



Department of Health

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Executive Deputy Commissioner

December 2, 2019

Dear NYS Health Insurance Plan:

HIV pre-exposure prophylaxis (PrEP) is highly effective at preventing HIV among adults and adolescents. The FDA has now approved two effective and distinct co-formulated antiviral agents for the prevention of HIV acquisition in adults and adolescents. Health insurance plans have an important role to play in supporting access to PrEP when it is clinically indicated. This letter will highlight three important new developments. To the extent possible, please forward this letter and its attachments to all providers in your network.

USPSTF Affords PrEP the A Grade: In June of 2019, the United States Preventive Services Task Force (USPSTF) issued its recommendation regarding HIV PrEP. Attached is a two-page document that summarizes the USPSTF findings relative to PrEP and HIV screening. As you are likely aware, under the Affordable Care Act, preventive services afforded an A grade are to be provided to patients, when indicated, without cost sharing. On July 23, 2019, the NYS Department of Financial Services issued an update that outlines the responsibility of New York State health insurance plans to begin covering PrEP without cost sharing no later than January 1, 2020. If you have questions about this, please review the [Supplement No. 1 to Insurance Circular Letter No. 21](#).

Updated Clinical Guidelines: The New York State HIV Clinical Guidelines Program has issued updated clinical guidelines regarding PrEP. The following elements of the updated guidelines will serve to make PrEP easier for individuals to use and easier for clinicians to prescribe and manage. These updated guidelines:

1. Allow for greater individualization of PrEP, including greater flexibility regarding follow-up medical appointments and how and where follow-up lab work can be completed;
2. Include the addition of a second FDA-approved PrEP medication;
3. Provide guidance for same day initiation of PrEP;
4. Provide guidance for on-demand PrEP dosing for cis-gender males; and,
5. Include new, simple tools for taking a sexual history and managing PrEP.

The complete guidelines are available at: <https://www.hivguidelines.org/prep-for-prevention/>

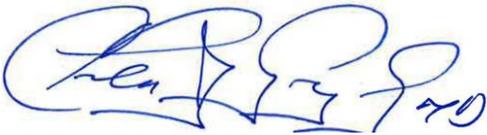
Fact Sheet: NYS Medicaid Coverage for PrEP: Attached is a Fact Sheet that reviews details of Medicaid Coverage for PrEP and PrEP-related services such as HIV testing and STI screening.

Because high rates of HIV are seen among people of transgender experience, this Fact Sheet also reviews Medicaid coverage of gender affirming medications.

New York is currently pursuing a ground-breaking effort to end the AIDS epidemic by the end of 2020. The three pillars of this effort are: 1) expanding access to PrEP, 2) proving HIV testing as a part of routine health care for all persons aged 13 and older, and, 3) ensuring access to life-saving medication for people living with HIV. If you would like to learn more about this effort, please visit: https://www.health.ny.gov/diseases/aids/ending_the_epidemic/.

The New York State Department of Health greatly appreciates your efforts in promoting and maintaining access to PrEP, HIV testing and HIV treatment. If you have questions, please contact the Office of the Medical Director at PrEP@health.ny.gov

Sincerely,

A handwritten signature in blue ink, appearing to read 'Charles John Gonzalez', with a stylized flourish at the end.

Charles John Gonzalez, M.D., Medical Director
Office of the Medical Director
AIDS Institute

cc: Lyn Stevens, Deputy Medical Director, AIDS Institute
Joseph Kerwin, Deputy Director, AIDS Institute



<p>IMPORTANCE:</p> <p>Expanding access to HIV screening and PrEP in NYS is critical to ending the epidemic.</p>	<p><i>HIV Screening:</i> It is estimated that only 49% of New Yorkers have ever been tested for HIV. According to 2017 data, more than 11,100 residents are unaware they are living with HIV and 20% of people newly diagnosed with HIV had a concurrent AIDS diagnosis, meaning the person was living with HIV for many years without an HIV test.*</p> <p><i>PrEP:</i> While the number of new infections in NYS has been decreasing since 2013, there were more than 2,220 new infections in 2017 that could have been prevented with PrEP.*</p>
<p>FINDINGS:</p> <ul style="list-style-type: none"> • HIV Screening • PrEP 	<p>In June of 2019, the USPSTF found convincing evidence that:</p> <ul style="list-style-type: none"> • Identification and early treatment of HIV infection is of substantial benefit in reducing the risk of AIDS-related events or death. • Use of antiretroviral therapy is of substantial benefit in decreasing the risk of HIV transmission to uninfected sexual partners. • Identification and treatment of pregnant women living with HIV infection is of substantial benefit in reducing the rate of mother-to-child transmission. • The overall magnitude of the benefit of screening for HIV infection in adolescents, adults, and pregnant women is substantial. • PrEP is of substantial benefit in decreasing the risk of HIV transmission to persons at risk of HIV acquisition. See table on next page for more information.
<p>CONCLUSIONS</p>	<p>The USPSTF recommends HIV screening for adolescents, adults, and pregnant women and HIV treatment for those with diagnosed HIV infection. GRADE: A</p> <p>The USPSTF recommends PrEP for persons at high risk of HIV acquisition. GRADE: A</p>

Importance of HIV Screening, HIV Treatment and PrEP in New York

<ul style="list-style-type: none"> • New York State’s three-point plan to end the AIDS epidemic emphasizes the importance of: <ul style="list-style-type: none"> ○ Promoting HIV screening for all individuals age 13 and older as a routine part of health care. <u>The offer of HIV testing is required by public health law. Testing can easily be incorporated into routine health care.</u> Visit: https://www.health.ny.gov/diseases/aids/providers/testing/docs/testing_toolkit.pdf ○ Ensuring access to HIV treatment for all those living with HIV. ○ Expanding access to PrEP for all those at high risk of acquiring HIV.
<ul style="list-style-type: none"> • New York State is seeking to increase the number of eligible individuals taking advantage of PrEP from 24,000 at the end of 2017 to 65,000 by the end of 2020.
<ul style="list-style-type: none"> • PrEP is a cornerstone of HIV prevention and is strongly endorsed by New York State. See NYS Clinical Guidelines at www.hivguidelines.org
<p>PrEP is a cornerstone of HIV prevention and is strongly endorsed by the NYS Department of Health. Find NYS HIV Clinical Guidelines at www.hivguidelines.org.</p>

Definition of USPSTF Grade A and Suggestions for Practice

Grade	Recommendation	Definition	Suggestion for Practice
A	Recommended	Evidence suggests with a high degree of certainty that the service has a substantial net benefit.	Offer/ provide the service.

What is the US Preventive Services Taskforce?

The U.S. Preventive Services Task Force (USPSTF) is an independent panel of clinical experts established by Congress to evaluate and make recommendations about the effectiveness of specific preventive care services for patients without related signs or symptoms. USPSTF recommendations only address services offered in the primary care setting or services referred by a primary care clinician.

The USPSTF grades recommendations based on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF assessment does not consider service provision costs.

USPSTF MISSION

To improve health by making evidence-based recommendations about clinical preventive services such as:

- Screenings
- Counseling services
- Preventive medicine

USPSTF and the Patient Protection and Affordable Care Act (ACA)

- The ACA requires non-grandfathered, private health plans to cover clinical preventive services given a grade A or B by the USPSTF **without cost sharing**.
- The ACA prohibits insurance companies from declining to sell or renew policies because of preexisting conditions.

USPSTF Guidance Regarding Persons at High Risk of HIV Acquisition

THE USPSTF RECOMMENDS THAT THE FOLLOWING PERSONS BE CONSIDERED FOR PrEP:

Men who have sex with men, who are sexually active who have a sero-discordant sex partner (i.e., in a sexual relationship with a partner living with HIV), have inconsistent use of condoms during receptive or insertive anal sex, or a sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia within the past 6 months.

Heterosexually active women and men who have a sero-discordant sex partner (i.e., in a sexual relationship with a partner living with HIV), have inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g. a person who injects drugs or a man who has sex with men and women), or an STI with syphilis or gonorrhea within the past 6 months.

Persons who inject drugs and have shared use of drug injection equipment or a risk of sexual acquisition of HIV (see above).

Other circumstances which warrant consideration of PrEP include:

- Persons who engage in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers or persons trafficked for sex work.
- Men who have sex with men and women are at risk of HIV acquisition and should be evaluated for PrEP according to the criteria outlined above.
- Transgender women and men who are sexually active may be at increased risk of HIV acquisition based on the criteria outlined above.

SEE NYS CLINICAL GUIDELINES FOR EXPANDED STATE-SPECIFIC GUIDANCE ON PrEP: WWW.HIVGUIDELINES.ORG.

The Full USPSTF Recommendation Statement on Preexposure Prophylaxis and HIV Screening are available at:

- <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>
- <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/human-immunodeficiency-virus-hiv-infection-screening1>

* Source: <http://etedashboardny.org/>

NYS Medicaid Coverage for HIV Pre-Exposure Prophylaxis (PrEP) Related Services

PrEP provides effective protection against HIV, a predominantly sexually transmitted disease. Information about PrEP should be included when counseling sexually active patients about pregnancy and STI prevention. HIV disproportionately affects the transgender or non-binary (TGNB) community and PrEP is often indicated. Information regarding Medicaid coverage for gender-affirming hormones is included in response to requests from PrEP providers.

	Fee for Service (FFS)	Medicaid Managed Care (MMC)*	Notes
1. Medication			
PrEP medication	Yes	Yes	
Prior Authorization (PA) required?	No - but an HIV test is required every 3 months to rule out HIV sero-positivity	No - but an HIV test is required every 3 months to rule out HIV sero-positivity	FFS Allows a one-time fill when HIV testing has not been done
2. Testing			
Test for HIV every 3 months while on PrEP			
Office-based HIV testing	Yes	Yes	
Home-based HIV testing	No	No	
Gonorrhea (GC) and chlamydia (CT) testing - including extragenital testing at exposed sites			
GC & CT NAAT testing (genital, rectal and pharyngeal sites)	Laboratories are reimbursed for multi-site testing. Provider reimbursement for specimen collection is included in the provider global fee.		
Self-collected specimens for genital and extragenital GC & CT testing	Yes, laboratory testing is covered when the provider supplies the collection device, a prescription/fiscal order (defined as an authenticated request to a clinical laboratory for the provision of a test) and the specimen is processed by Medicaid enrolled NYS certified laboratory		
Home STI testing	No	No	
3. Gender affirming medications			
Gender affirming hormones/drugs	Yes	Yes*	See Medicaid Updates 2016-05 and 2017 DOH Medicaid Updates – Volume 33
Medically necessary treatment with cross-sex hormone therapy including testosterone cypionate, conjugated estrogen, and estradiol, is covered for individuals 18 years of age and older. For patients who are 16 or 17 years of age and meet the applicable criteria listed in the 2016 update, payment is based upon a determination of medical necessity made by a qualified professional. Payment for a patient who is under 16 years of age and who otherwise meets these requirements will be made in specific cases if medical necessity is demonstrated by a qualified medical professional and prior approval is received.			
4. Non-prescriber care and services			
External and internal condoms and emergency contraceptives	Over-the-counter contraceptives and condoms can be obtained at participating pharmacies. Covered non-prescription drugs and over the counter items require a fiscal order (includes all the information contained on a prescription).		
RN visits - PrEP follow-up (99211)	Yes	Yes	

*** Please contact the MMC plan directly with questions or for additional information regarding a specific plan's coverage**

	Fee for Service (FFS)	Medicaid Managed Care (MMC)*	Notes
5. Telehealth			
Home and office-based telehealth visits	Yes	Yes	For visits equivalent to a face-to-face visit and meeting the requirements in the Telehealth Medicaid Update (provider, location, HIPAA-compliant).
Refer to Medicaid Update: Special Edition Expansion of Telehealth: https://www.health.ny.gov/health_care/medicaid/program/update/2019/2019-02_speced.htm			

Relevant ICD-10 codes, CPT codes, and Telehealth Modifiers

ICD-10 Codes	Code
PrEP (Contact with and (suspected) exposure to HIV)	Z20.6
HIV testing (Encounter for screening for human immunodeficiency virus)	Z11.4
STI Testing (Encounter for screening for infections with a predominantly sexual mode of transmission)	Z11.3
Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission	Z20.2
CPT- 4 Codes	
HIV-1 antibody test	86701
HIV-1 and HIV-2 antibody - single assay	86703
HIV-1 antigen(s) with HIV-1 and HIV-2 antibodies	87806
Telehealth Modifiers	Modifier
Synchronous telemedicine service rendered via real-time interactive audio and video telecommunication system <i>Note:</i> Modifier 95 may only be appended to the specific services covered by Medicaid and listed in Appendix P of the AMA's CPT Professional Edition 2018 Codebook. The CPT codes listed in Appendix P are for services that are typically performed face-to-face but may be rendered via a real-time (synchronous) interactive audio-visual telecommunication system.	95
Via interactive audio and video telecommunication systems <i>Note:</i> Modifier GT is only for use with those services provided via synchronous telemedicine for which modifier 95 cannot be used.	GT
Via asynchronous telecommunications system <i>Note:</i> Modifier GQ is for use with Store-and-Forward technology.	GQ
Significant, separately identifiable evaluation & management (E&M) service by the same physician or other qualified health care professional on the same day as a procedure or other service <i>Example:</i> The member has a psychiatric consultation via telemedicine on the same day as a primary care E&M service at the originating site. The E&M service should be appended with modifier 25.	25

For the most up-to-date PrEP recommendations and resources refer to [NYSDOH Clinical Guidelines for PrEP](#).