HIV Preexposure Prophylaxis (PrEP) Clinical Recommendations

Update December 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical evidence is available. The purpose of this document is to assist practitioners in clinical decision-making and to standardize and improve the quality of patient care. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient.
The Product Information should be consulted for detailed prescribing information. The VA National PBM-MAP-VPE Cabotegravir and Lenacapavir Drug Monographs and Cabotegravir, Lenacapavir & Tenofovir Alafenamide/Emtricitabine (FTC/TAF) Criteria for Use are available at www.pbm.va.gov.

Background:

By the end of 2022 an estimated 1.2 million people in the United States had a diagnosis of HIV, of which only 87% were aware of their infection.[1] HIV preexposure prophylaxis (HIV PrEP) with oral or injectable medications can assist in reduction of HIV acquisition in at risk individuals, including those with high-risk sexual or injection drug use behaviors.[2] The CDC estimated 31,800 people in the United States were infected with HIV in 2022, with gay and bisexual male populations making up the majority of new cases.[1] In 2019, the Department of Health and Human Services (DHHS) announced a Federal initiative to end the HIV epidemic in the United States by 2030.[3] Within VHA, over 31,000 Veterans with HIV are managed, between 400-500 new cases are identified and linked to care each year and many more are at risk of HIV acquisition.[4] The need for effective methods to prevent HIV is an important factor in the overall health and wellness of the Veteran population.

Medications for HIV PrEP have been shown in clinical trials to greatly reduce the risk of HIV acquisition when added to nonpharmacologic preventative behavior education. Tenofovir disoproxil fumarate with emtricitabine (**TRUVADA – FTC/TDF**) was approved for PrEP as a once daily oral tablet in 2012 for individuals at high risk of HIV sexual acquisition. FTC/TDF became available as low-cost generic preparations in 2021.[6] Tenofovir alafenamide with emtricitabine (**DESCOVY – FTC/TAF**) was approved in 2019 for individuals at risk for HIV-1 from sexual acquisition, excluding individuals at risk from receptive vaginal sex (e.g. female at birth).[7] Cabotegravir (**APRETUDE – CAB**) was approved in 2021 as a long-acting injectable formulation for those at risk for HIV sexual acquisition, including men who have sex with men (MSM), transgender women (TGW), cisgender men and women.[8] Most recently, lenacapavir **(YEZTUGO - LEN**), a multistage HIV-1 capsid inhibitor, was approved in 2025 as a long-acting subcutaneous injection for those at risk for HIV-1 acquisition through all types of sexual exposure.[9] Currently, nearly 5,000 Veterans are receiving HIV PrEP through VHA, but others would benefit from such therapy.

FTC/TDF, FTC/TAF, CAB and LEN have all been shown to be safe and effective as HIV PrEP in randomized controlled trials. Patient specific factors such as risk for vaginal acquisition of HIV, renal function, presence of osteoporosis, medication adherence, and costs (drug, monitoring and administration) should be considered when selecting between available agents. CDC/U.S. Public Health Service guidelines updated in 2019 designated HIV PrEP a recommended preventative service with an A rating, denoting good and consistent scientific evidence. Based on this, DHHS determined HIV PrEP was required to be covered by most commercial insurers and some Medicaid programs, with no out of pocket costs to patients.[3] The 2021 update to these guidelines outline appropriate use of PrEP and considerations for selection and monitoring of each of these medications.[2] As a result, these VHA Clinical Recommendations are intended to assist providers in selecting between the available agents based on patient factors. Key recommendations to the CDC guidelines are listed below, and key trial data for studies leading to an FDA indication are reviewed in **Table 1.** This is followed by a review of each drug. An algorithm to assist providers in making decision between available agents is in an appendix to this document.

CDC/USPSTF 2021and 2023 Guideline Recommendations:

- All sexually active patients should receive information about PrEP. (IIIB)
- For men and women, PrEP with daily FTC/TDF is recommended for HIV prevention in those who report sexual behaviors or injection practices (in persons who inject drugs) that place them at substantial ongoing risk of HIV acquisition. (IA)
- For **MEN only** (including TGW), PrEP with daily FTC/TAF is recommended as an option for HIV prevention in those who report sexual behaviors that place them at substantial ongoing risk of HIV acquisition. (IA)
    - PrEP with FTC/TAF is being studied in women (PURPOSE 1) but is **not yet recommended for persons at risk for vaginal acquisition of HIV**.
- PrEP with intramuscular cabotegravir (CAB) injection or subcutaneous lenacapavir (LEN) injection is recommended for HIV prevention in those who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. (IA)
- Acute and chronic HIV infection must be EXCLUDED by symptom history and HIV testing immediately before any PrEP regimen is prescribed. (IA)
- HIV infection should be assessed at least every 3 months for patients taking daily oral PrEP, every 2 months for patients receiving CAB injections for PrEP, and every 6 months for patients receiving lenacapavir so that persons with incident infection do not continue taking it. (IA)

Table 1: Select Trials of HIV PrEP (LEN, CAB, FTC/TDF, FTC/TAF)

Drug	Trial Design	Efficacy	Safety	Additional Considerations
Lenacapavir (YEZTUGO)	PURPOSE 1[10] Study Design: Phase 3, randomized, double-blind, control trial conducted in South Africa and Uganda. Population: Adolescent girls and young women Study Groups: Randomized 2:2:1 to receive subcutaneous lenacapavir (n=2,134), oral FTC/TAF (n=2,136) or oral FTC/TDF (n=1,068) All groups received the alternate subcutaneous or oral placebo MITT that excluded people adjudicated to have had HIV infection on date of randomization Endpoint: Primary - Incident HIV infection. Secondary – incidence rate ratio comparing HIV incidence with lenacapavir or FTC/TAF with the HIV incidence among those receiving FTC/TAF	55 new HIV cases during trial: 0 with lenacapavir (0/100 person-years PY); 39 with FTC/TAF (2.02/100 PY); 16 with FTC/TDF (1.69/100 PY). Of note: adherence to oral treatments was low. HIV incidence with: lenacapavir compared to background HIV incidence (incidence rate ratio, 0.00; 95% CI, 0.00 to 0.04; P<0.001) Lenacapavir compared to FTC/TDF (incidence rate ratio, 0.00; 95% CI, 0.00 to 0.10; P<0.001). FTC/TAF compared to background HIV incidence (incidence rate ratio, 0.84; 95% CI, 0.55 to 1.28; P=0.21), FTC/TAF compared to FTC/TDF (incidence rate ratio, 1.20; 95% CI, 0.67 to 2.14)	Adverse events (including grade 3 or higher and serious events) were similar across groups. More injection site reactions (ISRs) with LEN (68.8% v. 34.9%) including subcutaneous nodules (63.8% v. 16.6%); 0.2% v 0 discontinued due to ISRs in LEN group.	Black box warning: individuals must be tested for HIV-1 with a test cleared by the FDA for acute HIV before EACH dose of LEN. Do not initiate LEN unless negative infection status is confirmed. Drug resistant HIV-1 variants have been identified with use of LEN in persons with undiagnosed HIV-1 infection. Transition to a complete HIV-1 treatment regimen if HIV-1 is acquired while receiving LEN. Each dose given as 2 subcutaneous injections administered by healthcare provider. Improper administration (intradermal injection) has been associated with serious injection site reactions Residual concentrations of LEN may remain in systemic circulation for up to 12 months or longer
	PURPOSE 2 [11] Study Design: Phase 3, randomized, double-blind, active-controlled trial conducted in the US, South America, South Africa and Thailand. Population: Cisgender gay, bisexual and other men, transgender women and men, and gender non-binary individuals Study Groups: Randomized 2:1 to receive subcutaneous lenacapavir (n=2,179) or oral FTC/TDF (n=1,086) All groups received the alternate subcutaneous or oral placebo MITT that excluded people adjudicated	New HIV cases during trial: 2 with lenacapavir (0.10/100 PY; 95%CI 0.01 to 0.37); 9 with FTC/TAF (0.93/100 PY; 95%CI 0.43 to 1.77); Of note: all individuals in the FTC/TDF group with new HIV infection had low or no adherence to FTC/TDF. HIV incidence with: lenacapavir compared to background HIV incidence: incidence rate ratio, 0.04; 95% CI, 0.01 to 0.18; P<0.001)	Adverse events (including grade 3 or higher and serious events) were similar across groups. More injection site reactions (ISRs) with LEN (83.2% v. 69.5%) including subcutaneous nodules (63.4% v. 39.2%); 1.2% v 0.3% discontinued due to ISRs in LEN group.	

	to have had HIV infection on date of randomization Endpoint: Primary – New HIV infection. Rate of Incident HIV-1 infections per 100 person-years (PY) with LEN compared to background HIV incidence and compared to FTC/TDF.	Lenacapavir compared to FTC/TDF: incidence rate ratio, 0.11; 95% CI, 0.02 to 0.51; P<0.002).		
Cabotegravir (APRETUDE)	HPTN 083[13] Study Design: Phase 3, randomized, double-blind, active control trial conducted in South America, Asia, South Africa, and the U.S. Population: Adult men who have sex with men (MSM) and transgender women (TGW) at high risk for HIV Study Groups: Randomized to receive CAB (n=2,284) or FTC/TDF (n=2,284) Included 5-week lead in with oral cabotegravir (or placebo in the FTC/TDF group) The FTC/TDF group received placebo IM injections	52 new HIV cases during trial, 12 with CAB (0.37/100 person-years PY) and 39 with FTC/TDF (1.22/100 PY) HR 0.31 (95% CI 0.16 to 0.58; p<0.001) CAB associated with 66% reduction in the risk of HIV acquisition compared to the FTC/TDF	More injection site reactions (ISRs) with CAB (81% v. 31%) Slightly greater increases in weight and lipid measurements with CAB No difference in hepatotoxicity leading to discontinuation Minimal difference in renal adverse events (7% of CAB and 8% FTC/TDF had decrease in CrCl ≥ grade 3)	Black box warning: individuals must be tested for HIV-1 with a test cleared by the FDA for acute HIV before EACH dose of CAB Risk of resistance due to suboptimal concentrations during pharmacokinetic tail (should start oral PrEP within 8 weeks of last dose and continue to test for HIV quarterly for 12 months after discontinuation) Each dose given as gluteal IM injection administered by healthcare provider Oral lead is optional
	HPTN 084[14] Study Design: Phase 3, randomized, double-blind, active control trial conducted in multiple sites in Africa Population: Cisgender women at high risk for HIV acquisition Study Groups: Participants randomized to CAB (n=1614) or FTC/TDF (n=1610). Included 5-week oral lead-in	3 HIV infections with CAB (0.2%) & 36 with F/TDF (1.86%) HR 0.12 (95% CI 0.05 to 0.31; p<0.0001) CAB associated with 88% reduction in the risk of HIV acquisition vs. FTC/TDF	Mild to moderate ISRs were the most common adverse event No difference in grade 2 or higher ADEs, including decreased CrCl (72% CAB vs. 74% FTC/TDF) No difference in grade 3 lab abnormalities, or DC for hepatic ADE	If discontinuing CAB and restarting daily oral F/TDF or F/TAF start within 8 weeks after last injection

Tenofovir Alafenamide/ Emtricitabine (DESCOVY)	DISCOVER[15] Study Design: Phase 3, randomized, double-blind, active-controlled, non-inferiority trial conducted in 11 European and North American countries Population: MSM/TGW ≥ 18 years of age with one of the following: two or more condom-less anal sex episodes during the prior 12 weeks diagnosis of syphilis, rectal gonorrhea, or rectal chlamydia in the 24 weeks prior to enrollment. Study Groups: Daily oral dose of either F/TDF or F/TAF.	FTC/TAF demonstrated non-inferior efficacy to FTC/TDF 15 infections occurred in the FTC/TDF group (0.34/100 PY) and 7 in the FTC/TAF group (0.16/100 PY). IRR 0.47 (95% CI 0.19 to 1.15) No resistance detected among persons with HIV infections occurring after baseline 88% of subjects who acquired HIV during the study (after excluding likely baseline cases) had tenofovir diphosphate concentrations consistent with < 2 doses / week on the day of HIV diagnosis	FTC/TDF & FTC/TAF were equally well tolerated with low rates of side- effects Lipid-lowering agents were started more in the FTC/TAF group (43 [1.6%]) vs. the FTC/TDF group (21 [0.8%]; p=0.008) In the BMD sub-study, those on FTC/TDF had decreased BMD at the hip (-0.99%) and spine (-1.12%) vs. stable parameters with FTC/TAF No clinically significant difference in declines in median eGFR was noted (-2 ml/min with FTC/TDF vs. +1.8 mL/min with FTC/TAF) although differences in renal biomarkers favored FTC/TAF	Not to be used in women (unless not at risk for vaginal HIV infection) No generic currently available Limit to ≤ 90-day supply Consider in patients with multiple risk factors for significant renal dysfunction or CrCl 30-60 mL/min Cannot be used if CrCl < 30 mL/min
Tenofovir Disoproxil Fumarate/ Emtricitabine (TRUVADA)				Generic Product Available Limit to ≤ 90-day supply Cannot be used if CrCl < 60 ml/min

VHA VANF Clinical Recommendations:

FTC/TDF [2,6,15]

Tenofovir disoproxil fumarate and emtricitabine (FTC/TDF; TRUVADA) has a long record of safety and efficacy for HIV preexposure prophylaxis. Studies have demonstrated this in a wide variety of patient populations, including MSM, cisgender women, patients in HIV discordant relationships, and TDF alone was effective in preventing HIV in persons who inject drugs (PWID). The availability of a low-cost generic preparation provides the opportunity to treat more patients within specific budgetary constraints. The 2021 CDC/U.S. PHS Guidelines state for most patients, there is no need to switch from FTC/TDF to FTC/TAF. In the DISCOVER trial, the only large, randomized trial comparing FTC/TDF to FTC/TAF, the latter was found to be non-inferior in preventing HIV infection with overall similar safety. In these relatively young patients with baseline CrCl ≥ 60 mL/min, small differences were noted in change in bone mineral density parameters, renal biomarkers and CrCl, but the clinical significance of these findings in most patients is likely to be small in most PrEP patients. The guidelines state specific bone mineral density testing is optional as no increase in fragility fractures were noted and BMD parameters tended to stabilize.

- **FTC/TDF** is on the VA National Formulary (VANF) as a prior authorization (PA-F) medication and should be prescribed by Infectious Diseases, HIV, or other PrEP providers who have experience in managing patients on HIV PrEP. TMS courses are available to train providers on how to provide PrEP safely.
    - FTC/TDF is the workhorse product for those patients with CrCl ≥ 60 mL/min.
    - Most patients should initially be treated with FTC/TDF, unless there are circumstances that warrant alternative therapy, described under FTC/TAF, CAB and LEN below.
    - Patients started on FTC/TDF should receive adherence counseling and support.
    - Patients should be educated on side effects, particularly those during the first month of therapy.

- Patients should be provided no more than a 90-day supply of medication without refills.
- HIV should be excluded at baseline, and at least every 3 months while on therapy.
- CrCl should be monitored at least every 6 months for those aged ≥ 50 years or with baseline CrCl < 90 ml/min, and at least every 12 months for other patients.
- For additional monitoring recommendations (e.g., hepatitis B screening, screening for sexually transmitted infections): ***refer to the CDC/USPSTF Guidelines.***[2,5]

FTC/TAF [2,7,15]

Tenofovir alafenamide and emtricitabine (FTC/TAF; DESCOVY) was approved for HIV PrEP in 2019, based on the previously discussed DISCOVER trial in men and TGW. It was generally well-tolerated in that study. FTC/TAF is currently under investigation for women but is not currently recommended by the CDC guidelines for individuals at risk of HIV acquisition through vaginal intercourse. It can be used in patients with a CrCl ≥ 30 mL/min, highlighting a population ineligible for treatment with FTC/TDF (CrCl 30- 59 mL/min).

The DISCOVER trial demonstrated only small differences between FTC/TDF and FTC/TAF in bone mineral density changes and CrCl. However, it is important to note that the VA population receiving HIV PrEP is likely older and with more comorbidities than the population examined in the DISCOVER Trial. As a result, it is reasonable to consider FTC/TAF in individuals with CrCl >60 ml/min who have multiple risk factors for significant renal dysfunction or in those with osteoporosis or osteopenia. Of note, FTC/TAF was associated with greater increases in serum lipids and need for lipid lowering medications in DISCOVER, as well as a slightly greater increase in weight.

For both FTC/TDF and FTC/TAF, efficacy is notably impacted by adherence to the daily regimen. DISCOVER confirmed several earlier trials suggesting efficacy was decreased in those taking less than 2 doses / week at the time of HIV diagnosis. Observational trials demonstrated lower adherence and persistence rates especially in young African American MSM populations. The iPrEx study showed a reduction in HIV acquisition of 50% in those with reported adherence of ≥ 50% which increased to 73% in those reporting adherence of ≥ 90%.[17]

- **FTC/TAF** is on the VANF as PA-F with Criteria for Use (CFU) and should be prescribed by Infectious Diseases, HIV, or other PrEP providers who have training or experience in managing patients on HIV PrEP. CFU developed to target those populations most likely to benefit from the small safety differences in kidneys and bone.
  - FTC/TDF is the workhorse product for those patients with CrCl ≥ 60 mL/min
  - FTC/TAF can be considered for those patients with CrCl of 30-59 mL/min.
  - FTC/TAF may also be particularly beneficial in patients with:
    - Multiple risk factors for nephrotoxicity (e.g., comorbidities and medications)
    - Osteoporosis or osteopenia
  - FTC/TAF is not indicated for those at risk for vaginal acquisition of HIV or in those receiving contraindicated medications concomitantly with FTC/TAF (e.g., strong CYP inducers).
  - Patient started on FTC/TAF should receive adherence counseling and support and be educated on side effects, particularly during the first month of therapy.
  - Patients should be provided no more than a 90-day supply of medication without refills.
  - HIV should be excluded at baseline, and at least every 3 months while on therapy.
  - CrCl should be monitored at least every 6 months for those aged 50 years or older or with a baseline CrCl < 90 ml/min, and at least every 12 months for other patients.
  - For additional monitoring recommendations (e.g., hepatitis B screening, screening for sexually transmitted infections, serum lipids, weight) ***refer to the CDC/USPSTFGuidelines.***[2,5]

Cabotegravir (CAB) [2,8,13,14]

Cabotegravir (APRETUDE) intramuscular injection was approved for HIV PrEP in MSM/TGW and cisgender men and women, where superiority over FTC/TDF was documented in randomized trials (HPTN 083 and 084). It can be used as an alternative to oral PrEP in patients with renal dysfunction, or those with intolerance or a contraindication to FTC/TDF or FTC/TAF. It is unlikely to have an impact on either renal function or bone mineral density so may also be an appropriate alternative to FTC/TDF in those populations. Warnings exist in the prescribing information for CAB about rare cases of serious hypersensitivity reactions and hepatotoxicity. Use of an oral lead-in may allow for an assessment of early tolerance prior to administration of a

long-lasting injection but is **not required**. Oral CAB must be procured from Theracom. For more information see the specialty procurement medications page on the PBM SharePoint. Cabotegravir Oral

Based on the demonstrated superiority in clinical trials, CAB may be a good choice for those who are at very high risk of transmission (such as those similar to patients enrolled in the trials, those with frequent incidents of condom-less sexual encounters or with partners who have uncontrolled HIV infection). The CDC/USPSTF Guidelines Clinical Providers' Supplement provides scoring systems to aid in identifying which patients are at the highest risk to guide treatment decisions.

Given the impact of poor adherence on efficacy of FTC/TDF and FTC/TAF, another patient population likely to derive significant benefit from CAB are those who have difficulty maintaining daily adherence due to specific factors such as, but not limited to, unstable housing, stigma, cognitive difficulties, uncontrolled mental illness or substance use disorders, etc. The ability to directly observe therapy ensures PrEP adherence with CAB, provided patients attend all injections on time (within 1 week before or after the date the next dose is due). That being said, the long half-life may be a disadvantage for those who abruptly discontinue therapy but continue to engage in high-risk behaviors as subtherapeutic serum concentrations may be seen for as long as a year in some patients. This could increase the risk for resistance to integrase strand transfer inhibitors, should HIV acquisition occur during this period. Patients should be carefully selected to include those who agree to the required injection dosing and testing schedule, which is more frequent than with oral PrEP.

- **CAB** is on the VANF as PA-F with CFU and should be prescribed by Infectious Diseases, HIV, or other PrEP providers who have training or experience in managing patients on HIV PrEP. In addition, additional criteria for use have been developed to target those populations most likely to benefit from CAB over FTC/TDF or FTC/TAF.
    - FTC/TDF is the workhorse product for those patients with CrCl ≥60 mL/min.
    - CAB may be beneficial in patients with:
        - CrCl < 30 mL/min or multiple risk factors for nephrotoxicity (e.g., comorbidities and medications)
        - Osteoporosis or osteopenia
        - Those unable to adhere to oral daily dosing for reasons such as those described above but who agree to comply with every 2-month visits and administrations
        - Those who have concerns about stigma or discovery of the use of HIV PrEP
        - Those with contraindications or intolerance to tenofovir or emtricitabine
    - CAB should not be used in those receiving contraindicated medications (strong CYP inducers).
    - Patient started on CAB should receive adherence counseling and support and be educated on side effects, particularly during the first month of therapy.
    - HIV should be excluded at baseline, and at least every 2 months while on therapy.
    - For additional monitoring recommendations (e.g., screening for sexually transmitted infections, serum lipids, weight) ***refer to the CDC/USPSTF Guidelines.***[2,5]

Lenacapavir (LEN)[9,-10,11]

Lenacapavir (YEZTUGO) subcutaneous injection every six months is approved for HIV PrEP for all sexual exposures with superiority to oral PrEP regimens as documented in the PURPOSE 1 and PURPOSE 2 randomized trials. Based on the demonstrated superiority in clinical trials, lenacapavir may be a good choice for those who are at very high risk of transmission (frequent sex without condoms, recent or frequent sexually transmitted infections, or sexual partners with HIV infection, etc.) and those with poor adherence to oral PrEP. It can be used as an alternative to oral PrEP in patients with renal dysfunction, or those with intolerance or a contraindication to FTC/TDF, FTC/TAF or cabotegravir.

Given the impact of poor adherence on efficacy of FTC/TDF and FTC/TAF for PrEP, those who have difficulty maintaining daily adherence due to specific factors such as, but not limited to, unstable housing, stigma, cognitive difficulties, uncontrolled mental illness or substance use disorders, may particularly benefit from lenacapavir. The ability to directly observe therapy ensures extended PrEP adherence with lenacapavir given the every six-month injection schedule.

Lenacapavir is a moderate inhibitor of CYP3A and a P-gp, and a substrate of P-gp, UGT1A1, and CYP3A, hence drugs that

are strong or moderate inducers of CYP3A may significantly decrease plasma concentrations of lenacapavir, which may reduce its effectiveness. As residual concentrations of lenacapavir may remain in the systemic circulation for 12 months or longer, lenacapavir may increase the risk of adverse reactions from drugs metabolized by CYP3A initiated within 9 months after the last dose.

The long half-life may be a disadvantage for those who abruptly discontinue therapy but continue to engage in high-risk behaviors as subtherapeutic serum concentrations may extend beyond 12 months. In clinical trials, lenacapavir resistance-associated capsid substitutions were detected in individuals who acquired HIV while receiving lenacapavir treatment.

Warnings exist in the lenacapavir prescribing information about serious injection site reactions with improper administration which can result in necrosis or ulcer.

Patients should be carefully selected to include those who agree to the required injection and testing schedule, and individuals who expect to require longer PrEP coverage.

- **LEN** is on the VANF as PA-F with CFU and should be prescribed by Infectious Diseases, HIV, or other PrEP providers who have training or experience in managing patients on HIV PrEP. Additional criteria for use have been developed to target those populations most likely to benefit from LEN over FTC/TDF .
    - FTC/TDF is the workhorse product for those patients with CrCl ≥60 mL/min
    - LEN may be beneficial in patients with:
        - CrCl 15 to 59mL/min or multiple risk factors for nephrotoxicity (e.g., comorbidities and medications)
        - Osteoporosis or osteopenia
        - Those unable to adhere to oral daily dosing for reasons such as those described above but who agree to comply with every 6-month visits and administrations
        - Those who have concerns about stigma or discovery of the use of HIV PrEP
        - Those with contraindications or intolerance to tenofovir, emtricitabine, or cabotegravir
    - LEN should not be used in those receiving contraindicated medications (moderate or strong CYP or P-gp inducers)
    - Patient started on LEN should receive adherence counseling and support and be educated on side effects including injection site reactions.
    - HIV should be excluded at baseline, and before each lenacapavir injection is administered.
    - For additional monitoring recommendations (e.g., screening for sexually transmitted infections, serum lipids, weight) ***refer to the CDC/USPSTF Guidelines.***[2,5]

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APPENDIX 1: HIV PrEP Algorithm