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## **BULLETIN NO. 25-01**

TO: ALL HOSPITAL, MEDICAL AND HEALTH SERVICE CORPORATIONS,

INSURANCE COMPANIES AND HEALTH MAINTENANCE ORGANIZATIONS AUTHORIZED TO ISSUE HEALTH BENEFITS

PLANS IN NEW JERSEY

FROM: JUSTIN ZIMMERMAN, COMMISSIONER

**RE:** COVERAGE FOR HIV PRE-EXPOSURE PROPHYLAXIS

The purpose of this Bulletin is to remind all hospital, medical and health service corporations, insurance companies, and health maintenance organizations authorized to issue health benefits plans in this State (collectively, "carriers") that the Affordable Care Act ("ACA")<sup>1</sup> requires coverage of certain preventative health services, including coverage for HIV pre-exposure prophylaxis ("PrEP") without cost-sharing for those individuals at increased risk of contracting HIV.

The ACA prohibits the imposition of cost-sharing for evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force ("USPSTF").<sup>2</sup> In 2019, the USPSTF released a recommendation with an "A" rating that clinicians offer PrEP with "effective antiretroviral therapy to persons who are at high risk of HIV acquisition." At that time, the only formulation of PrEP approved by the FDA was a once-daily oral treatment with combined tenofovir disoproxil fumarate and emtricitabine (TDF/FTC; brand name Truvada®). In 2023, the USPSTF updated their recommendation. <sup>3</sup> The USPSTF recommended additional FDA-approved formulations of PrEP to include:

<sup>&</sup>lt;sup>1</sup> The Patient Protection and Affordable Care Act (Pub. L. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) are collectively known as the ACA.

<sup>&</sup>lt;sup>2</sup> Carriers are required to provide coverage for evidence-based items or services that have in effect a rating "A" or "B" in the current recommendations of the USPSTF. N.J.S.A. 17:48-6tt, N.J.S.A. 17:48A-7qq, N.J.S.A. 17:48E-35.44, N.J.S.A. 17B:26-2.1mm, N.J.S.A. 17B:27-46.1tt, N.J.S.A. 17B:27A-7.27, N.J.S.A. 17B:27A-19.31, N.J.S.A. 26:2J-4.45.

<sup>&</sup>lt;sup>3</sup> See Recommendation: Prevention of Acquisition of HIV: Preexposure Prophylaxis | United States Preventive Services Taskforce and FAQs about Affordable Care Act and Women's Health

- 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.

Accordingly, carriers must cover specified oral and injectable formulations of PrEP, as well as specified baseline and monitoring services, without cost-sharing, for plan years beginning on or after August 31, 2024. Carriers are not permitted to use medical management techniques to direct individuals prescribed PrEP to utilize one of the specified formulations over another.

Other covered baseline and monitoring services include:

- **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 so that, if they have become infected, the medication can be stopped promptly before it could cause a harmful drug resistance to develop.
- **Hepatitis B and C testing.** Persons should be screened for hepatitis B virus ("HBV") at baseline for the initiation of PrEP consistent with Centers for Disease Control ("CDC") guidelines, so that when the PrEP medications, which suppress HBV replication in the liver, are stopped, persons can be monitored to ensure safety and to rapidly identify any potential injury. 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 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 while on PrEP medication to assess for potential kidney injury and to ensure that it is safe to continue PrEP medication.
- **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 so that pregnant patients, together with their health care providers, can make a fully informed and individualized decision about taking PrEP.
- 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, the presence of which may increase the likelihood of acquiring HIV sexually.
- 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.

and Cancer Rights Act Implementation Part 68 (October 21, 2024), available at www.cms.gov/files/document/faqs-implementation-part-68.pdf.

Carriers are also reminded that they are required to cover, without cost sharing, office visits associated with each recommended preventive service applicable to the covered person when the service is not billed separately from an office visit, and the primary purpose of the office visit is the delivery of the recommended preventive service.

Should you have any questions regarding the content of this Bulletin, please contact the Department's Office of Life and Health at <a href="mailto:lifehealth@dobi.nj.gov">lifehealth@dobi.nj.gov</a>.

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Date

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Commissioner

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