

# State of California—Health and Human Services Agency California Department of Public Health



Office of AIDS (OA)

Management Memorandum

Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)

Memorandum Number: 2019-33

DATE: November 25, 2019

TO: PREP-AP ENROLLMENT WORKERS AND CLINICAL PROVIDERS

SUBJECT: HOW CLIENTS ACCESS NON-OCCUPATIONAL POST-EXPOSURE

PROPHYLAXIS (nPEP) THROUGH PREP-AP

The purpose of this management memo is to clarify the current process for accessing nonoccupational post-exposure prophylaxis (nPEP) through PrEP-AP.

#### **Background**

nPEP involves taking antiretroviral medication after potential exposure to HIV to prevent HIV acquisition. nPEP must be started within 72 hours after a possible HIV exposure and should be initiated as soon as possible.

# nPEP Benefits Available Through PrEP-AP

PrEP-AP can provide assistance with nPEP medications and associated medical services including healthcare provider fees and testing for acute HIV infection, sexually transmitted infections, renal function, and pregnancy. Clinical providers are able to bill the PrEP-AP using the same ICD-10 and billing codes found on the <u>Allowable PrEP</u> <u>Related Medical Services</u> document. The <u>PrEP-AP drug formulary</u> currently lists the following nPEP regimens for people with normal renal function (including pregnant women):

1. Dolutegravir 50mg once daily (Tivicay®) *plus* tenofovir disoproxil fumarate 300mg/ emtricitabine 200mg once daily (Truvada®) is the preferred first line regimen for nPEP per the <u>Centers for Disease Control and Prevention's (CDC) Updated nPEP Guidelines</u>. Both pills should be taken daily for 28-days¹.



<sup>&</sup>lt;sup>1</sup> Although nPEP is prescribed for 28 days, antiretroviral medications are often pre-packaged in 30-day bottles that cannot be redistributed by the pharmacy into a smaller number of doses. PrEP-AP will cover a 30-day supply of medication. PrEP-AP clients can discuss with their healthcare provider what to do with any medication leftover from a 28-day course.

November 25, 2019

- 2. Raltegravir (Isentress®) **plus** Truvada® (once daily) is also a preferred first line regimen for nPEP in <u>CDC's Updated nPEP Guidelines</u>. This regimen is preferred in people who are early in pregnancy or who may become pregnant while receiving nPEP because of concerns of an increased risk of neural tube defects associated with exposure to dolutegravir at conception. Raltegravir can be dosed 1200mg (HD formulation: two 600 mg pills) once daily or 400mg twice daily. The 400mg twice daily dosing is recommended in pregnancy.
- 3. Darunavir 800 mg once daily (Prezista®) and ritonavir 100 mg once daily (Norvir®) **plus** Truvada® (once daily) is an alternative regimen in CDC's Updated nPEP Guidelines.
- 4. Bictegravir 50mg/tenofovir alafenamide 25mg/emtricitabine 200mg once daily (Biktarvy®) is a preferred regimen in the <u>Pacific AIDS Education & Training</u> Center (PAETC) HIV Essentials and Quick Clinical Guides.

Tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy®) can be substituted for Truvada®.

<u>Please Note:</u> PrEP-AP clients must access Truvada® and Biktarvy® for PEP through a Gilead assistance program, if eligible. For uninsured clients, Gilead will pay for the full cost of Truvada® or Biktarvy® and PrEP-AP will pay for the full cost of dolutegravir, raltegravir, darunavir and ritonavir. For clients with prescription drug coverage, PrEP-AP will provide copayment assistance for dolutegravir, raltegravir, darunavir and ritonavir, and Gilead will pay for up to \$7,200 in Truvada® or Biktarvy® copayments (PrEP-AP will provide wrap-around coverage after the Gilead copayment benefit of \$7,200 is exhausted).

# **Process for Existing Clients**

Clients currently enrolled in the PrEP-AP and a Gilead assistance program are able to access nPEP immediately if clinically indicated. Existing PrEP-AP clients who have discontinued PrEP and had a potential exposure to HIV within 72 hours should be evaluated by their healthcare provider for nPEP. CDC and PAETC guidelines should be used to determine if nPEP is clinically indicated. If the indications for nPEP are unclear, healthcare providers can also call the National Clinician's Post-Exposure Prophylaxis Hotline at 888-448-4911 for expert advice.

Enrolled clients who meet nPEP criteria must receive a prescription for nPEP from their provider, or if they are uninsured, from a clinical provider in the PrEP-AP Clinical Provider Network. Uninsured clients currently enrolled in the PrEP-AP can access a Truvada®-based nPEP regimen immediately due to their enrollment in the manufacturer assistance program for Truvada®. Clients with insurance should be able to access Truvada® and Biktarvy® under their current Gilead copayment assistance benefit.

November 25, 2019

#### **Process for New Clients**

# Step 1: Enroll into PrEP-AP via the CDPH Call Center

- Contact the CDPH Call Center at (844) 421-7050
- The Call Center is available Monday through Friday, 8:00 a.m. 5:00 p.m.
- Clients can call directly or with the assistance of an Enrollment Worker
- Call Center staff will:
  - Screen the client for PrEP-AP eligibility
  - Enroll the client into PrEP-AP on a 30-day Temporary Access Period (TAP), if eligible

#### Step 2: Consult with a PlushCare Doctor

- CDPH Call Center staff will assist the client with contacting PlushCare
- PlushCare will:
  - Schedule a same-day doctor's appointment appointments occur by phone or video-chat
  - After the doctor's appointment, PlushCare will enroll insured clients who are prescribed Truvada® or Biktarvy® into the Gilead Copayment Assistance Program, and uninsured clients prescribed Truvada® or Biktarvy® will be enrolled into the Gilead Patient Assistance Program with short-term (30-day) eligibility
  - PlushCare will then refer the client to a local Quest laboratory for HIV/STI testing and send the client's nPEP prescription to a local <u>Magellan Rx</u> <u>Network Pharmacy</u>

#### Step 3: Visit a Magellan Rx Network Pharmacy

- Clients can access nPEP through a <u>Magellan Rx Network Pharmacy</u> immediately after consulting with a PlushCare provider
- PlushCare will provide the client's preferred Magellan Rx pharmacy with prescription details prior to the client arriving
- The client will not be required to pay out of pocket for nPEP

# Step 4: Fully enroll into PrEP-AP

- CDPH staff will follow-up with the client 1-2 business days after the PlushCare appointment to provide instruction on how to fully enroll into PrEP-AP
- Clients will be referred to a local enrollment site of choice where a certified Enrollment Worker will assist the client with fully enrolling into PrEP-AP

November 25, 2019

#### **Process for New Kaiser Clients**

# Step 1: Enroll into PrEP-AP via the CDPH Call Center

- Contact the CDPH Call Center at (844) 421-7050
- The Call Center is available Monday through Friday, 8:00 a.m. 5:00 p.m.
- Clients can call directly or with the assistance of an Enrollment Worker
- Call Center staff will:
  - Screen the client for PrEP-AP eligibility
  - Enroll the client into PrEP-AP on a 30-day Temporary Access Period (TAP), if eligible

#### Step 2: Consult with a Kaiser Doctor

 Kaiser clients must see a Kaiser clinician and receive any nPEP-related medical services through Kaiser

#### Step 3: Visit a Magellan Rx Kaiser Pharmacy

- Clients must access nPEP through a Kaiser pharmacy that is in the <u>Magellan Rx</u> Pharmacy Network
- The client will provide the pharmacy with their Kaiser card, PrEP-AP client ID number, BIN, PCN, and group number
- The client will not be required to utilize the Gilead Copayment Coupon Card or pay out of pocket for nPEP copayments

# Step 4: Fully enroll into PrEP-AP

- CDPH staff will follow-up with the client 1-2 business days after their doctor's appointment to provide instruction on how to fully enroll into PrEP-AP
- Clients will be referred to a local enrollment site of choice where a certified Enrollment Worker will assist the client with fully enrolling into PrEP-AP

#### **After Hours Access**

PrEP-AP is currently working on developing a process new clients can use for accessing nPEP after hours and on weekends. Enrollment Workers and PrEP-AP Providers will be notified once a process is in place.

Management Memorandum No. 2019-33

November 25, 2019

## Questions

If you have any questions regarding the information provided in this memo, please contact the PrEP Assistance Program by phone at (844) 421-7050 or by email at <a href="mailto:PrEPSupport@cdph.ca.gov">PrEPSupport@cdph.ca.gov</a>.

Thank you,

Sandra Robinson, MBA

Merden Fore

ADAP Branch Chief

California Department of Public Health

## Enclosures:

1) Process Flow: How Clients Access PEP via PrEP-AP

# **How Clients Access PEP via PrEP-AP**



Receives initial call, enrolls client into PrEP-AP with 30-days of eligibility, transfers caller to PlushCare (Kaiser clients will be referred to Kaiser Member Services or Kaiser emergency room) Performs
assessment, enrolls
client into a Gilead
assistance program,
sends labs to Quest,
sends Rx to Magellan
pharmacy

Follows-up with client and PlushCare in 1-2 business days (to determine if PEP/PrEP was prescribed and, if so, what regimen, & to refer client to enrollment site for full enrollment into PrEP-AP, if desired)