



PrEP Access in California: Updates on the U.S. Preventive Services Task Force Grade A Recommendation and Senate Bill 159

Key Points

- As a result of the U.S. Preventive Services Task Force (USPSTF) Grade A recommendation for pre-exposure prophylaxis (PrEP), private health plans in California – with some exceptions – are required to cover both PrEP drugs and related medical services without cost sharing beginning no later than the 2021 plan year.
- If PrEP costs are not fully covered by a health plan – or if someone is uninsured – financial assistance for PrEP is available through drug manufacturers, private foundations, the California PrEP Assistance Program, and the federal Ready, Set, PrEP program.
- Under Senate Bill (SB) 159, pharmacists in California who complete an approved training course can furnish specified quantities of PrEP and post-exposure prophylaxis (PEP) without a doctor's prescription.
- SB 159 also prohibits most private health plans in California from requiring [prior authorization or step therapy](#) for patients to access PrEP and PEP beginning January 1, 2020.
- If a health plan is not properly implementing the USPSTF recommendation or SB 159, individuals are strongly encouraged to call the Department of Managed Health Care (DMHC) help center at 1-888-466-2219. Notifying the DMHC is extremely important so that regulators can work with the health plan to comply with state and federal law.

USPSTF Grade A Recommendation for PrEP

In June 2019, the U.S. Preventive Services Task Force (USPSTF) issued a [grade A recommendation](#) for pre-exposure prophylaxis (PrEP). This recommendation will help improve access to PrEP by urging health care providers to offer PrEP to people at risk for HIV. In addition, [patient protections under the Affordable Care Act \(ACA\)](#) require private health plans – with some exceptions – to cover preventive services recommended by the USPSTF with an A or B rating without patient cost sharing such as copayments, coinsurance, or deductibles (see below for more details).

Most California Health Plans Now Required to Cover PrEP Without Cost Sharing

In California, the large majority of health plans are regulated by two state departments – the California Department of Insurance (CDI) and the Department of Managed Health Care (DMHC). Both the CDI

and the DMHC have issued guidance regarding implementation of the USPSTF recommendation to require most private health plans in California to cover both PrEP drugs and related medical services without cost sharing.

On June 10, 2020, the CDI issued a [notice](#) to insurance companies providing health coverage in California informing them of their obligation to cover PrEP without cost sharing. The CDI's notice explains that under California law:

- PrEP drugs approved by the Federal Drug Administration (FDA) and recommended by the Centers for Disease Control and Prevention (CDC) must be covered in-network without a deductible, copayment, or coinsurance;
- Health plans cannot require prior authorization or step therapy for patients to access PrEP (see below for more details);
- Health plans are required to cover all medical services necessary for PrEP initiation and follow-up care, as recommended by the USPSTF and the CDC, without cost sharing.

The DMHC issued similar [guidance](#) on July 8, 2020 (see below for more details).

Health Plans Exempt from State Insurance Laws

Some group health plans in California, known as self-insured employee health benefit plans, are [exempt from state insurance laws](#). These health plans are regulated by the Federal Department of Labor. In 2018, approximately 5.5 million Californians were enrolled in self-insured employee health benefit plans.

Individuals enrolled in these health plans do not have the same protections as those enrolled in health plans regulated by the CDI and the DMHC. However, the ACA requires these plans to at least cover PrEP drugs without cost sharing. These plans are allowed to have prior authorization or step therapy requirements for patients to access PrEP.

The HIV Health Care Access Working Group, a coalition of over 100 national and community-based HIV service organizations, is [urging federal regulators](#) to close these loopholes and require more comprehensive implementation of the USPSTF PrEP recommendation, including coverage of PrEP-related medical services without cost sharing.

Health Plans Exempt from the Affordable Care Act Preventive Care Coverage Mandate

Health plans that maintain "grandfathered" status are exempt from the preventive care coverage mandate in the ACA, thus not required to cover PrEP drugs or related medical services without cost sharing. In order to have been classified as "grandfathered," plans must have been in existence prior to March 23, 2010, and cannot make significant changes to their coverage (for example, increasing patient cost sharing, cutting benefits, or reducing employer contributions). In 2019, approximately 1.5 million Californians were enrolled in grandfathered health plans (roughly 1.3 million were Kaiser Permanente[®] enrollees).

When Changes Go into Effect

Assuming a health plan is not exempt from the ACA preventive care coverage mandate, it is important to understand when these changes go into effect. While all health plans in California have been encouraged to provide coverage for PrEP without cost sharing immediately, the exact date health

plans are required to implement the USPSTF recommendation varies depending on the type of health coverage. Below is a brief summary of the various types of health coverage and when they are mandated to cover PrEP without cost sharing:

Individual Health Plans

- New coverage and renewals for individual health plans generally occur on January 1
 - Individual health plans must cover PrEP without cost sharing no later than January 1, 2021

Group Health Plans

- Group health plans, including self-insured employee health benefit plans, renew annually on a rolling basis throughout the year
 - New group health plans must cover PrEP without cost sharing immediately
 - Existing group health plans must cover PrEP without cost sharing when coverage renews

Implications for Medicaid and Medicare

Medicaid is a public insurance program that provides health coverage to low-income individuals. While the USPSTF Grade A recommendation has implications for state Medicaid programs, California's Medicaid program – also known as [Medi-Cal](#) – already covers PrEP drugs and related medical services without cost sharing for all beneficiaries. In addition, PrEP drugs do not require prior authorization or step therapy through Medi-Cal.

[Medicare](#) is a public insurance program for older adults and individuals living with disabilities. Medicare prescription drug plans are required to cover all PrEP drugs without prior authorization or step therapy as part of the [six protected classes rule](#). However, there is no requirement that Medicare prescription drugs plans cover USPSTF-recommended drugs like PrEP without cost sharing. Medicare beneficiaries may also have cost sharing for some PrEP-related medical services. Financial assistance programs for PrEP may help to defray these costs (see below for more details).

Compliance with the USPSTF Recommendation

California has taken several important steps towards implementing the USPSTF Grade A recommendation for PrEP. Because these changes are relatively new, it is imperative that providers and patients remain vigilant to ensure health plans are in compliance. In particular, it is important to monitor the degree to which state regulated health plans are covering both PrEP drugs and related medical services without cost sharing.

If a health plan is not properly implementing the USPSTF recommendation, individuals are strongly encouraged to call the [DMHC help center](#) at 1-888-466-2219. Contacting the DMHC is extremely important so that state regulators can work with the health plan to comply with state and federal law.

California Senate Bill 159

In October 2019, Governor Newsom signed into law landmark legislation to increase access to PrEP and PEP. [Senate Bill \(SB\) 159](#), the first law of its kind in the nation, authorizes pharmacists in California to furnish specified quantities of PrEP and PEP without a doctor's prescription. The legislation also

prohibits insurance companies from requiring prior authorization or step therapy for PrEP and PEP (see below for more details).

Prior authorization requires that a medication receive special approval by a health plan before it can be dispensed by a pharmacy. **Step therapy** requires a patient to use a less costly medication and fail and/or have adverse side effects before a more costly medication can be approved by a health plan. Prior authorization and step therapy are practices that insurance companies use to reduce costs.

Pharmacists Can Furnish PrEP and PEP After Completing Approved Training

Under SB 159, pharmacists who complete an approved training course can provide up to 60 days of PrEP without a doctor's prescription. This includes Descovy®, Truvada®, and generic TDF/FTC. Pharmacists will not be able to provide a 60-day supply of PrEP to a single patient more than once every two years. Before dispensing PrEP, a pharmacist must:

- Confirm the patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days;
- Confirm the patient does not report any signs or symptoms of acute HIV infection;
- Confirm the patient does not report taking any contraindicated drugs;
- Provide counseling on the ongoing use of PrEP, including education about side effects, adherence, and the importance of testing and treatment for HIV and other sexually transmitted infections (STIs);
- Notify the patient that they must be seen by a primary care provider to receive subsequent PrEP prescriptions;
- Document the services provided in the record system maintained by the pharmacy;
- Notify the patient's primary care provider or provide the patient with a list of physicians, clinics, or other health care providers to contact regarding ongoing PrEP care.

Pharmacists who complete an approved training course can also provide the full 28-day medication regimen for PEP without a doctor's prescription. There is no limit to the number of times a pharmacist can furnish PEP to a single patient. Before dispensing PEP, a pharmacist must:

- Screen the patient and determine the exposure occurred within the previous 72 hours and the patient meets the clinical criteria for PEP consistent with CDC guidelines;
- Provide an HIV test or determine the patient is willing to receive an HIV test. However, even if the patient is unwilling to receive an HIV test, the pharmacist can still provide PEP;
- Provide counseling on the use of PEP, including education about side effects, adherence, and the importance of testing and treatment for HIV and other STIs;
- Inform the patient of the availability of PrEP for individuals who are at risk for HIV;

- Notify the patient's primary care provider or provide the patient with a list of physicians, clinics, or other health care service providers to contact regarding follow up for PrEP.

The California State Board of Pharmacy recently [approved](#) the first training course for pharmacists to begin furnishing PrEP and PEP. While some pharmacists will complete the training and begin furnishing PrEP and PEP in the coming months, it may take some time before pharmacist-delivered PrEP and PEP becomes widely available.

Most California Health Plans Prohibited from Requiring Prior Authorization or Step Therapy for PrEP and PEP

Under SB 159, private health plans in California – with the exception of self-insured employee health benefit plans – are prohibited from requiring prior authorization or step therapy for patients to access PrEP and PEP beginning January 1, 2020. Insurance companies are only allowed to require prior authorization or step therapy for PrEP and PEP when the FDA has approved therapeutically equivalent versions of a drug. For example, because generic TDF/FTC and Truvada[®] are therapeutically equivalent, health plans are only required to cover one of these drugs without prior authorization or step therapy.

Despite this new law, some health plans continue to require prior authorization or step therapy patients to access PrEP. In addition, some health plans have removed Descovy[®] from their formularies and patients are required to complete a formulary exception request to access the medication. State regulators are responding to these actions to ensure health plans are in compliance with state law, but providers and patients are strongly encouraged to contact the DMHC to report any challenges accessing PrEP. If a health plan requires prior authorization for PrEP or is not covering Descovy[®], individuals can call the [DMHC help center](#) at 1-888-466-2219.

Financial Assistance Programs for PrEP

If PrEP costs are not fully covered by a health plan – or if someone does not have insurance – financial assistance for PrEP is available through drug manufacturers, private foundations, and the state-funded California PrEP Assistance Program (PrEP-AP).

For Individuals with Private Insurance:

- Gilead provides [copay assistance](#) for Truvada[®] and Descovy[®] to individuals with private insurance, regardless of immigration status. The Gilead copay card covers out-of-pocket costs for either of the two drugs up to \$7,200 per year. It does not cover out-of-pocket costs for clinical visits or labs. There are no income restrictions to access this program.
- Teva provides [copay assistance](#) for generic TDF/FTC to individuals with private insurance, regardless of immigration status. The Teva copay card covers out-of-pocket costs for the drug up to \$600 a month. It does not cover out-of-pocket costs for clinical visits or labs. There are no income restrictions to access this program.
- California's [PrEP-AP](#) covers PrEP-related medical out-of-pocket costs and drug costs not covered by an insurance plan or manufacturer assistance program. This includes out-of-pocket costs for Descovy[®], Truvada[®], and generic TDF/FTC as well as clinical visits and labs. The program is available to California residents, regardless of immigration status, earning less than 500% of the federal poverty level (approximately \$63,800 annually for a single person).
- Minors, ages 12 through 17, are not required to use their insurance and can be enrolled in

the PrEP-AP as uninsured clients.

- Individuals 18 years of age and older who have insurance through a parent, spouse or registered domestic partner, but have concerns about their confidentiality, can be enrolled in the PrEP-AP as uninsured clients.
- In addition to the programs outlined above, financial assistance may be available from the [Patient Advocate Foundation](#), [Good Days](#), and the [PAN Foundation](#).

For Individuals with Medicare:

- Medicare beneficiaries with prescription drug coverage are not eligible for copay assistance from Gilead or Teva, but are eligible to enroll in the [PrEP-AP](#) for copayment assistance for PrEP drugs. Medicare beneficiaries without prescription drug coverage are eligible to enroll in the Gilead [Advancing Access](#) program to receive Truvada® or Descovy® for free. These programs are available to California residents earning less than 500% of the federal poverty level (approximately \$63,800 annually for a single person).
- All Medicare beneficiaries with outpatient coverage through Medicare are eligible to receive assistance with PrEP-related medical out-of-pocket costs through the PrEP-AP, if they qualify for the program.

For Uninsured Individuals:

- Uninsured individuals, regardless of immigration status, can access PrEP medication and related medical services for free by enrolling in both the [PrEP-AP](#) and the Gilead [Advancing Access](#) program. These programs are available to California residents earning less than 500% of the federal poverty level (approximately \$63,800 annually for a single person).
- The federal [Ready, Set, PrEP](#) program also provides free PrEP medication to uninsured individuals, regardless of immigration status. There are no income restrictions to access this program.