIV. While the CDC's recommendation of lenacapavir as a PrEP option mentions MSM, it does not specifically mention transgender or gender nonbinary people. However, the medication's efficacy was established in the PURPOSE 2 trial that included transgender and gender nonbinary participants. As such, lenacapavir should be offered to all patients who would benefit from it.

Minors' Right to Consent to Sexual Health Care Under New York State Law

Lenacapavir for HIV PrEP does not have an age threshold for use and should be offered to adolescent patients who would benefit from PrEP. Minors in New York State have the right to consent to sexual health care, including PrEP, without parent/guardian notification or consent. Providers may not release medical or billing records related to this care to a minor patient's parent/guardian without the minor patient's permission.

Coverage Under Federal and New York State Law

Currently, federal and state mandates that eliminate patient cost-sharing for HIV PrEP do not include lenacapavir. Under the Affordable Care Act and New York State law, commercial health insurers and Medicaid must cover PrEP medications recommended by the U.S. Preventive Services Task Force (USPSTF) and related services (e.g., clinic visit co-pays, laboratory services) without patient cost-sharing. Currently, USPSTF-recommended PrEP medications include tenofovir disoproxil fumarate and emtricitabine, branded as Truvada; tenofovir alafenamide and emtricitabine, branded as Descovy; and cabotegravir, branded as Apretude. The USPSTF has not expanded its PrEP recommendation to include lenacapavir; however, lenacapavir currently appears in the New York State Medicaid Pharmacy Program (NYRx) formulary, though coverage may be subject to plan-specific requirements.

As insurance policies evolve and coverage takes shape, providers should assist patients in contacting their insurers to determine coverage for lenacapavir; advocate with insurers to ensure coverage, as needed; and connect patients with patient assistance programs for those facing coverage barriers. For patients who are uninsured or underinsured, the New York State PrEP Assistance Program (PrEP-AP) may help cover costs. PrEP-AP reimburses health care providers for costs associated with clinic visits and laboratory services. Providers should regularly check the New York State Department of Health's Payment Options for Adults and Adolescents for PrEP webpage for updates.

The NYC Health Department recommends that providers:

- Familiarize themselves with lenacapavir as an HIV PrEP option and discuss it with patients who might benefit from a twice-yearly injectable prevention option

- Update clinic policies and protocols to include lenacapavir as part of comprehensive PrEP offerings
- Recommend same-day lenacapavir initiation even while waiting for the patient's laboratory-based HIV RNA test result, provided the patient has a negative rapid HIV antigen/antibody test and has no symptoms of acute HIV infection
- Recommend STI screening three to four times a year for patients taking lenacapavir for PrEP, regardless of the medication's twice-yearly dosing schedule; and remind patients that lenacapavir does not protect against other STIs
- Ensure that clinic staff receive support on lenacapavir procurement, storage, scheduling, and billing procedures to support seamless implementation

Open conversations and shared decision making will ensure patients choose the regimen that best fits their needs and preferences. When counseling patients on HIV PrEP, providers should discuss the advantages of reduced dosing frequency, the nature of subcutaneous injections, potential side effects and drug-drug interactions to medications and substances, what to do if a scheduled dose is missed, and the importance of adherence.

Sincerely,

Sarah L. Braunstein, PhD, MPH
Acting Deputy Commissioner for the Division of Disease Control
Assistant Commissioner for the Bureau of Hepatitis, HIV, and STIs
New York City Department of Health and Mental Hygiene

Resources

- CDC's Clinical Recommendation for the Use of Injectable Lenacapavir as PrEP — U.S., 2025
- New York State HIV Clinical Guidelines Program's PrEP to Prevent HIV and Promote Sexual Health
- National Clinician Consultation Center's PrEPLine
- NYC Health Department's Injectable PrEP: A User's Guide
- New York State Department of Health AIDS Institute's Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis (PrEP)
- NYRx, the New York Medicaid Pharmacy Program
- NYRx Drug Coverage Overview: Yeztugo