



SONIA Y. ANGELL, MD, MPH
State Public Health Officer & Director

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



GAVIN NEWSOM
Governor

Office of AIDS (OA)
Provider Network Policy Document

Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)
Policy Document number: **2020-01**

****CORRECTED** Provider Network Policy Memo:**

Initiation of Rapid Antiretroviral Therapy (ART) Due to Seroconversion

Overview

The purpose of this document is to inform contracted clinical providers in the PrEP-AP Provider Network of policy requirements enforced by the PrEP-AP with respect to initiating ART for clients who test HIV positive when being screened for PrEP at initiation or during follow-up.

Background

Immediate initiation of ART after a new HIV diagnosis, also known as rapid ART, has been evaluated in several clinical studies and may be helpful in promoting virologic suppression, medication adherence, and retention in care. These outcomes are consistent with goals outlined in [Laying a Foundation for Getting to Zero: California's Integrated HIV Surveillance, Prevention, and Care Plan](#), which provides the framework for getting to a time when there are: zero new HIV infections, zero AIDS-related deaths, and zero stigma and discrimination against people living with HIV.

New Policy

To remove barriers to rapid treatment for people in PrEP-AP who test positive for HIV, PrEP-AP will pay for one 30-day dispense of ART to allow time for navigation to other payer sources. ART should be initiated as soon as possible after diagnosis. Providers are encouraged to follow their own internal protocols when initiating ART rapidly, or if internal protocols are not available, reference the [San Francisco General Hospital "Rapid" Antiretroviral Therapy Standard Operating Procedures](#) or contact the Clinician Consultation Center at (800) 933-3413 for a phone consultation.

Providers are also encouraged to navigate individuals who test positive to enroll in the AIDS Drug Assistance Program (ADAP) by referring them to a certified [ADAP enrollment site](#) and to a local [Ryan White clinic](#) for follow-up care and treatment. Providers should fill out the [ADAP Diagnosis Form](#) to confirm an HIV diagnosis and facilitate enrollment into ADAP. The [PrEP-AP Provider Referral Form for Uninsured Clients](#) has been updated to provide instruction on initiating rapid ART. Both the ADAP Diagnosis Form and the PrEP-AP Provider Referral Form must be completely filled out by the attending provider and returned to the client. Due to confidentiality and privacy concerns, these documents are precluded from being sent directly to the PrEP-AP enrollment site by the provider for clients who test positive for HIV, as the site performing PrEP-AP enrollment may not be a certified ADAP enrollment site.

Prescriptions for approved medications must be filled at a pharmacy in the Magellan network, PrEP-AP is not able to pay for ART dispenses administered in a clinical setting.

Approved ART Regimens

Multiple preferred antiretroviral regimens are available for rapid ART on the [PrEP-AP formulary](#) (see below). A prior authorization is not needed but providers will be contacted by Magellan Rx Management, OA's contracted pharmacy benefits management company, after the prescription has been filled to confirm that initiation of rapid ART was the prescriber's intent and to ensure that linkage to ADAP or other payer sources has been initiated. Integrase inhibitor-based regimens with a high barrier to resistance and fixed dose combination regimens are generally preferred for rapid ART. Although rapid ART can be initiated before drug resistance test results are available, genotypic drug resistance testing should still be performed before initiation of ART. PrEP-AP covers the laboratory cost of three different genotypic drug resistance assays. Please see the [list of Allowable PrEP-related Medical Services](#). Antiretroviral regimens can be modified later upon receipt of genotypic drug resistance results.

Antiretroviral regimens for rapid ART initiation available on the PrEP-AP formulary:

1. Bictegravir/emtricitabine/tenofovir alafenamide (Biktarvy®) fixed dose combination 1 tablet once daily.
2. Dolutegravir (Tivicay®) 50 mg once daily + tenofovir alafenamide/emtricitabine (Descovy®)* 1 tablet once daily.
3. Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza®) fixed dose combination 1 tablet once daily (an option if drug resistance suspected).
4. Raltegravir (Isentress® HD) 1200 mg (two pills) once daily + tenofovir alafenamide/emtricitabine (Descovy®)* 1 tablet once daily (raltegravir can also be dosed 400mg twice daily).

* Tenofovir disoproxil fumarate/emtricitabine (Truvada®) can be used instead of Descovy®.

For Questions or Comments Please Contact:

Magellan Rx (available 24/7) at (800) 424-5906

Or

The Office of AIDS via e-mail at

PrEPSupport@cdph.ca.gov