



## CALIFORNIA HIV / AIDS POLICY RESEARCH CENTERS

### ***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 limited exceptions – are required to cover both PrEP medication and related clinical services without cost sharing.
- 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, and the California PrEP Assistance Program (PrEP-AP).
- As a result of [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 private health plans in California – with limited exceptions – from requiring prior authorization or step therapy for individuals to access PrEP and PEP.
- If a health plan is not properly implementing the USPSTF recommendation or SB 159, individuals enrolled in state-regulated health plans are strongly encouraged to [submit a complaint](#) to the California Department of Managed Health Care (see [How to Submit a Complaint](#) section).

#### **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 to improve access to PrEP by urging health care providers to offer PrEP to those at risk for HIV. In addition, [patient protections under the Affordable Care Act \(ACA\)](#) require most private health plans to cover preventive services recommended by the USPSTF with an A or B rating without cost sharing such as copayments, coinsurance, or deductibles. State and federal regulators recently issued guidance clarifying that health plans must cover both PrEP medication and related clinical services without cost sharing (see [Most California Health Plans Now Required to Cover PrEP Without Cost Sharing](#) section).

**What are the different types of PrEP?** There are two medications approved for PrEP: Truvada® and Descovy®. A generic version of Truvada® is also available.

## 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](#) issued guidance clarifying that all state-regulated health plans are required to cover both PrEP medication and related clinical services without cost sharing. The guidance explains that under California law:

- Health plans generally cannot require prior authorization or step therapy for individuals to access PrEP (see [Most California Health Plans Prohibited from Requiring Prior Authorization or Step Therapy for PrEP and PEP](#) section);
- Health plans are required to cover both PrEP medication and clinical services necessary for PrEP initiation and followup care without cost sharing, including but not limited to: provider office and telehealth visits; HIV testing; kidney function testing; testing for hepatitis B and C; hepatitis B vaccination; and testing for other sexually transmitted infections (STIs).

Some employer health plans in California, known as self-insured employer health plans, are [not regulated](#) by the CDI or the DMHC. These health plans are regulated by the federal Department of Labor. On July 19, 2021, the U.S. Departments of Health and Human Services, Labor, and Treasury jointly issued [guidance](#) requiring that these plans also cover both PrEP medication and related clinical services without cost sharing. However, unlike state-regulated health plans, self-insured employer health plans are allowed to require prior authorization or step therapy for individuals to access PrEP (see [Most California Health Plans Prohibited from Requiring Prior Authorization or Step Therapy for PrEP and PEP](#) section).

**Is my employer health plan self-insured?** Your rights regarding your health plan depend on whether the plan is fully insured or [self-insured](#). To find out, contact your employee benefits administrator in your employer’s human resources department.

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

Some health plans – known as “grandfathered” health plans – are exempt from the preventive care coverage mandate in the ACA. Thus, these plans are not required to cover PrEP medication or related clinical services without cost sharing. In order to have been classified as “grandfathered,” plans must have been in existence prior to March 23, 2010 when the ACA was passed, and cannot make significant changes to their coverage.

**Is my health plan “grandfathered”?** If you’ve been in the same health plan since March 23, 2010 or prior, and there have been no major benefit or contribution changes, your plan is probably “grandfathered”.

## Implications for Medicaid and Medicare

California’s Medicaid program – known as [Medi-Cal](#) – covers PrEP medication and related clinical services without cost sharing for individuals earning less than 138% of the federal poverty level (approximately \$17,775 for a single individual). Medi-Cal does not require prior authorization or step therapy for individuals to access PrEP and PEP.

[Medicare](#) is a public insurance program for older adults and individuals living with disabilities. While the USPSTF recommendation does not apply to Medicare, most Medicare plans cover PrEP and related

clinical services, but with applicable cost sharing. Financial assistance programs for PrEP are available to help cover these costs (see [Financial Assistance Programs for PrEP](#) section).

## California Senate Bill 159

In October 2019, Governor Newsom signed into law landmark legislation to increase access to PrEP and post-exposure prophylaxis (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 generally prohibits insurance companies from requiring prior authorization or step therapy for individuals to access PrEP and PEP (see [Most California Health Plans Prohibited from Requiring Prior Authorization or Step Therapy for PrEP and PEP](#) section).

**Prior authorization** requires an individual to receive special approval from their health plan before a medication can be dispensed by a pharmacy.

**Step therapy** an individual to use a less costly medication and fail or have adverse side effects before a more costly medication can be approved by their health plan.

### 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<sup>®</sup>, brand name Truvada<sup>®</sup>, and generic Truvada<sup>®</sup>. Pharmacists can only provide a 60-day supply of PrEP to a single individual once every two years. Before dispensing PrEP, a pharmacist must:

- Confirm the individual is HIV negative, as documented by a negative HIV test result obtained within the previous seven days;
- Confirm the individual does not report any signs or symptoms of acute HIV infection;
- Confirm the individual does not report taking any contraindicated medication;
- 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 STIs;
- Notify the individual 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; and
- Notify the individual's primary care provider or provide the individual 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 individual. Before dispensing PEP, a pharmacist must:

- Screen the individual and determine the exposure occurred within the previous 72 hours and the individual meets the clinical criteria for PEP consistent with CDC guidelines;
- Provide an HIV test or determine the individual is willing to receive an HIV test. However, even if the individual 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 individual of the availability of PrEP for individuals who are at risk for HIV; and
- Notify the individual's primary care provider or provide the individual with a list of physicians, clinics, or other health care service providers to contact regarding follow up for PEP.

The California State Board of Pharmacy [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. The Board of Pharmacy maintains a [website](#) where you can find out if pharmacist-delivered PrEP and PEP is available in your area.

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

Under SB 159, state-regulated health plans are generally prohibited from requiring prior authorization or step therapy for individuals to access PrEP and PEP. However, if the FDA has approved therapeutically equivalent versions of a drug, the plan is only required to cover one of the therapeutically equivalent versions without prior authorization or step therapy.

The DMHC recently issued [guidance](#) clarifying health plan requirements under SB 159. The guidance states that – because brand name Truvada<sup>®</sup> and generic Truvada<sup>®</sup> are therapeutically equivalent – health plans can require prior authorization or step therapy on brand name Truvada<sup>®</sup> so long as the plan offers generic Truvada<sup>®</sup> without prior authorization or step therapy. However, the plan must cover Descovy<sup>®</sup> without prior authorization or step therapy because the FDA has not approved a therapeutically equivalent version of Descovy<sup>®</sup>.

In addition, the DMHC [guidance](#) states that removing PrEP medication from a formulary is a form of prior authorization or step therapy and is inconsistent with the requirements under SB 159. Thus, health plans are required to keep PrEP medication, including medication with no therapeutically equivalent version such as Descovy<sup>®</sup>, on their formularies.

It is important to remember that some employer health plans in California, known as self-insured employer health plans, are [not regulated](#) by the CDI or the DMHC. These health plans are regulated by the federal Department of Labor. Self-insured employer health plans are allowed to require prior authorization or step therapy for individuals to access PrEP and PEP. However, federal [guidance](#) states that clinical management techniques such as prior authorization must be expedient and allow individuals to start PrEP on the same day as their visit or negative HIV test.

In addition, the federal [guidance](#) notes that “plans and issuers must accommodate any individual for whom a particular PrEP medication (generic or brand name) would be clinically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.” This means, for example, that self-insured employer health plans must have a mechanism in place to approve Descovy<sup>®</sup> based on clinical criteria and if approved, it must be available without cost sharing.

### **How to Submit a Complaint**

If a health plan is not in compliance with the USPSTF recommendation or SB 159, individuals enrolled in state-regulated health plans are strongly encouraged to [submit a complaint](#) to the DMHC.

Contacting the DMHC is extremely important so that regulators can work with the health plan to comply with the law.

Individuals have the option to submit a complaint form either online, by mail, or by fax. The DMHC strongly encourages individuals to file a complaint form electronically through the [online option](#) to process the request as quickly as possible. Be sure to complete all fields and include any copies of supporting documents.

### **What if my health plan is not regulated by the DMHC?**

The DMHC regulates the vast majority of health plans in California. If you contact the DMHC and they find that your health plan is under the jurisdiction of CDI, they will forward your complaint to CDI.

### **Do I need to file a complaint with my health plan first?**

No. Individuals are usually required to file a complaint with their health plan before submitting a complaint to the DMHC. However, in the case of PrEP and PEP, this requirement has been waived and individuals can submit a complaint directly to the DMHC.

### **What if I need assistance with filing a complaint?**

The DMHC contracts with the [Health Consumer Alliance](#), a group of local, community-based organizations that can provide you with assistance filing a complaint. If you need one-on-one assistance, please contact the Health Consumer Alliance Consumer Assistance Program at 1-888-804-3536.

### **If I am a provider, can I file a complaint on behalf of a patient?**

Yes. However, the DMHC must have on file a completed and signed [Authorized Assistant Form](#). Completion and submission of the Authorized Assistant Form tells the DMHC that it has permission to speak with you on behalf of a patient. You have the option to send the form either as an attachment with your online complaint form or with your supporting documents by mail or fax.

### **How long will it take for my complaint to be resolved?**

The DMHC will review your complaint and send you an acknowledgement of receipt letter within 7 days. If your problem is urgent, the complaint is usually resolved within 7 days. A problem is deemed urgent if it is a serious and immediate threat to your health. If your problem is not urgent, the complaint is usually resolved within 30 days.

### **What if I am enrolled in a self-insured employer health plan?**

Most self-insured employer health plans fall under the jurisdiction of Employee Retirement Income Security Act (ERISA). ERISA is federal law that is enforced by the federal Department of Labor, Employee Benefits Security Administration (DOL-EBSA). If you have a complaint against a self-insured employer health plan, you can contact the DOL-EBSA for assistance at 1-866-444-3272 or [submit a complaint online](#).

### **How do I find out if I am enrolled in a self-insured employer health plan?**

Your rights regarding your health plan depend on whether the plan is fully insured or [self-insured](#). Because many employers use a third party administrator, such as an insurance company, to handle claims, you may not necessarily know if your plan is self-insured. To find out, contact your employee benefits administrator in your employer's human resources department.

## 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 [California PrEP Assistance Program \(PrEP-AP\)](#). These programs are available to all California residents regardless of immigration status.

For individuals with private insurance:

- Gilead provides [copay assistance](#) for brand name Truvada® and Descovy® up to \$7,200 per year. The program does not cover PrEP-related clinical costs such as provider visits and labs. There are no income restrictions to access the program.
- California's [PrEP-AP](#) covers PrEP-related clinical costs and medication costs not covered by an insurance plan or drug manufacturer assistance program. The program is available to individuals earning less than 500% of the federal poverty level.
- 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, but are eligible to enroll in the [PrEP-AP](#) for copayment assistance for PrEP medication. The program is available to individuals earning less than 500% of the federal poverty level.
- Medicare beneficiaries without prescription drug coverage are eligible to enroll in Gilead's [Advancing Access](#) program to receive brand name Truvada® or Descovy® for free. The program is available to individuals earning less than 500% of the federal poverty level.
- All Medicare beneficiaries are eligible to receive assistance with PrEP-related clinical costs through the PrEP-AP, if they qualify for the program.

For uninsured individuals:

- Uninsured individuals can access PrEP medication and related clinical services for free by enrolling in both the [PrEP-AP](#) and Gilead's [Advancing Access](#) program. These programs are available to individuals earning less than 500% of the federal poverty level.
- The federal [Ready, Set, PrEP](#) program also provides free PrEP medication to uninsured individuals. There are no income restrictions to access the program.