

Frequently Asked Questions: Accessing Pre-exposure Prophylaxis (PrEP) in Massachusetts

Must private insurers cover PrEP for free?

The Affordable Care Act (ACA) requires most private insurance plans and some Medicaid programs to cover key preventive services at no cost beyond any monthly plan premiums. These plans must cover preventive services recommended by various groups of experts and government agencies, specifically:

- 1) Items and services rated "A" or "B" by the United States Preventive Services Task Force (USPSTF);
- 2) Immunizations recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC);
- 3) Preventive care and screenings for infants, children, and adolescents supported by the Health Resources and Services Administration (HRSA); and
- 4) Preventive care and screenings for women is supported by HRSA.

In 2019, the USPSTF rated PrEP "A", its highest recommendation. Therefore, most private insurance plans were required to cover PrEP and ancillary services at no additional cost. This recommendation was updated in 2023 to incorporate research on new formulations of PrEP. The current USPSTF rating remains an "A".

Ongoing litigation (*Braidwood Management v. Becerra*) has called into question the ACA requirement that private insurance plans cover PrEP (and related services), and other preventive services without cost sharing (or at no cost to a consumer). However, the Massachusetts Fiscal Year 2024 Budget included provisions to require various state-regulated insurance plans to cover USPSTF-, ACIP-, and HRSA- recommended preventive services (established by federal regulation/guidance on or before July 1, 2023) at no additional cost to consumers. The Massachusetts Division of Insurance is expected to issue guidance about this requirement and future updates. Currently, the ACA requirement that private insurers cover preventive services remains in effect nationwide.

For more information about this court case and its potential impact, see the Center for Health Law and Policy Innovation's *Braidwood Management v. Becerra*: Frequently Asked Questions.

Are all forms of PrEP covered at no additional cost?

The Food & Drug Administration (FDA) has approved three medications for use as PrEP: emtricitabine/tenofovir disoproxil fumarate (available as generic and branded Truvada), emtricitabine/tenofovir alafenamide (available as branded Descovy), and cabotegravir (available as branded Apretude). VI Currently, insurers are not required to cover all forms of PrEP at no additional cost to consumers and may use reasonable medical management techniques to encourage individuals to use a preferred medication over a non-preferred one.

However, insurers must have "an easily accessible, transparent, and sufficiently expedient exceptions process" for individuals when a health care provider determines the preferred PrEP medication is not medically appropriate. When an insurer approves such an exception, the insurer must cover that alternative medication at no additional cost.

What other PrEP-related services are covered?

Insurers that are required to cover PrEP at no additional cost are also expected to cover certain associated baseline and monitoring services at no additional cost. In 2021, the federal government indicated this should include: viii

- HIV testing
- Hepatitis B and C testing
- Creatinine testing and calculated estimated creatinine clearance (eCrCl) or glomerular filtration rate (eGFR)
- Pregnancy testing
- Sexually transmitted infection (STI) screening and counseling
- Medication adherence counseling

The 2023 USPSTF recommendation includes a slightly different set of baseline and monitoring services, and it is unclear how this will change the federal government's guidelines. The newer set of baseline and monitoring services include: HIV testing; STI testing; pregnancy testing; kidney function testing and hepatitis B testing (for TDF/FTC or TAF/FTC); lipid profile testing (for TAF/FTC); and medication adherence support. In some instances, such as hepatitis C testing, other USPSTF recommendations may separately require insurers to cover the service at no cost to consumers.

What should providers consider when submitting a claim for reimbursement for PrEP?

Each insurance company has different procedures for submitting claims for reimbursement. This is particularly true for preventive care that is covered with no additional cost to consumers, as these services may be subject to cost sharing when provided for a non-preventive purpose. (For example, a colonoscopy conducted as part of colorectal cancer screening would be covered without cost sharing, but a diagnostic colonoscopy might not.)

To help distinguish services that are covered without cost sharing due to a recommendation from the USPSTF, some insurance companies ask providers to use modifier 33 when submitting claims for reimbursement. *i For more information, look to the insurance company's specific policy. Examples of this type of guidance are available here and here. For more information about billing and coding, see the National Alliance of State and Territorial AIDS Directors (NASTAD) resource here.

Does MassHealth cover PrEP?

Yes. While the ACA only requires some Medicaid programs to cover key preventive services at no additional cost, MassHealth's benefit package includes all USPSTF- and ACIP-recommended preventive services at no additional cost. As of April 2023, all MassHealth Managed Care Organizations and Accountable Care Organizations (including Accountable Care Partnership Plans and Primary Care Accountable Care Organizations) must use the MassHealth Drug List for their prescription drug coverage. These plans will cover the same drugs, have the same drug preferences, and use the same prior authorization processes.

The MassHealth Drug List includes all PrEP options, with prior authorization needed for the branded version of emtricitabine/tenofovir disoproxil fumarate (Truvada). As of July 31, 2023, prior authorization is no longer required for cabotegravir (Apretude). xiv

Does Medicare cover PrEP?

Yes. Due to a <u>September 2024 decision</u> by the federal Centers for Medicare and Medicaid Services (CMS), Medicare now covers PrEP under Medicare Part B, the part of Medicare that covers outpatient services. As a result, Medicare beneficiaries can obtain PrEP with zero cost-sharing. Medicare Part B also covers related services, such as counseling visits and HIV screening; however, the coverage for these services is different than what private plans are required to cover. In addition to medication, Medicare covers:

- Up to eight individual counseling visits every 12 months for HIV risk assessment, HIV risk reduction, and medication adherence;
- HIV screening up to eight times a year; and
- A single screening for hepatitis B virus (HBV).xv

CMS's decision regarding Medicare and PrEP does not cover creatinine testing, STI counseling, or hepatitis C testing, so coverage of these services remains subject to Medicare's preexisting rules. See CHLPI's <u>additional</u> resource on Medicare and PrEP for more details.

Note that Medicare Part D, the Medicare prescription drug program, covers all antiretroviral drugs used for the *treatment* of HIV without prior authorization or step therapy requirements. xvi However, Medicare Part D plans can require deductible, coinsurance, or copayments for plan members, including for drugs to treat HIV.

Do Qualified Health Plans on the Massachusetts Health Connector cover PrEP?

Yes. The following chart indicates how each carrier that sells 2024 Qualified Health Plans on the Massachusetts Health Connector describes their coverage of PrEP on publicly available formulary documents or the Health Connector Plan Comparison Tool for silver level plans according to data collected in December 2023. (Some insurers may cover Apretude as a medical benefit and thus do not list it on their formularies.)

	FTC/TDF (200-300 mg)	Truvada (200-300 mg)	Descovy (200-25 mg)	Apretude (600 mg/ 3 ml)
BCBSMA	<u>Tier 1</u>	NC*	Tier 2	Tier 2
Fallon Health	<u>Tier 1</u>	NC*	Tier 3 (PA)	NC
Harvard Pilgrim Health Care ¹	Tier 2	NC	Tier 2 (PA)	NC
Health New England	Tier 1	Tier 3 (PA)	Tier 2 (PA)	Tier 3 (PA)
MGB Health Plan ²	Tier 1	NC*	Tier 2	MB (PA)
Tufts Health Plan	<u>Tier 2</u>	NC	Tier 2 (PA)	NC
UnitedHealthcare	<u>Tier 1</u>	NC	NF (PA, ST)	NC
WellSense Health Plan ²	<u>Tier 2</u>	NC	Tier 2 (PA)	Tier 3 (PA)

KEY:

- Underline: The formulary mentions the drug may have a \$0 copay if used as PrEP.
- (PA): Prior Authorization may be required for general use and/or use as PrEP.
- (ST): Step Therapy is required. Step Therapy requires members to try a preferred medication before getting coverage for a non-preferred medication.
- NF: The drug is designated as nonformulary or is not listed on the formulary.
- NC: The drug is designated as not covered or is listed as an excluded benefit.
- MB: The drug is listed as a Medical Benefit.
- 1: ACA notations not included in plan's online search tool.
- 2: Tiering has been adjusted for standardization.
- *: Denotes difference in coverage reported on the public formulary and in the Plan Comparison tool. The less generous coverage is included in the chart.

Because formularies can be updated on a regular basis, be sure to refer to the most recently published formulary when assisting patients or clients.

As noted above, some insurance companies do not clearly indicate in their public formularies that when medications are prescribed as PrEP, they are covered without any cost sharing. When not clearly indicated, providers should contact insurance representatives to ask whether specific prior authorization or procedures are necessary to avoid erroneous charges for patients.

What should I do if my patient or client has trouble accessing PrEP or related services?

The Massachusetts <u>Pre-Exposure Prophylaxis Drug Assistance Program</u> (PrEPDAP) can help Massachusetts residents access PrEP medications. To enroll in the program, a person must meet certain income eligibility guidelines. (Immigration status does <u>not</u> affect eligibility.) The program helps clients cover costs of PrEP medications (e.g., co-pays) and can cover the full cost of PrEP for clients who are uninsured. PrEPDAP can also provide navigation resources to help clients identify where to obtain PrEP, where to obtain financial help for PrEP-related costs, and how to access the PrEP medication best suited for their needs.

PrEPDAP is funded by the Massachusetts Department of Public Health and is administered by Community Resource Initiative (CRI). For more information, call PrEPDAP at (617) 502-1700 (select Option 4) or e-mail prepdap@crihealth.org. To submit applications or supporting documentation, please use AccessHealth MA's secure email portal.

Individuals who are on someone else's insurance plan may be reluctant to access PrEP through their health insurance due to privacy concerns. A Massachusetts law called the PATCH Act can help keep information about health services private by allowing members (including members under 18 years of age who are covered by the insurance plan of a parent or guardian) to request to send certain documents like Explanation of Benefits (EOBs) or Summary of Payments (SOPs) to a different address or confidential patient portal. An individual only needs to contact their health insurance plan one time and changes made to EOBs/SOPs will be applied to future visits. The law also prohibits health insurance plans from listing "sensitive" services, including PrEP, on SOPs/EOBs

MassHealth plans do not generate EOBs/SOPs. For more information about how PATCH Act can help clients to access PrEP, we have developed a tool, <u>Keeping Your Health Information Private When You're On Someone Else's Insurance</u>, which provides additional information and a sample script when contacting health insurance plans.

NOTE: If you believe an insurer has engaged in a pattern of inappropriately charging members for PrEP or PrEP-related services or has implemented a burdensome exceptions process, please e-mail the Center for Health Law and Policy Innovation at chlpi@law.harvard.edu. Helpful information includes the name of the insurance company, name of the relevant plan or plans, type of PrEP impacted, and prior authorization rationales submitted.

¹ 42 USC §300gg–13 "Coverage of Preventive Health Services"

[&]quot;While this category of preventive services is commonly referred to as "Women's Preventive Services Guidelines," insurers are not permitted to limit the services based on an individual's sex as assigned at birth, gender identity, or recorded gender. FAQs About Affordable Care Act Implementation (Part XXVI) (May 11, 2015), https://perma.cc/T28Z-Z3J7. "[If] a recommended preventive service is medically appropriate for the individual – such as, for example, providing a mammogram or pap smear for a transgender man who has residual breast tissue or an intact cervix – and the individual otherwise satisfies the criteria in the relevant recommendation or guideline as well as all other applicable coverage requirements, the plan or issuer must provide coverage for the recommended preventive service, without cost sharing. . . . "

Id at 6.

United States Preventive Services Task Force, Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection Preexposure Prophylaxis (June 11, 2019), https://perma.cc/SY27-H662.

^{iv} United States Preventive Services Task Force, *Final Recommendation Statement: Prevention of Acquisition of HIV: Preexposure Prophylaxis* (August 22,2023), https://perma.cc/PB6S-V87G.

^v Commonwealth of Massachusetts Budget Summary 2024 Enacted: Sections 4-115 Outside Sections, https://perma.cc/9QZ9-UK7K.

vi Food & Drug Administration (FDA), Press Release, FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention (December 20, 2021); FDA, Press Release, FDA approves second drug to prevent HIV infection as part of ongoing efforts to end the HIV epidemic (October 3, 2019); CDC, Media Statement, CDC Statement on FDA Approval of Drug for HIV Prevention (July 16, 2012).

vii FAQs About Affordable Care Act Implementation Part 47 (July 19, 2021), https://bit.ly/3qKNfPV.

viii FAQs About Affordable Care Act Implementation Part 47 (July 19, 2021), https://bit.ly/3qKNfPV.

^{ix} United States Preventive Services Task Force, *Final Recommendation Statement: Prevention of Acquisition of HIV: Preexposure Prophylaxis* (August 22,2023), https://perma.cc/PB6S-V87G.

^x United States Preventive Services Task Force, *Final Recommendation Statement: Hepatitis C Virus Infection in Adolescents and Adults: Screening* (March 2, 2020), https://perma.cc/S6V5-93UP ("The USPSTF recommends screening for hepatitis C virus (HCV) infection in adults aged 18 to 79 years.... The USPSTF also suggests that clinicians consider screening persons younger than 18 years and older than 79 years who are at high risk for infection (eg, those with past or current injection drug use).").

xi Modifier 33 is not specific to PrEP and may be used with other USPSTF A- or B-rated services.

xii Letter from Director James G. Scott, Division of Program Operations, Center for Medicare & Medicaid Services, United States Department of Health & Human Services, to Secretary Marylou Sudders, Executive Office of Health and Human Services, Massachusetts (January 5, 2021), https://perma.cc/42KX-96WP.

xiii MassHealth, The Prescriber e-Letter, Volume 13, Issue 1, April 2023, https://perma.cc/SCC2-RAKK.

xiv MassHealth, July 2023 MassHealth Drug List Summary Update, https://perma.cc/T8P7-8QVG.

xv Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection, National Coverage Analysis, Decision Memo (September 30, 2024), https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=310.

^{xvi} See 42 C.F.R. § 423.120(b)(2)(vi)(C); 84 Fed. Reg. 23,832 (May 23, 2019).

xvii Mass. General Laws, c. 1760 § 27, *Development and use of common summary of payments form; implementation of education plan*, https://bit.ly/430e0B2; CHLPI, Keeping Your Health Information Private When You're On Someone Else's Insurance: The PATCH Act (June 2023), https://perma.cc/YH87-BT4X.