CLINICIANS' QUICK GUIDE

# What Is Oral HIV PrEP?

The US Food and Drug Administration (FDA) has approved two oral pre-exposure prophylaxis (PrEP) medications. Each medication is a combination of two antiretroviral drugs in a single oral tablet used to prevent HIV:

- Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F/TDF—brand name **Truvada**® or generic equivalent).
- Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F/TAF—brand name **Descovy**®).

Oral PrEP is up to 99% effective at preventing HIV acquisition from sex and at least 74% effective at preventing HIV acquisition from injection drug use.

## Who Is Oral PrEP for?

**PrEP is for people who don't have HIV and are at risk of getting HIV from sex or injection drug use.**

- F/TDF is approved for adults and adolescents who weigh at least 35 kg (77 lb) and have an estimated creatinine clearance (eCrCl), determined using the Cockcroft-Gault formula, of at least 60 mL/min.
- F/TAF is approved for adults and adolescents who weigh at least 35 kg (77 lb), are not at risk of getting HIV through receptive vaginal sex, and have an eCrCl of at least 30 mL/min.

To learn more about prescribing HIV prevention, visit:
cdc.gov/HIVNexus

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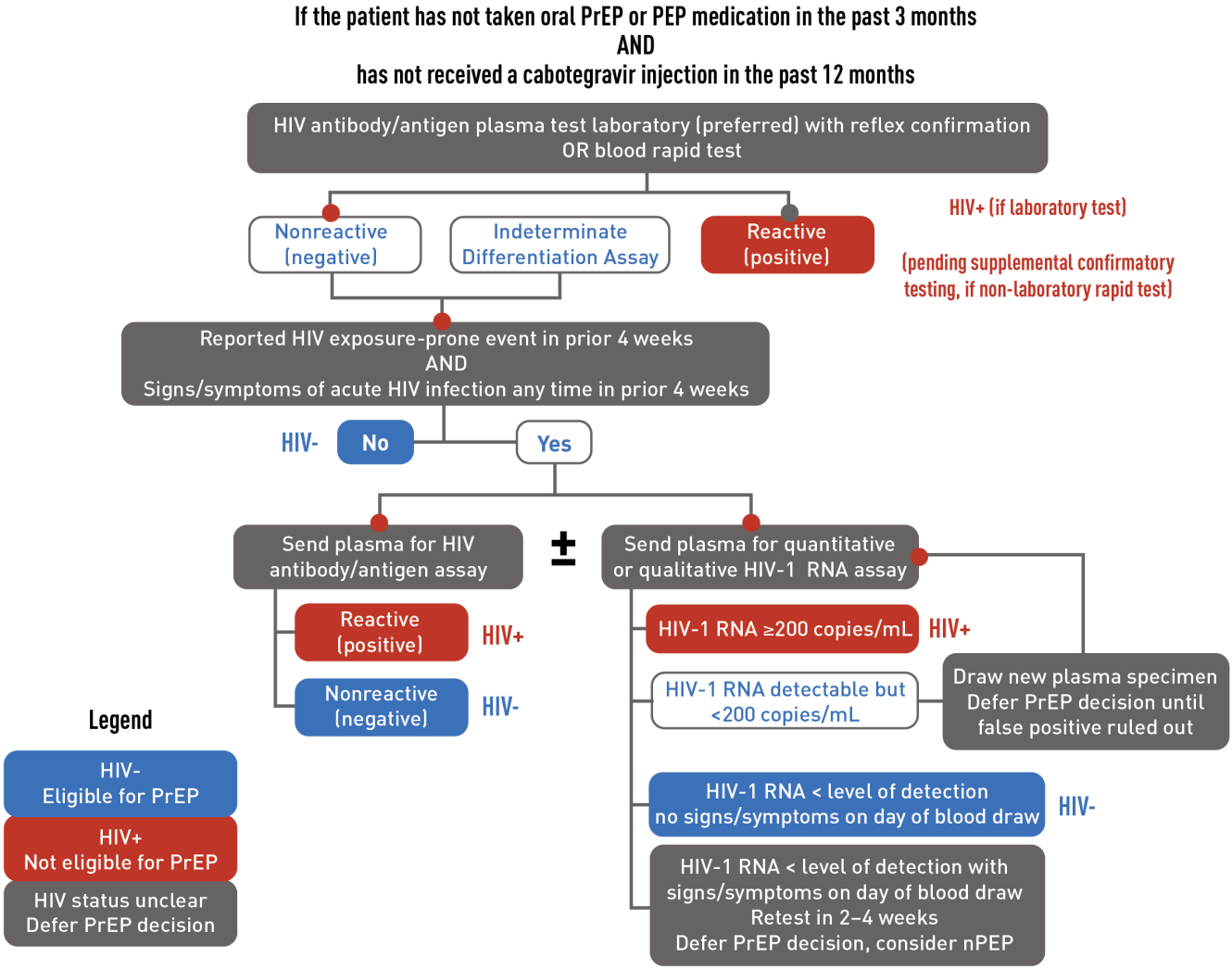
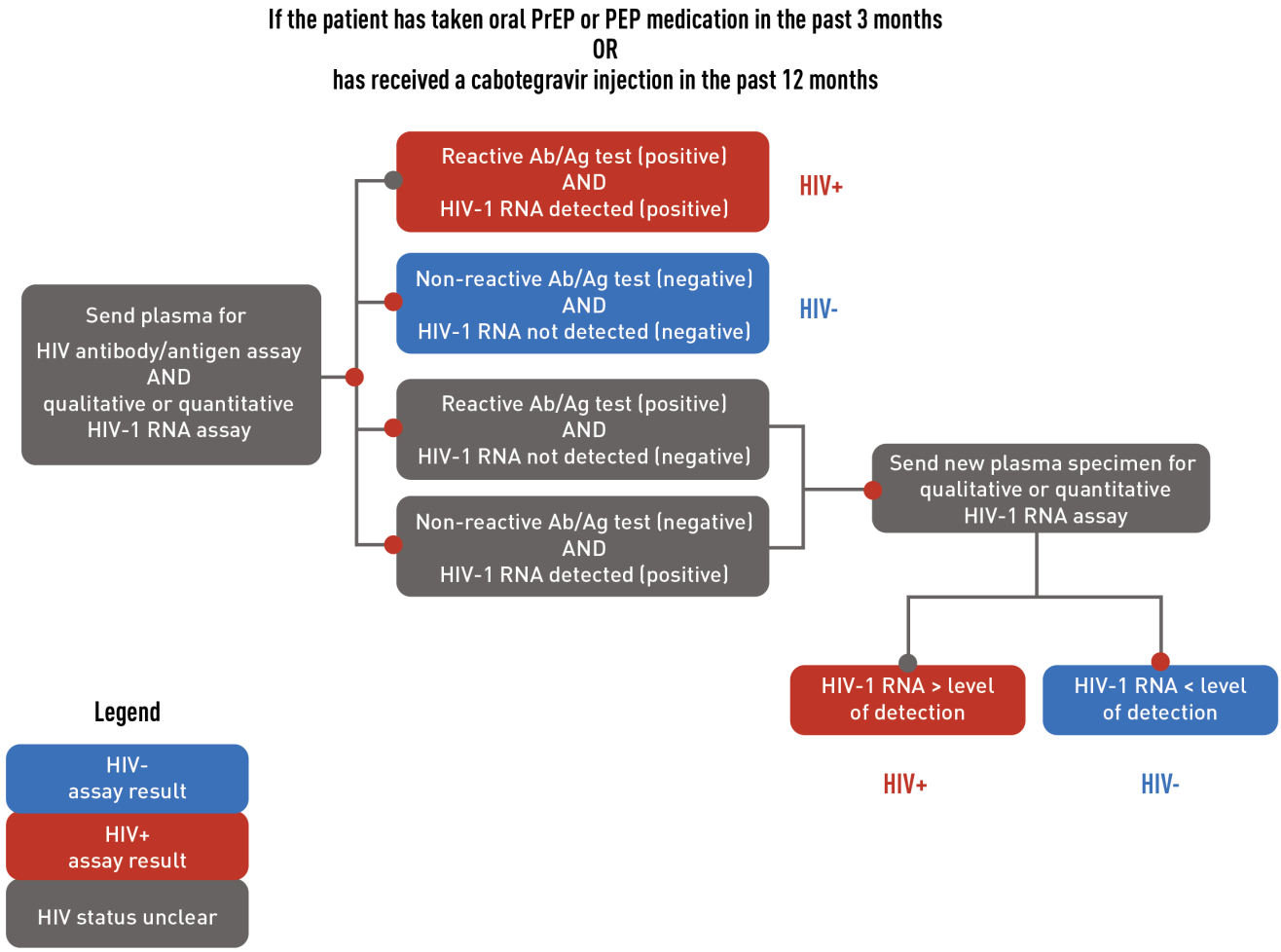
## What Baseline Assessments Are Required Before Prescribing Oral PrEP?

Perform the following baseline assessments for all oral PrEP candidates:

- **HIV testing:** Confirm that the patient does not have HIV before prescribing PrEP. The flowcharts below provide more information about HIV testing for PrEP candidates.
- **Sexually transmitted infection (STI) testing:** Screen oral PrEP candidates who are sexually active for chlamydia, gonorrhea, and syphilis.
- **Kidney function assessment:** Assess kidney function using the Cockcroft-Gault formula with the patient's serum creatinine value to calculate their eCrCl. F/TAF is approved for use by patients with eCrCl ≥30 mL/min. Either F/TAF or F/TDF can be used by patients with eCrCl ≥60 mL/min.
- **Hepatitis B (HBV) serology:** HBV infection is not a contraindication to oral PrEP. However, stopping use of emtricitabine and tenofovir can cause a rebound of HBV replication. Therefore, patients with active HBV infection who stop using oral PrEP medications should be closely monitored for reactivation of HBV replication, which could lead to liver damage. Educate oral PrEP candidates who have HBV infection about the risks of stopping oral PrEP without appropriate follow up.
- **Lipid profile:** Assess cholesterol and triglyceride levels before prescribing F/TAF.






## What Oral PrEP Dosing Options Are Available?

**Daily oral PrEP.** Daily oral F/TDF can be prescribed to any patient who is at risk of HIV through sex or injection drug use, regardless of their gender or biological sex, if they meet the weight and kidney function criteria. F/TAF can only be prescribed to patients who were assigned male at birth; it has not yet been studied in patients who were assigned female at birth and are at risk of getting HIV through receptive vaginal sex.

**2-1-1**

**2-1-1 dosing of oral PrEP.** F/TDF can be prescribed off-label using 2-1-1 dosing for adult gay, bisexual, and other men who have sex with men (MSM). This is also known as event-driven, intermittent, on-demand, or coitally timed PrEP. When using 2-1-1 dosing, the patient takes F/TDF doses based on when they plan to have sex:

- Two pills 2–24 hours before sex.
- One pill 24 hours after the first two-pill dose.
- One pill 48 hours after the first two-pill dose.

Patients who could benefit from 2-1-1 dosing are those who:

- Request non-daily dosing.
- Have sex less often than once per week.
- Can anticipate or delay sex to permit the first two-pill dose at least 2 hours before sex.

*Note that 2-1-1 dosing is not approved by the FDA and is not recommended by the Centers for Disease Control and Prevention (CDC).*

## What Ongoing Support and Assessments Are Required for Patients on Oral PrEP?

PrEP should be prescribed as part of a combination prevention plan. At minimum, while patients are on oral PrEP, CDC recommends that health care providers:

### Provide the following services

**At least every 3 months**

- Repeat HIV antigen/antibody and HIV-1 RNA tests and assess for signs or symptoms of acute infection to confirm that patients are still HIV negative.
- Provide a prescription or refill authorization of daily oral PrEP medication for no more than 90 days (until the next HIV test).
- Assess and provide support for medication adherence and risk-reduction behaviors.
- Test sexually active patients with signs or symptoms of STIs. Screen asymptomatic MSM at high risk for recurrent bacterial STIs (oral, rectal, urine, blood). Examples of MSM who should be screened include those with syphilis, gonorrhea, or chlamydia at prior visits or multiple sex partners.
- Provide access to sterile needles/syringes and substance use disorder treatment services for people who inject drugs.
- Respond to new questions and provide any new information about PrEP use.

**At least every 6 months**

- Monitor eCrCl for patients age ≥50 years or who had an eCrCl <90 mL/min when they started oral PrEP.
  - If there are other threats to kidney safety (e.g., hypertension, diabetes), kidney function may need to be monitored more often or checked using additional tests (e.g., urinalysis for proteinuria).
  - A rise in serum creatinine is not a reason to withhold PrEP if eCrCl remains ≥60 mL/min for F/TDF or ≥30 mL/min for F/TAF.
  - If eCrCl is declining steadily (but sill ≥60 mL/min for F/TDF or ≥30 mL/min for F/TAF), consult with a nephrologist, if needed, or evaluate other possible threats to kidney health.
- Screen sexually active people for STIs (vaginal, oral, rectal, urine, as indicated; blood):
  - Syphilis for all PrEP users.
  - Gonorrhea for all PrEP users.
  - Chlamydia for MSM and transgender women, even if asymptomatic.
- Assess interest in continuing or stopping PrEP.

**At least every 12 months**

- Monitor eCrCl for all patients continuing on oral PrEP medication.
- Monitor triglyceride and cholesterol levels and weight for patients prescribed F/TAF for PrEP.
- Screen heterosexually active people for chlamydia (vaginal, urine), even if asymptomatic.

## Other Considerations for Prescribing Oral PrEP

### How Can My Patients Get Help Paying for Oral PrEP?

Up-to-date information on options for paying for PrEP can be found on CDC's *HIV Nexus*: cdc.gov/hiv/clinicians/prevention/prep.html.

### Where Can I Learn More About Prescribing and Managing Patients on Oral PrEP?

CDC offers a variety of resources for providers, patients, and practices.

- Access comprehensive guidelines in CDC's *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update—A Clinical Practice Guideline*: cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.
- Download additional *Clinicians' Quick Guides* on PrEP, as well as other materials, such as brochures and posters: cdc.gov/hiv/clinicians/materials/prevention.html.

### What If My Patient Wants to Discontinue Oral Prep?

How to safely discontinue and restart daily oral PrEP use should be discussed with patients both when starting PrEP and when discontinuing PrEP. Protection from HIV infection will wane over 7-10 days after ceasing daily oral PrEP use. Because some patients have acquired HIV soon after stopping PrEP, providers should assess ongoing HIV risk factors and discuss other prevention methods if HIV exposure is anticipated, including nonoccupational post-exposure prophylaxis (PEP).

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