AdvancedHealth
Bridging the Future of Healthcare

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Drug Use Criteria for Pre-exposure prophylaxis (PrEP) against HIV infection
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Truvada © *Generic tenofovir disoproxil fumarate 300mg / emtricitabine 200mg*

GUIDELINE FOR USE:
PrEP is of substantial benefit for decreasing the risk of HIV infection in persons at high risk of HIV infection, either via sexual acquisition or through injection drug use. The only medication regimen approved by the FDA and recommended for PrEP is once daily tenofovir disoproxil fumarate 300mg co-formulated with emtricitabine 200mg (Truvada).

Initial Request:

1. Is member at high risk for HIV acquisition? Please see the following clinical considerations below for information about identification of persons at high risk.
    a. If yes, continue to #2
    b. If no, deny as criteria not met. PrEP is a covered benefit for members who are at high risk of HIV acquisition.

Persons at risk of HIV infection include men who have sex with men, persons at risk via heterosexual contact, and persons who inject drugs. Within these groups, certain risk factors or behaviors (outlined below) can place persons at high risk of HIV infection.

The United States Preventive Services Task Force (USPSTF) recommends that the following persons be considered for PrEP:

- Men who have sex with men, are sexually active, and have 1 of the following characteristics:
    a. A serodiscordant sex partner (ie, in a sexual relationship with a partner living with (HIV)
    b. Inconsistent use of condoms during receptive or insertive anal sex
    c. A sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia within the past 6 months

- Heterosexually active women and men who have 1 of the following characteristics:
    a. A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
    b. Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (eg, a person who injects drugs or a man who has sex with men and women)
    c. An STI with syphilis or gonorrhea within the past 6 month

- Persons who inject drugs and have 1 of the following characteristics:
    a. Shared use of drug injection equipment
    b. Risk of sexual acquisition of HIV (see above)

- Persons who engage in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers or persons trafficked for sex work, constitute another

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group at high risk of HIV acquisition and should be considered for PrEP based on the criteria outlined above.

2. Has member been assessed for acute HIV infection and has a recent HIV screening confirmed member is HIV negative? (Patients with acute HIV infection may present with a viral syndrome (eg, lymphadenopathy, fever, malaise, and/or a maculopapular eruption).
    a. If yes, continue to #3.
    b. If no, deny as not meeting criteria. Member must be screened for acute HIV infection and have a documented negative HIV test result prior to starting PrEP.

3. Does member have reduced kidney function? (Serum creatinine should be measured prior to initiating PrEP. Truvada (tenofovir disoproxil/ emtricitabine) should not be prescribed to patients with an estimated glomerular filtration (eGFR) rate <60 mL/min/1.73 m^2).
    a. If no, continue to #4.
    b. If yes, deny as criteria not met. PrEP should not be used in members with reduced kidney function.

4. Has member been screened for hepatitis B (HBC) and hepatitis C infection (HCV)? (Patients should be evaluated for the presence of HBV and HCV infection prior to initiating PrEP. This includes testing for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc), and hepatitis B surface antibody (anti-HBs). Vaccination against HBV is recommended for all members at substantial risk for HIV infection. HBV infection is not a contraindication to PrEP).
    a. If yes, continue to #5.
    b. If no, deny as not meeting criteria. Member should have HBV and HCV screening as part of initial laboratory assessment prior to starting PrEP.

5. Is the requested dose supported by the package insert?
    a. If yes, continue to #6.
    b. If no, deny as criteria not met. Off-label use of medication is not a covered benefit on OHP.

6. Does member have osteoporosis or osteopenia or is member at risk for osteoporosis? (Tenofovir disoproxil fumarate is associated with reductions in bone density).

    For members who can become pregnant:
    a. If yes, the risk of further bone loss must be balanced against the risk of acquiring HIV infection. Continue to #7.
    b. If no, continue to #7.

    For members who cannot become pregnant:
    a. If yes, the risk of further bone loss must be balanced against the risk of acquiring HIV infection. Approve for 90 days.
    b. If no, approve for 90 days.

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7. Has a recent pregnancy test been administered? (Women of childbearing potential should have a pregnancy test prior to initiating PrEP).
    a. If yes, approve for 90 days.
    b. If no, deny as criteria not met. A pregnancy test should be administered as part of initial laboratory assessment prior to starting PrEP.

Renewal Request:

1. Does member continue to be at high risk of HIV acquisition?
    a. If yes, continue to #2.
    b. If no, deny as criteria not met. PrEP is a covered benefit for members who are at high risk of HIV acquisition

2. Has member received appropriate follow-up monitoring and screening for continuation of PrEP? Please see following requirements.
    a. If yes, approve for 90 days.
    b. If no, deny as criteria not met. Appropriate follow-up monitoring and screening is required to continue PrEP.

Patients receiving PrEP should receive the following at 3 months:

- Repeat HIV testing and assess for signs or symptoms of acute infection to document that patients are still HIV negative
- Repeat pregnancy testing for women who may become pregnant
- Assess side effects, adherence, and HIV acquisition risk behaviors
- Provide support for medication adherence and risk-reduction behaviors
- Test for STIs among individuals with high-risk sexual behaviors, even if patient is asymptomatic
- Monitor creatinine in patients at risk for renal disease, all others should have creatinine checked every six months (Discontinue PrEP if estimated glomerular filtration rate <60 mL/minute/1.73 m^2, or if there is evidence of moderate or severe proximal tubular dysfunction or Fanconi syndrome).

Rationale: To ensure safe and effective use of PrEP in members at high risk for HIV acquisition.

FDA Approved Indication:

HIV-1 infection, treatment: Treatment of HIV-1 infection in combination with other antiretroviral agents in adults and pediatric patients weighing ≥17 kg

HIV-1 infection, preexposure prophylaxis: Preexposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing ≥35 kg, in combination with safer sex practices.

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Mechanism of Action: Nucleoside and nucleotide reverse transcriptase inhibitor combination; emtricitabine is a cytosine analogue while tenofovir is an analog of adenosine 5'-monophosphate. Each drug interferes with HIV viral RNA dependent DNA polymerase resulting in inhibition of viral replication.

Dosing: Preexposure prophylaxis (PrEP) in uninfected high-risk individuals: Adolescents weighing ≥35 kg: Oral: One tablet (emtricitabine 200 mg/tenofovir 300 mg) once daily; **Note:** Patients should be screened for HIV infection prior to initiation of therapy and at least once every 3 months; adherence should also be closely monitored (CDC2018).

Drug Interactions: Acyclovir, valacyclovir, cidofovir, ganciclovir, valganciclovir, aminoglycosides, high-dose or multiple NSAIDS or other drugs that reduce renal function or compete for active renal tubular secretion - serum concentrations of these drugs and/or tenofovir disoproxil fumarate may be increased. Monitor for dose-related renal toxicities. No data on interactions with emtricitabine.

Ledipasvir/sofosbuvir - serum concentrations of tenofovir disoproxil fumarate may be increased. Monitor for toxicities. No significant effect on emtricitabine.

Contraindications: As PrEP in patients with unknown or HIV-1 positive status.

References:

1. Preexposure Prophylaxis for the Prevention of HIV Infection in the United State – 2017 Update Clinical Practice Guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf

2. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

3. UptoDate. Administration of pre-exposure prophylaxis against HIV infection. Topic last updated: Jul 16, 2019.