NASTAD PrEP Coverage Brief: PrEP Services Covered with No Cost-Sharing

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Pre-exposure prophylaxis (PrEP) – a once daily antiretroviral medication taken to prevent HIV – is an incredibly effective HIV prevention tool. In light of its effectiveness and safety, in June, 2019, the US Preventive Services Task Force (USPSTF) gave PrEP an "A" grade recommendation, noting that "the USPSTF concludes with high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial." This fact sheet will walk through the coverage and cost-sharing requirements for public and private payers that come with this USPSTF Grade A recommendation.

What Does a USPSTF Grade A Recommendation Mean for Coverage and Cost Sharing?

The Affordable Care Act (ACA) requires commercial health plans and Medicaid expansion programs to cover select preventive services – including any service with a Grade A or B from the USPSTF – without cost-sharing, which means that these services must be covered before any deductible and without coinsurance or a copayment.[1] Now that PrEP has a Grade A recommendation from USPSTF, most commercial health plans and Medicaid expansion programs must cover PrEP without cost sharing as of January 1, 2021.

Preventive Services

The list of preventive services that must be covered without cost-sharing is based on the recommendations of several expert bodies, including the USPSTF, which is an independent, volunteer panel of national experts in prevention and evidence-based medicine. The USPSTF works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. In addition to PrEP, there are other sexual health services that have a USPSTF A or B grade, including screening for HIV, chlamydia, gonorrhea, HBV, HCV, and Syphilis. A list of preventive services is available at healthcare.gov/preventive-care-benefits

What Plans Must Cover PrEP without Cost Sharing?

All non-grandfathered commercial health plans are required to cover PrEP services without cost sharing. This includes individual marketplace plans, and small and large group employer-sponsored plans. In addition, state Medicaid expansion coverage programs, including Basic Health Plans, must also cover PrEP without cost sharing.

[1] A summary of Section 2713 in the context of HIV, hepatitis, and STI prevention is available at cdc.gov/nchhstp/highqualitycare/preventiveservices

These coverage and cost-sharing requirements do not automatically apply to Medicare prescription drug coverage (Medicare Part D already requires HIV ARVs to be covered, but there will still be cost sharing).

Traditional Medicaid programs (i.e., benefits available to groups outside of the Medicaid expansion population) also have the option of covering recommended preventive services, including USPSTF Grade A and B services, without cost-sharing. States that choose to do this will receive enhanced federal funding. To receive the enhanced federal funding, states must cover all preventive services with a Grade A or B from USPSTF without cost-sharing in both fee-for-service and managed care traditional Medicaid plans. Since 2013, at least fifteen states and the District of Columbia[2] have opted to provide preventive services without cost sharing in their traditional Medicaid programs.

When Do These New Coverage and Cost-Sharing Requirements for PrEP Go into Effect?

The coverage and cost-sharing requirements for PrEP went into effect for the plan year starting at least one year after the final USPSTF recommendation was released. For most plans and for Medicaid, this was January 1, 2021 (though some plans with non-calendar year plan years had to implement the requirements earlier). All non-grandfathered plans should now cover PrEP without cost-sharing requirements.

What PrEP Services Have to Be Covered without Cost Sharing?

In July 2021, CMS released a set of Frequently Asked Questions, clarifying the requirements for plans to cover the entire PrEP intervention in line with CDC guidelines for provision of ancillary services and testing. The guidance clarifies that plans must cover the following services without cost sharing, in addition to the medication for PrEP. Importantly, these services must be covered at the intervals recommended by CDC guidelines, and plans cannot use medical management techniques to cover these services at more limited intervals.

Required PrEP Services to Be Covered without Cost Sharing

HIV testing	Persons must be tested and confirmed to be HIV uninfected before starting PrEP and tested again for HIV every three months while taking PrEP.
Hepatitis B and C testing	Persons should be screened for hepatitis B virus (HBV) at baseline for the initiation of PrEP consistent with CDC guidelines. Additionally, persons should be screened for hepatitis C virus (HCV) infection at baseline and periodically consistent with CDC guidelines. Screening for HCV infection is indicated for all people

[2] States with Medicaid State Plans covering preventive services without cost sharing include California, Colorado, Delaware, Hawaii, Iowa, Kentucky, Louisiana, Massachusetts, Montana, Nevada, New Hampshire, New Jersey, Oregon, Washington, and Wisconsin.

	with ongoing risk of contracting HCV.
Creatinine testing and calculated estimated creatine clearance (eCrCl) or glomerular filtration rate (eGFR)	For persons taking PrEP, their estimated eCrCl or eGFR must be measured and calculated at the beginning of treatment to assess if kidney function is in the range for safe prescribing of PrEP medication. Creatinine and eCrCL or eGFR should be checked periodically consistent with CDC guidelines.
Pregnancy testing	Persons with childbearing potential taking PrEP must be tested for pregnancy at baseline and should be tested again periodically thereafter consistent with CDC guidelines until PrEP is stopped.
Sexually transmitted infection (STI) screening and counseling	Persons taking PrEP must be screened for STIs at baseline and should be screened periodically thereafter consistent with CDC guidelines, which may require multiple anatomic site testing (i.e., genital, oropharyngeal, and rectal) for gonorrhea and chlamydia, and testing for syphilis, together with behavioral counseling, which are recommended to reduce the risk of STIs.
Adherence counseling	Persons taking PrEP must be offered regular counseling for assessment of behavior and adherence consistent with CDC guidelines to ensure that PrEP is used as prescribed and to maximize PrEP's effectiveness. Components of adherence support also include patient education, reminder systems for taking medication, and developing a plan to address medication adverse effects.

The guidance specifies that medical management techniques such as prior authorization should be expedient and allow patients to start PrEP on the same day as their visit or negative HIV test.

The newly released guidance also provides clarification about which medication must be covered without cost sharing in recognition of the fact that there have been several approved products since the final USPSTF recommendation went into effect. The guidance notes that "plans and issuers must accommodate any individual for whom a particular PrEP medication (generic or brand name) would be medically 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." NASTAD interprets this to mean that while TDF/FTC may be appropriate for most consumers, plans must have a mechanism in place to approve TAF/FTC (sold under the brand name, Descovy) based on clinical criteria and if approved, it must be available without cost sharing.

Do Individuals Have to Go to a Particular Provider to Ensure There Is No Cost Sharing?

Health plans must cover PrEP services delivered by in-network providers. Plans only have to cover out-of-network providers without cost-sharing when no in-network

provider is available. Consumers should check their plan's provider network to make sure their PrEP provider is in-network.

Can Plans Limit Which Patients Are Eligible for PrEP?

The USPSTF recommendation for PrEP is based on the CDC guidelines for PrEP indication. This means that PrEP services are covered as a preventive service for a subset of individuals in a health plan based on risk for HIV. Federal guidance clarifies that the attending provider, using clinical expertise, is the individual who determines whether a patient belongs to a group at "high risk" for HIV and therefore qualifies to receive PrEP without cost-sharing.

Are There Any Billing Considerations to Ensure a Service is Categorized as an ACA Preventive Service That Has to Be Covered without Cost Sharing?

Although some preventive services have dedicated CPT codes and don't require providers to append "modifier 33" when billing, that is not the case with PrEP-related services, such as lab tests. PrEP services must be billed separately and may require the use of CPT modifier 33. CPT developed modifier 33 in response to ACA to let commercial health plans know when a service is provided as a covered preventive service, as discussed above. Adding modifier 33 ensures that commercial plans will pay the claim without a patient due amount for patients. More information is available on NASTAD's Billing Coding Guide for HIV Prevention at nastad.org/resource/billing-coding-guide-hiv-prevention.

> *"When the primary purpose of the service is the delivery of an evidence-based service in accordance with a US Preventive Services Task Force A or B rating in effect and other preventive services identified in preventive services mandates (legislative or regulatory), the service may be identified by adding 33 to the procedure. For separately reported services specifically identified as preventive, the modifier should not be used" (NASTAD Billing Coding Guide).*

What Should Consumers Do If a Health Plan Is Not Providing PrEP without Cost Sharing?

Providers and patients may appeal to the Health Insurance Commissioner in their state regarding discriminatory practices or non-compliance. Contact information is available at content.naic.org/state-insurance-departments.

RESOURCES

State Insurance Bulletins and Reports

The following states have issued their own guidance to plans and issuers on PrEP coverage and cost sharing.

- California: Insurer Underwriting Practices for Truvada/PrEP Users http://www.insurance.ca.gov/0250-insurers/0300-insurers/0200-bulletins/bulletin-notices-commiss-opinion/upload/TruvadaPrEPUsersNotice.pdf
- Colorado: New Bulletin B-4.1XX - HIV PrEP Ancillary Services https://drive.google.com/file/d/1TfBMHKqx6dwFTn08F0hJv1bA3G77kcka/view
- New Jersey: Bulletin Addresses Naloxone & HIV Prevention Medication https://www.state.nj.us/dobi/bulletins/blt19_07.pdf
- New York: Supplement No. 2 to Insurance Circular Letter No. 21 (2017), Health Insurance Coverage for Pre-exposure Prophylaxis ("PrEP") for the Prevention of Human Immunodeficiency Virus ("HIV") Infection and Testing and Ongoing Follow-up and Monitoring Related Thereto. https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2020_s02_cl2017_21

Please contact NASTAD at PrEP@NASTAD.org with questions or comments.