



Prescribing Injectable HIV PrEP

Updated February 2023

Efficacy Key Messages:

- PrEP is highly effective for preventing HIV infection when used as prescribed ($\geq 99\%$ for sexual transmission, 74% for IDU transmission).
- PrEP prevents HIV only; use other methods to prevent pregnancy and STDs.

Indications (recent history):

- Inform all patients who are sexually active or inject drugs about PrEP.
- Prescribe for patients: who request PrEP; with any sex partner with untreated HIV or HIV risk factors; who report a history of STD, condomless anal, vaginal, or front hole sex, or transactional sex; or who used PEP in the past year.

Contraindication:

- HIV positive

Patient Eligibility:

- FDA approved for adults and adolescents ≥ 77 lbs (35kg); protective for receptive and insertive vaginal, front hole, and anal sex.

Considerations:

- HIV exposure < 72 hours: evaluate/prescribe PEP (*post-exposure prophylaxis*), then consider PrEP.
- Acute HIV symptoms (order venous draw Ag/Ab test, consider HIV treatment, or delay PrEP).
- Pregnancy or breast-/chestfeeding (discuss risk and benefits).

Side Effects:

- Injections: pain, tenderness, nodules, hardening, swelling, itching; usually resolves within a few days; treat with over-the-counter meds.
- Injections/pills: about 1 in 20 may have side effects (nausea, vomiting, abdominal pain, headache, fever, fatigue, dizziness); treat with over-the-counter meds.

Lab Screening & Visits:

- INITIAL LABS: HIV test result within 7 days before PrEP start (Ag/Ab, RNA result pending); HCV antibody; gonorrhea/chlamydia (oral, urine, vaginal, front hole, anal sites as applicable); syphilis; pregnancy. Consider: HAV, HBV, and HPV vaccines.
- BASELINE: Administer 1 injection; OR prescribe oral pills.
- MONTH 1: Administer 1 injection; HIV tests (RNA and Ag/Ab); start injections if pills used at baseline.
- Q2 MONTHS: Administer 1 injection; HIV tests (RNA and Ag/Ab); review PrEP care visit history, adherence, and PrEP indications.

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- Q4 MONTHS: gonorrhea/chlamydia (3 sites) and syphilis for MSM and transgender women; pregnancy.
- Q6 MONTHS: gonorrhea/chlamydia and syphilis for heterosexually active women and men.
- Documentation: ICD-10 Z20.6: Contact with and (suspected) exposure to HIV

Prescription:

- Cabotegravir injection: one 600 mg IM gluteal injection (ventrogluteal preferred) at baseline, 1 injection 4 weeks later, 1 injection every 8 weeks thereafter (+/-7days).
- Optional oral cabotegravir start: 30 mg pill once daily for 28 days* before 1st injection, 1st injection on last day of oral lead-in (or <3 days after), continue injection protocol; OR prescribe up to 8 weeks around missed injection.
- Missed injection: Administer injection 4 weeks later if >7 days late for 2nd dose or >1 month late for 3rd or later dose.

Adherence Counseling:

- Appointment reminders and other tools to keep PrEP care appointments.
- Plan for STD prevention and contraception or safer conception.
- Encourage patient to report if they want to stop or have stopped PrEP.
- Support additional prevention methods when needed.

*Oral cabotegravir has not been FDA-approved for PrEP, efficacy for preventing HIV transmission is unknown.

ABBREVIATIONS: Ag/Ab: antigen/antibody. CAB: cabotegravir. MSM: men who have sex with men.

Need Help?

National PrEPline: 855-448-7737



Prescribing Oral HIV PrEP

Updated February 2023

Efficacy Key Messages:

- PrEP is highly effective for preventing HIV infection when used as prescribed (99% for sexual transmission, 74% for IDU transmission).
- Full protection after 7 daily doses for anal sex; after 20 daily doses for vaginal or front hole sex or sharing needles.
- PrEP prevents HIV only; use other methods to prevent pregnancy and STDs.
- Off-label use of 2-1-1 PrEP for anal sex is highly effective in MSM and transgender women.

Indications (recent history):

- Inform all patients who are sexually active or inject drugs about PrEP.
- Prescribe for patients: who request PrEP; with any sex partner with untreated HIV or HIV risk factors; who report an STD, condomless anal, vaginal, or front hole sex, or transactional sex; or who used PEP in past year.

Contraindications:

1. HIV positive;
2. eCrCl <60 mL/min for F/TDF or eCrCl <30 mL/min for F/TAF.

Patient Eligibility:

- FDA approved for adults and adolescents ≥ 77 lbs (35kg).
- F/TDF: approved for cisgender women and men, transgender women; protective for receptive and insertive anal, vaginal, and front hole sex, sharing needles.
- F/TAF: approved for cisgender men, transgender women; protective for receptive and insertive anal sex, insertive vaginal and front hole sex.

Considerations:

- HIV exposure <72 hours: evaluate/prescribe PEP (*post-exposure prophylaxis*), then consider PrEP.
- Acute HIV symptoms (order venous draw Ag/Ab test, consider HIV treatment, or delay PrEP).
- HBV infection and ALT >2 x upper limit of normal (continue HBV treatment if stopping PrEP).
- Age >50 years or eCrCl <90 mL/min (check creatinine every 6 mos); other risks for kidney disease such as diabetes or hypertension; consider frequent checks.
- Osteoporosis or history of non-traumatic fracture (consider F/TAF, cabotegravir; check vitamin D, DXA scan).
- Pregnancy or breast-/chestfeeding (discuss risk and benefits)



Prescribing Oral HIV PrEP

Updated February 2023

Side Effects:

- 1 in 10 patients may have side effects (nausea, vomiting, abdominal pain, headache); usually resolves by 1 month; treat with over-the-counter meds.
- F/TDF: 1 in 200 may have renal dysfunction (usually reversible if PrEP is stopped); 1% average BMD loss (reversible if PrEP is stopped, no increased risk of fractures).
- F/TAF: small increase in cholesterol, body weight.

Lab Screening & Visits:

- INITIAL LABS: HIV test result within 7 days before PrEP start (Ag/Ab preferred, rapid blood Ag/Ab possible, RNA if needed); HBV serology; HCV antibody; creatinine; gonorrhea/chlamydia (oral, urine, vaginal, front hole, anal sites as applicable), syphilis; pregnancy; lipid panel (F/TAF only). Consider HAV, HBV, and HPV vaccines.
- WEEK 1 & MONTH 1: Check on prescription fill, adherence, education needs, cost, or other PrEP care issues.
- Q3 MONTHS: HIV tests (RNA and Ag/Ab); gonorrhea/chlamydia (3 sites) and syphilis for MSM/transgender women; pregnancy, check adherence and PrEP indications.
- Q6 MONTHS: gonorrhea/chlamydia and syphilis for heterosexually active women/men; eCrCl for >50yo or <90 mL/min at baseline.
- Documentation: ICD-10 Z20.6: Contact with and (suspected) exposure to HIV

Prescription:

- T/TDF (generics, Truvada): 200 mg/300 mg once a day, prescribe 90-day supply.
- F/TAF (Descovy): 200 mg/25 mg once a day, prescribe 90-day supply.

Adherence Counseling:

- Link dosing to routine or use adherence tools.
- Plan for STD prevention and contraception or safer conception.
- Encourage patient to report if they want to stop or have stopped PrEP.
- Support additional HIV/STD prevention methods when needed.

ABBREVIATIONS: Ag/Ab: antigen/antibody. BMD: bone mineral density. F/TAF: emtricitabine/tenofovir alafenamide. F/TDF: emtricitabine/tenofovir disoproxil fumarate. MSM: men who have sex with men.

Need Help?

National PrEPline: 855-448-7737

PrEP Information



ORAL PrEP

Taking PrEP: one pill once a day

- There are three FDA-approved oral medications for PrEP: F/TDF Generic, Truvada®, and Descovy®. All are highly effective in clinical trials, however, various personal factors and your provider will determine which one is best for you.
- PrEP can be taken even if drinking alcohol or using recreational substances.
- It is very important to take PrEP as prescribed, and at the same time each day.
- Missed a dose? Take the missed dose right away when you remember. An occasional missed dose of PrEP is okay, but adherence is what makes it effective.

INJECTABLE PrEP

Taking PrEP: one injection every 2 months

- There is one FDA-approved injectable medication for PrEP: Cabotegravir (Apretude). Insurance may be a barrier to obtaining Cabotegravir in Alaska.
- Apretude is an intramuscular injection in the buttocks initiated as a first injection followed by a second injection 1 month after the first and then continued with an injection every 2 months thereafter.

COST

- Oral PrEP medication and all services associated with it, including labs, should be covered by your insurance. Injectable PrEP may have insurance barriers.
- If you are uninsured, or are having trouble paying for PrEP, there are assistance programs that may be able to help cover the cost. Visit www.readysprep.hiv.gov for payment resources.

STAY PROTECTED

Stopping PrEP

- Do not stop PrEP before talking with your healthcare provider.
- If you have condomless or barrierless sex while not taking PrEP, call your provider within 72 hours for post-exposure prophylaxis (PEP).
- If you've stopped PrEP for more than 7 days, it is important to get an HIV test before you restart.
- Report any flu-like symptoms or rashes to your healthcare provider as they could be symptoms of HIV.

Staying Healthy

- PrEP is highly effective but doesn't protect against other STDs. Using condoms and other barriers provide additional protection from HIV and STDs.
- Protect yourself from other diseases: Get vaccinated for Hepatitis A and B, HPV, and meningitis.



PREP Referral

Clinic	Phone	Address	Appt. Time
Notes			

Scan for FREE
at-home
HIV/STD tests
and condoms
for Alaska
residents



Scan for PREP
Providers and
HIV/STD
Testing Locations
In Alaska





PrEP Basics for Oral PrEP



PrEP is safe and can reduce your risk of HIV from sex by more than 99%.



It takes 1 week before protection for anal sex, and 3 weeks for vaginal sex



Take 1 pill once a day. Finding a routine is essential



Get tested for HIV and STDs every 3 months



Tell your provider if you plan to stop or restart PrEP

HOW TO GET PREP

- Tell your primary care provider you'd like to start PrEP. Doctors, Nurse Practitioners, and Physician Assistants can prescribe PrEP.
- Visit www.prelocator.org to find PrEP providers in your area.

TAKING THE PILL

One pill per day

- There are three FDA-approved oral medications for PrEP: F/TDF Generic, Truvada®, and Descovy®. All are highly effective in clinical trials, however, various personal factors and your provider will determine which one is best for you.
- PrEP (pre-exposure prophylaxis) is most effective if taken daily. PrEP can be taken even if drinking alcohol or using recreational substances.

Getting into a routine

- It is very important to take PrEP as prescribed, such as taking it at the same time each day. To help with this try:
 - Taking a pill with you if you will be out late.
 - Set a text or calendar reminder.
 - Take your PrEP medicine with things you already do each day, like eating a meal or drinking your coffee.

Missed a dose?

- Take the missed dose right away when you remember. An occasional missed dose of PrEP will be okay once in a while, but it is important to take the medication as prescribed. For example: If you usually take it at 10AM, but realize at 10PM that you forgot, it's okay to take 1 pill then continue with your usual schedule the next day. Don't double-dose PrEP pills to make up for a missed dose.

Possible side effects

- Some people experience gas, nausea, or headache when starting PrEP. These symptoms usually go away within the first month.
- Some PrEP medications can cause small changes in kidney function and bone mineral density, or small changes in cholesterol and weight, which return to normal once PrEP is stopped. While taking PrEP, your provider will routinely monitor your health for any changes.

YOUR PRESCRIPTION

Lab testing

- Before starting PrEP, you will get tests for HIV, STDs, kidney function, and Hepatitis B and C.
- You will also get tested for HIV and STDs every 3 months and a kidney function test every 6 months.

Filling your prescription

- Refills are not always automatic. Contact your pharmacy when you have 5 pills left so you don't run out.
- Before traveling, let your healthcare provider and/or pharmacy know that you may need an extra refill if you are low on medication.

Cost

- If you are having trouble paying for PrEP, there are assistance programs that may help cover the cost. Visit www.readysprep.hiv.gov for payment resources.

STAY PROTECTED

Stopping PrEP

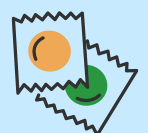
- Do not stop PrEP before talking with your healthcare provider about your options. If taking a daily pill is not working for you, ask your healthcare provider about whether 2-1-1 PrEP (scheduling PrEP pills based on the timing of when you will have sex) or injectable PrEP could work for you.
- If you have condomless or barrierless sex while *not* taking PrEP, call your provider within 72 hours for post-exposure prophylaxis (PEP).

Restarting PrEP

- If you've stopped PrEP for more than 7 days, it is important to get an HIV test before you restart.
- Report any flu-like symptoms or rashes to your healthcare provider as they could be symptoms of HIV.

STAYING HEALTHY


- PrEP is highly effective but doesn't protect against other STDs. Condoms provide additional protection from HIV and STDs.
- Protect yourself from other diseases: Get vaccinated for Hepatitis A and B and meningitis.



PrEP Medications



There are three FDA-approved oral medications for pre-exposure prophylaxis (PrEP): F/TDF Generic, Truvada®, and Descovy®. All are safe and highly effective in clinical trials. There were no differences in adverse clinical outcomes such as broken bones or heart disease between people taking either regimen. Choice may be limited by insurance coverage.

	Generic or Truvada® Tenofovir disoproxil fumarate 300 mg + Emtricitabine 200 mg (F/TDF) <i>generic version available</i>	Descovy® Tenofovir alafenamide 25 mg + Emtricitabine 200 mg (F/TAF)
Indications	F/TDF is approved for use for all adults and adolescents ≥35 kg with indications for PrEP	F/TAF is approved for use for adults and adolescents ≥35 kg at risk for sexually acquired HIV, excluding individuals at risk only from receptive vaginal sex or only from injection drug use
Dosing	1 pill once daily unless using a PrEP 2-1-1 schedule	1 pill once daily
"On Demand" PrEP: 2-1-1 Dosing <i>This strategy has not yet been reviewed by the FDA, but is recommended by the CDC in their 2021 PrEP Guidelines</i>	2-1-1 for people with anal exposures only: 2 pills 2-24 hours before anal sex (24 hours before for optimal protection) <ul style="list-style-type: none"> • then 1 pill 24 hours after first dose • then 1 pill 24 hours after second dose For a detailed 2-1-1 prescribing guide, refer to the CDC's 2021 PrEP Guidelines	The PrEP 2-1-1 dosing schedule is not recommended for use with F/TAF (Descovy®) outside of a clinical trial
Side Effects	Generally safe and well tolerated <ul style="list-style-type: none"> • Headache and abdominal discomfort which often resolves in a few weeks • Weight loss • Small decrease in eGFR, which improves upon discontinuation of F/TDF 	Generally safe and well tolerated <ul style="list-style-type: none"> • Abdominal discomfort, nausea, and headache, which often resolves in a few weeks • Small increase in LDL cholesterol • Slight increase in body weight
Other Notes	Estimated GFR or CrCl by serum labs should be ≥60 ml/min to safely use F/TDF	Estimated GFR or CrCl by serum labs should be ≥30 ml/min to safely use F/TAF


Questions?

Call The National Clinicians Consultation Center
 PrEPline at 1-855-448-7737

PrEP Medications



The US Food and Drug Administration (FDA) has approved one injectable pre-exposure prophylaxis (PrEP) medication: cabotegravir (CAB) 600 mg (brand name Apretude®). CAB is a single antiretroviral drug given as an intramuscular injection every 2 months to prevent HIV. This option may be limited by insurance coverage.

Injectable PrEP 	Apretude® Cabotegravir 600 mg
Indications	<p>In 2021, the US Preventative Services Task Force issued a graded recommendation to prescribe Cabotegravir (CAB) for PrEP to adult patients who are at risk of getting HIV through sex (grade IA).</p>
How is Injectable PrEP Used?	<p>CAB is FDA approved as an intramuscular injection in the buttocks initiated as a first injection followed by a second injection 1 month after the first and then continued with an injection every 2 months thereafter. A 4-week lead-in period of 30 mg daily oral CAB prior to the first injection is optional for patients who are worried about side effects.</p>
Baseline Assessments	<p>Perform the following baseline assessments for all injectable PrEP candidates:</p> <ul style="list-style-type: none"> • HIV Testing: Confirm that the patient does not have HIV before prescribing PrEP. CDC guidelines using HIV-1 RNA assay to rule out acute infection. • STD Testing: Screen injectable PrEP candidates who are sexually active for chlamydia, gonorrhea, and syphilis.
Clinical Follow-up and Monitoring	<p>Once CAB injections are initiated, patients should return for follow-up visits 1 month after the initial injection and then every 2 months.</p> <p>At each bimonthly visit (beginning with the third injection - month 3)</p> <ul style="list-style-type: none"> • Repeat HIV-1 RNA test and assess for signs and symptoms of acute infection • Administer CAB injection. • Provide access to clean needles/syringes and substance treatment services for PWID • Respond to new questions and provide new information about CAB PrEP • Discuss the benefits of persistent CAB PrEP use and adherence to scheduled injections <p>At least every 4 months (every other injection visit)</p> <ul style="list-style-type: none"> • Conduct STD screening for MSM and transgender women who have sex with men - oral, rectal, urethral, blood <p>At least every 6 months</p> <ul style="list-style-type: none"> • Conduct STD screening for all heterosexually active women and men

Questions?

Call The National Clinicians Consultation Center
PrEPline at 1-855-448-7737

Prescribing

Oral PrEP



What is PrEP?

- Pre-exposure prophylaxis (PrEP) is medication for HIV negative individuals that helps prevent HIV before an exposure event occurs. This is different than post-exposure prophylaxes (PEP).
- Two fixed-dose antiretroviral oral medications are FDA approved for PrEP: tenofovir disoproxil/emtricitabine (Generic or Truvada®), and tenofovir alafenamide/emtricitabine (Descovy®).
- No negative significant health effects have been observed among individuals who have taken PrEP for up to 5 years.
- The FDA has approved one injectable PrEP medication: cabotegravir (CAB) 600 mg. CAB is a single antiretroviral drug given as an intramuscular injection initially 1 month apart for 2 months, then every 2 months to prevent HIV.

***PrEP can reduce the risk of acquiring HIV from sex by >99%,
and from IDU by ~74%.***

Who May Benefit from PrEP?

- Anyone who self-identifies a need or want for PrEP
- Men who have sex with men (MSM)
- People who inject drugs and use stimulants like methamphetamine
- People with partners with or at risk for HIV
- Transgender persons
- People who have had an STD, condomless/barrierless (vaginal or anal) sex, or transactional sex

Taking a Sexual History Prior to Prescribing PrEP

- Partners: Do you have sex with men and/or women and/or transgender individuals?
- Practice: In the past year, what type(s) of sex have you had: vaginal, oral, anal receptive, anal insertive?
- Protection: From STDs: What methods do you use to prevent STDs including HIV? How often do you use condoms for vaginal, anal, oral sex?
- Past: History of STDs: Have you ever had an STD?
- Pregnancy: Are you trying to conceive or father a child? Are you trying to avoid pregnancy?

PrEP Clinical Visits: Initial Visit

- Discuss HIV/STD risk reduction; offer condoms, clean syringe resources, contraceptive counseling if applicable
- Screen for signs and symptoms of HIV
- Evaluate HAV, HBV, & HPV vaccination status; vaccinate as appropriate
- If high risk sexual exposure in the last 72 hours do not prescribe PrEP; prescribe HIV PEP
- Prescribe initial 30-day supply of PrEP after negative HIV test and schedule follow-up visit prior to end of 30-day prescription

Baseline Assessment (within 7 days prior to PrEP initiation)

- Screen for symptoms of acute HIV infection (fever, rash, headache, sore throat, etc.)
- HIV test (4th generation Ag/Ab recommended) - Consider HIV RNA PCR viral load if possible exposure in the last month
- All appropriate site gonorrhea & chlamydia NAAT (urine, pharyngeal, rectal), syphilis screen
- Serum creatinine (TDF/FTC or Truvada® are contraindicated if CrCl <60 ml/min, FAF/FTC or Descovy may be used if CrCl >30ml/min)
- Pregnancy test*
- Hepatitis B Surface Antigen (HBsAg)*
- Hepatitis C Antibody*
 - *not a contraindication, but follow up is indicated if positive

Rare potential risks of TDF/FTC (Generic or Truvada®)



Decline in renal function:

Consider more frequent monitoring in patients with risk factors for kidney disease. Descovy may be a safe option for patients with known chronic renal disease.



Decrease in bone-mineral density:

Caution in those with osteoporosis or history of pathology/fragility fractures. Consider baseline DEXA for patients with history of or at high risk of osteoporosis.

Rare potential risks of TAF/FTC (Descovy®)



Small increase in LDL cholesterol:

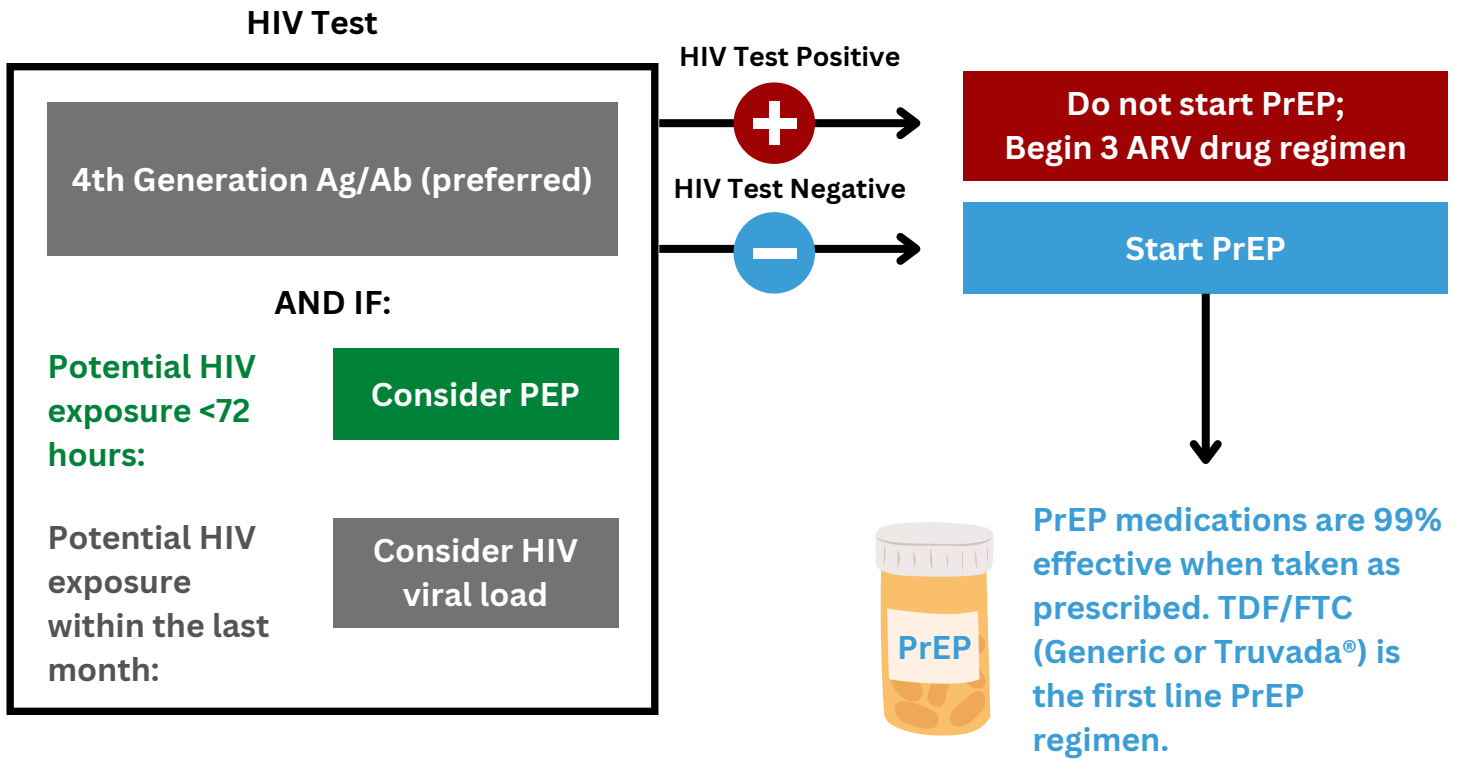
Increases in cholesterol are reversible if the medication is stopped.



Small amount of weight gain:

Average weight gain of 2-3 pounds.

HIV Assessment at PrEP Initiation



Prescribing PrEP

1 tablet PO daily, 30-day supply with 2 refills (after negative HIV test)

- **Generic:** emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg **OR**
- **Truvada®:** emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg **OR**
- **Descovy®:** emtricitabine 200 mg/tenofovir alafenamide fumarate 25 mg

Check Your Billing Codes!

ICD-10: Z20.6 - Contact with and (suspected) exposure to human immunodeficiency virus

Follow-up Assessment Every 3 Months

- | | |
|---|---|
| <ul style="list-style-type: none"> <input type="checkbox"/> Screen for symptoms of acute HIV infection <input type="checkbox"/> HIV test: 4th gen Ab/Ag test; HIV RNA PCR if concern for acute HIV infection <input type="checkbox"/> All-site testing for gonorrhea and chlamydia, syphilis screen <input type="checkbox"/> Evaluate for medication side effects, adherence and continue risk reduction counseling | <ul style="list-style-type: none"> <input type="checkbox"/> Serum creatinine every 6 months <input type="checkbox"/> Hepatitis C Ab every 12 months <input type="checkbox"/> Pregnancy test if applicable <input type="checkbox"/> Give 90-day prescription, and schedule follow-up prior to end of 90-day prescription |
|---|---|

Annual Assessment

- Urinalysis is recommended

PrEP is Affordable in Alaska

- Alaska Medicaid plans pay for PrEP including visits, labs, and medication costs.
- Most private insurance plans pay for PrEP.
- Additional assistance is available through:
 - Gilead medication and copay assistance programs: gileadadvancingaccess.com, 800-226-2056.
 - Patient Advocate Foundation (<400 percent of federal poverty line), www.copays.org.
 - PAN Foundation (<500 percent of federal poverty line), www.panfoundation.org.

What if My Patient Tests Positive for HIV while on PrEP?

In the rare event that your patient has a positive HIV test while daily PrEP as prescribed:

- Discontinue PrEP immediately to avoid potential development of HIV drug resistance.
- Determine the last time PrEP was taken and recent pattern of taking PrEP.
- Report new HIV diagnosis to the Alaska Department of Health, Section of Epidemiology using an HIV/STD Confidential Case Report Form.
- Ensure Linkage to HIV care for prompt initiation of ARV treatment regimen, counseling/support services.

Post-exposure Prophylaxis (PEP)

PEP Details:

- Highly effective in preventing HIV if taken within 72 hours after potential exposure.
- Potential HIV exposure within 72 hours and patient has not taken PrEP for past 7 days.
- Provide a 28-day supply of PEP, and then transition seamlessly to PrEP.
- There is no evidence that PEP "masks" HIV seroconversion.

Three antiretroviral drugs are recommended for PEP regimen:

Tenofovir DF (300 mg)/Emtricitabine (200 mg) daily + Raltegravir (400 mg) BID twice daily

OR

Tenofovir DF (300 mg)/Emtricitabine (200 mg) daily + Dolutegravir (50 mg) daily

PrEP and PEP Resources

- For free clinician to clinician advice from HIV experts call the National Clinicians Consultation Center **PrEPline at 1-855-448-7737**.
- CDC PrEP Clinical Guidelines: www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf
- AK DOH PrEP Provider Packet at health.alaska.gov/dph/epi/hivstd.

Adapted from resources developed by getSFcba.org