



KEY UPDATES

FEDERAL LAW AND POLICY

- » As a result of the U.S. Preventive Services Task Force (USPSTF) [Grade A recommendation](#) for pre-exposure prophylaxis (PrEP), most private health plans in California are [required to cover PrEP medication and related clinical services](#)—such as provider visits and labs—without cost sharing.
- » The USPSTF has extended its [Grade A recommendation](#) to Apretude® (cabotegravir), the first long-acting injectable PrEP medication approved by the FDA.
- » 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’s PrEP Assistance Program \(PrEP-AP\)](#).
- » Pending litigation (*Braidwood v. Becerra*) is challenging the USPSTF’s current PrEP mandate. The final outcome and impact on PrEP access remains undetermined.

STATE LAW AND POLICY

- » As a result of [Senate Bill \(SB\) 339](#), pharmacists in California who complete an approved training course can furnish PrEP to an individual without an outside provider’s prescription.
- » Most private health plans in California are prohibited from requiring individuals to receive special approval—known as prior authorization or step therapy—to access medication for PrEP and post-exposure prophylaxis (PEP).
- » If a health plan is not in compliance with USPSTF or SB 339 guidelines, individuals are strongly encouraged to submit a complaint to the [California Department of Managed Health Care](#).

THE USPSTF'S 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) and urged health care providers to offer PrEP to those at risk for HIV. On August 22, 2023, the USPSTF issued an update to their grade A recommendation, resulting in several changes and clarifications regarding PrEP. The current USPSTF recommendation is as follows:

What does USPSTF recommend?

The USPSTF recommends that clinicians prescribe pre-exposure prophylaxis (PrEP) using effective antiretroviral therapy to adults and adolescents weighing at least 35 kg (77 lb) who are at increased risk of acquiring HIV.

To whom does this apply?

This recommendation applies to adolescents and adults who do not have HIV and are at increased risk of HIV.

Those at “increased risk” include: Sexually active adults and adolescents weighing at least 35 kg (77 lb) who have engaged in anal or vaginal sex in the past 6 months and meet the following conditions.

The person has/had:

- » A sexual partner who has HIV;
- » A bacterial sexually transmitted infection (syphilis, gonorrhea, or chlamydia for men who have sex with men and transgender women; gonorrhea or syphilis for heterosexual women and men) in the past 6 months;
- » A history of inconsistent or no condom use with sex partner(s) whose HIV status is not known;
- » Injected drugs or a drug injecting partner who has HIV or who shares injection equipment;
- » Engaged in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers or persons trafficked for sex work; or
- » Requested PrEP.

What's new?

USPSTF identified two additional FDA-approved formulations of PrEP:

- » **Emtricitabine/tenofovir alafenamide (TAF/FTC)**; brand-name Descovy®, the second daily oral medication approved by the FDA for PrEP in October 2019; and
- » **Cabotegravir** (brand-name Apretude®), the first long-acting injectable PrEP medication approved by the FDA in December 2021.

What does this mean for plans and providers?

The current USPSTF recommendation for PrEP specifies three formulations of medications (two oral—Truvada® and Descovy®, and one injectable—Apretude®) approved by the FDA for use as PrEP. Therefore, plans and issuers must cover, without cost sharing, these three formulations and are not permitted to use medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another.

STATE AND FEDERAL GUIDANCE ON HEALTH PLANS

In California, most 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 including but not limited to: provider office and telehealth visits; HIV testing; kidney function testing; testing for hepatitis B and C; and testing for other sexually transmitted infections (STIs) without cost sharing.

PRIVATE HEALTH PLANS

- » Roughly 2/3 of private health plans in California are regulated by the California Department of Insurance (CDI) or Department of Managed Health Care (DMHC).
- » These plans are required to cover both PrEP medication and related clinical services without cost sharing.
- » Regulated health plans are also required to cover Descovy® without prior authorization or step therapy but can require prior authorization or step therapy for brand name Truvada® as long as generic Truvada® is available without restriction.

SELF-INSURED EMPLOYER HEALTH PLANS

- » Roughly 1/4 of private health plans in California—known as self-insured employer health plans—are regulated by the federal Department of Labor rather than the CDI or DMHC.
- » As of October 21, 2024, these plans are required to cover all three FDA-approved PrEP formulations (two oral and one injectable) and related clinical services, without cost sharing, and are not permitted to use medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another.

IS MY EMPLOYER'S 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.

"GRANDFATHERED" OR LEGACIED HEALTH PLANS

- » Some health plans—known as “grandfathered” or legacied health plans—are exempt from the preventive care coverage mandate in the Affordable Care Act (ACA). Thus, they are not required to cover PrEP medication or related clinical services without cost sharing.
- » These plans are also allowed to require prior authorization or step therapy for individuals to access PrEP.
- » Less than 1 in 10 private health plans in California are legacied health plans.

IS MY HEALTH PLAN LEGACIED?

- » 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 likely legacied.

MEDI-CAL

- » 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. Medi-Cal does not require prior authorization or step therapy for individuals to access PrEP and PEP.

MEDICARE

- » Medicare is a public insurance program for older adults and individuals living with disabilities. As of September 2024, Medicare also [covers PrEP without cost sharing](#).

HEALTH PLAN COMPLAINTS

If a health plan is not in compliance with the USPSTF recommendation or SB 339, individuals enrolled in state-regulated health plans may submit a complaint to the California Department of Managed Health Care (DMHC). Individuals have the option to [submit a complaint](#) form either online, by mail, or by fax, though online complaint form submissions are encouraged to process the request as quickly as possible.

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 the 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. A fully insured plan is a group health plan in which the employer or association purchases health insurance from a commercial insurer in order to provide coverage for its employees or association members. To find out, contact your employee benefits administrator in your employer's human resources department.

CALIFORNIA SENATE BILLS 159 & 339

In October 2019, Governor Newsom signed into law Senate Bill (SB) 159, the first law of its kind in the U.S., which authorized pharmacists in California to furnish specified quantities of PrEP and PEP without a provider's prescription. The legislation also generally prohibited insurance companies from requiring prior authorization or step therapy for individuals to access PrEP and PEP. Though implementation of SB 159 began in late 2020, as of late 2022, [few pharmacists reported that these services were available in their pharmacies](#). To help realize the goal of widespread access to PrEP and PEP, SB 339 was signed into law in 2024. The current authorizations under SB 159 and SB 339 are as follows:

Current law under Senate Bills 159 (2019) and 339 (2024)

BASIC REQUIREMENTS

- » Authorizes pharmacists to furnish PrEP/PEP, including Descovy®, brand name Truvada®, generic Truvada®, and cabotegravir (Apretude®).
- » Pharmacist consultation with a patient cannot be waived for PrEP.
- » A drug must be approved by the FDA or recommended by the CDC to reduce a person's chance of contracting HIV.
- » Pharmacists must notify patients' primary care provider (PCP) or give patients a list of providers that can provide ongoing care for PrEP.

TRAINING AND REQUIREMENTS

- » Pharmacists must complete a training program approved by the California State Board of Pharmacy, in consultation with the Medical Board of California.

PREP INITIATION AND CONTINUATION

- » Pharmacists may furnish **up to 90 days of PrEP** if the following conditions are met:
 - » Confirm the individual is HIV negative, as documented by a negative HIV test result obtained in accordance with CDC guidelines;
 - » 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.

- » Maximum may be increased **beyond 90 days** if the following conditions are met:
 - » Pharmacists ensure that patients receive testing and follow-up care consistent with CDC guidelines, which may include timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity;
 - » Pharmacists notify patient's primary care provider of the services provided or give patients a list of providers in the region;
 - » Counseling is provided;
 - » Pharmacists maintain records of PrEP provided.

PEP INITIATION AND CONTINUATION

- » Pharmacists may furnish PEP if the following conditions are met:
 - » Screen the individual and determine the HIV 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 whether 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.
- » There is no limit to the number of times a pharmacist can furnish PEP to a single individual.

PAYMENT FOR SERVICES

- » Prohibits health insurers or pharmacy benefit managers from preventing pharmacists from dispensing PrEP/PEP.
- » Prohibits insurance companies from requiring prior authorization or step therapy for PrEP/PEP except:
 - » 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.
 - For example, brand name Truvada® and generic Truvada® are therapeutically equivalent, so plans can require prior authorization or step therapy on brand name Truvada® so long as they also offer generic Truvada® without prior authorization or step therapy;
- » However, a plan must cover Descovy® and Apretude®/cabotegravir without prior authorization or step therapy because the FDA has not approved therapeutically equivalent versions.
- » Self-insured employer health plans, regulated by the federal Department of Labor rather than the CDI or DMHC, are **not permitted** to use medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another.
- » Insurers are required to pay for a pharmacist's services (e.g., counseling, testing) and related testing ordered by the pharmacist.

FINANCIAL ASSISTANCE PROGRAMS FOR PrEP

If PrEP costs are not fully covered by a health plan, if someone does not have insurance, or in situations where an individual has health insurance through a parent, spouse, or domestic partner but cannot use it to access PrEP medication due to privacy reasons, financial assistance for PrEP is available through drug manufacturers, private foundations, and California's [PrEP Assistance Program \(PrEP-AP\)](#), administered through the [AIDS Drug Assistance Program \(ADAP\)](#). These programs are available to qualifying California residents regardless of immigration status.

ADAP AND PrEP-AP

The AIDS Drug Assistance Program (ADAP) supports people living with HIV and AIDS in California and supports those at risk for HIV through its [Pre-Exposure Prophylaxis Assistance Program \(PrEP-AP\)](#) for people who are HIV negative in California.

Effective January 1, 2025, the following changes will take effect:

INCREASED FINANCIAL ELIGIBILITY

- » More people will qualify for ADAP and PrEP-AP, as the financial eligibility will rise from 500% of the federal poverty level to 600% (around \$90,000 for a household of one, or \$122,000 for a household of two).

PAYMENT ASSISTANCE PROGRAMS

Some drug manufacturers provide patient assistance programs. Programs provide information on coverage and financial support options for individuals who have been prescribed HIV-treatment and HIV-prevention medication. Financial support may include co-pay coupon cards that may help eligible, commercially insured individuals lower their out-of-pocket costs. While such programs may decrease treatment costs, lowering costs for some medications to \$0, program guidelines are subject to change. For example, the Medication Assistance Program offered by Gilead's [Advancing Access® Program](#), will soon remove coverage for the cost of [Truvada®](#). Other eligibility requirements apply—this may include exclusions for those individuals insured by other federal and state-funded prescription drug programs.

ASSISTANCE BY INSURANCE TYPE

A general overview of potential assistance by insurance type is as follows:

INDIVIDUALS WITH PRIVATE INSURANCE

- » In most cases, private insurance companies are required to cover PrEP and related services without cost-sharing.
- » Gilead provides co-pay 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. 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](#).

INDIVIDUALS WITH MEDICARE

- » In most cases, private insurance companies are required to cover PrEP and related services without cost-sharing.
- » Medicare beneficiaries with prescription drug coverage are not eligible for co-pay assistance from Gilead but are eligible to enroll in the PrEP-AP for co-payment assistance for PrEP medication.
- » 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.
- » The Centers for Medicare & Medicaid Services (CMS) recently announced its final [National Coverage Determination](#) (NCD) for PrEP, which shifts coverage of these services from Medicare Part D to Part B. This means PrEP will be treated as a covered preventive service, which will allow patients to receive this care without cost sharing.
- » However, shifting PrEP medication coverage to Part B will affect PrEP access provided by pharmacists, since under the new NCD, valid prescriptions written by pharmacists might not be reimbursed because pharmacists cannot enroll as prescribers and thus cannot receive payment from Medicare for PrEP/PEP service delivery.

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.

PREP AND INTEGRAL SERVICE FREQUENCY AND BILLING GUIDELINES

The California Department of Insurance (CDI) established [best practices](#) for health insurers' reimbursement policies for billing and coding claims for PrEP services delivery. The CDI's [charts](#) outline codes for daily oral PrEP and long-acting injectable PrEP, their CDC-recommended integral services, such as billing codes for each service, and the frequency of each service. Under current CDC guidelines, these must all be covered as preventive care without cost sharing, and if an insurer imposes frequency limits on any integral services, the limits must not be more restrictive than those set forth by the CDC.

POTENTIAL LEGAL CHALLENGES

There is pending litigation that may affect PrEP access, specifically the case of *Braidwood Management, Inc. et al. v. Xavier Becerra et al.* The plaintiffs in the Braidwood case challenge the legality of the current PrEP preventative care mandate—the USPSTF's "A" rating for PrEP medication, which, through the U.S. Department of Health and Human Services, compels private health insurers to cover these medications without cost sharing. The plaintiffs claim this is a violation of their rights under the Religious Freedom Restoration Act (RFRA). This case has important implications, as a decision in favor of the plaintiffs, and applied nationwide, could mean striking down the requirement for private insurers and employers to cover PrEP services without cost sharing. This may jeopardize access to these services, as it could mean that coverage of PrEP and preventive services without cost sharing could again be at the individual discretion of plans and employers. The ruling at the District Court was narrow in determining that only the specific employers that were parties to the case could justify denying coverage of PrEP services to their employees based on the employers' right to religious freedom. Braidwood's most recent ruling by the Fifth Circuit Court of Appeals in June 2024, however, held that USPSTF's role in determining mandatory preventive coverage under the ACA was unconstitutional. The case is currently being appealed to the U.S. Supreme Court. California has since codified the ACA's preventive care mandate and subsequent guidance through [Senate Bill \(SB\) 406](#) and [Assembly Bill \(AB\) 2258](#). As a result, most private health plans in California will be required to cover PrEP and other preventive services without cost sharing, regardless of the outcome of this case.

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KEY TERMS

Advancing Access®: A patient support program administered by Gilead that provides information on coverage and financial support options for individuals who have been prescribed a Gilead HIV-treatment, HIV-prevention, or COVID-19 medication.

Cost Sharing: A patient's portion of healthcare costs under their insurance plan, usually in the form of co-pays, deductibles, or co-insurance.

DMHC: California Department of Managed Health Care. Regulates most private health plans in California.

CDI: California Department of Insurance. Regulates some private health plans in California.

Medi-Cal: California's Medicaid program. Provides free or low-cost health coverage to low-income Californians.

Medicare: A public insurance program for older adults and individuals living with disabilities.

PEP: Post-exposure prophylaxis. Medication started within 72 hours (3 days) after a possible exposure to HIV to prevent HIV acquisition.

PrEP: Pre-exposure Prophylaxis. A medication that is over 99% effective in preventing HIV. There are currently three medications approved for use as PrEP:

Emtricitabine/Tenofovir Disoproxil Fumarate (TDF/FTC) (brand-name Truvada®), the first daily oral medication approved by the FDA for PrEP.

Emtricitabine/Tenofovir Alafenamide (TAF/FTC) (brand-name Descovy®) the second daily oral medication approved by the FDA for PrEP.

Cabotegravir (brand-name Apretude®), the first long-acting injectable PrEP medication approved by the FDA.

PrEP-AP: Pre-Exposure Prophylaxis Assistance Program (PrEP-AP), which helps cover medications and PrEP-related medical services for the prevention of HIV.

Prior Authorization: Requiring an individual to receive special approval from their health plan before a medication can be dispensed by a pharmacy.

Step Therapy: Requiring 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.

USPSTF: U.S. Preventive Services Task Force. An independent panel of national experts in disease prevention and medicine who make evidence-based recommendations about clinical preventive services.