

CENTER for HEALTH LAW and POLICY INNOVATION HARVARD LAW SCHOOL

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:ⁱ

- 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 womenⁱⁱ supported by HRSA.

In 2019, the USPSTF rated PrEP "A", its highest recommendation.^{III} Therefore, most private insurance plans were required to cover PrEP and ancillary services at no additional cost.

Providers and consumers should be aware that ongoing litigation (*Braidwood Management v. Becerra*) has called into question the ACA requirement that private insurance plans cover PrEP and other preventive services at no cost. 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 PrEP medications: emtricitabine/tenofovir disoproxil fumarate (available as generic and branded Truvada), emtricitabine/tenofovir alafenamide (available as branded Descovy), and cabotegravir (available as branded Apretude).^{iv} Insurers are not required to cover all forms of PrEP at no additional cost 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.^v When an insurer approves such an exception, the insurer must cover that alternative medication at no additional cost.

NOTE: When the USPSTF issued its 2019 recommendation for PrEP, only one form of PrEP was FDAapproved for HIV prevention. The recommendation for PrEP is currently under review, and updates to the recommendation will consider research on more recently approved PrEP options.

What other PrEP-related services are covered?

Insurers that are required to cover PrEP at no additional cost are also expected to cover certain baseline and monitoring services at no additional cost. This includes:

- 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
- Adherence counseling

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 at no additional cost, 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. For more information, look to the insurance company's specific policy. Examples of this type of guidance are available <u>here</u> and <u>here</u>.

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.^{vi} Additionally, 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 <u>MassHealth Drug List</u> for their prescription drug coverage.^{vii} 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). Effective July 31, 2023, prior authorization will no longer be required for cabotegravir (Apretude).^{viii}

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

Yes. The following chart indicates how each carrier that sells Qualified Health Plans on the Massachusetts Health Connector describes their coverage of PrEP on publicly available formulary documents according to data collected in June 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>	Tier 3	Tier 2	Tier 2
Fallon Health	<u>Tier 1</u>	<u>Tier 3 (PA)</u>	<u>Tier 3 (PA)</u>	NC
Harvard Pilgrim Health Care	<u>Tier 2</u>	<u>NF (PA)</u>	<u>Tier 2 (PA)</u>	NF
Health New England	Tier 1	NC	Tier 2 (PA)	NF
MGB Health Plan ¹	Tier 1	NF	Tier 2	MB (PA)
Tufts Health Plan	<u>Tier 2</u>	NF	<u>Tier 2 (PA)</u>	NF
UnitedHealthcare	<u>Tier 1</u>	NC	NF (PA)	NC
WellSense Health Plan ¹	Tier 2	NF	Tier 2 (PA)	Tier 3 (PA)

KEY:

- <u>Underline</u>: 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.
- 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: Tiering adjusted for standardization.

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 out-of-pocket costs related to PrEP, 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.

(Some individuals may be unwilling to access PrEP through their health insurance due to privacy concerns. A state law called the PATCH Act can help protect confidentiality by allowing members to send certain insurance forms to a different address or confidential patient portal.^{ix} The law also prohibits health insurance plans from listing "sensitive" services, including PrEP, on these insurance forms. If an individual is still concerned about accessing PrEP despite these protections, PrEPDAP may be able to assist.)

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

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 <u>chlpi@law.harvard.edu</u>. 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.

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

ⁱⁱ While this category of preventive services is commonly referred to as "Women's Preventive Services Guidelines," insurers are <u>not</u> 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), <u>https://perma.cc/T28Z-Z3J7</u>. "[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.

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

^{iv} 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).

^v FAQs About Affordable Care Act Implementation Part 47 (July 19, 2021), <u>https://bit.ly/3qKNfPV</u>.

^{vi} 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), <u>https://perma.cc/42KX-96WP</u>.

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

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

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