October 21, 2022

Dear Colleague,

No provider of healthcare or health insurance in New York State should charge insured consumers any out-of-pocket expenses for pre-exposure prophylaxis (PrEP) to prevent HIV infection. This includes medication as well as office visits, testing, labs, and adherence counseling.

Right now, state and federal regulations exist to protect consumers from any out-of-pocket expenses related to PrEP. However, the New York State Department of Health AIDS Institute has learned that some health insurers are wrongly holding their consumers responsible for costs associated with PrEP, potentially violating regulations set by both NYS and the federal government which require issuers to provide coverage for HIV PrEP at no cost sharing, meaning services must be covered before any deductible and without coinsurance or a copayment. Specifically:

- 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 from the USPSTF, such as PrEP—without cost sharing effective as of January 1, 2021. In June 2019, the U.S. Preventive Services Task Force (USPSTF) gave PrEP an “A” grade recommendation. See the Federal Guidance (July 2021) for more information.

- Effective January 1, 2020, N.Y. Insurance Law states that insurers must provide coverage for PrEP for the prevention of HIV infection at no cost sharing and cover screening for HIV infection at no cost-sharing. See the NYS Department of Financial Services Circular Letter (October 2020) for more information.

There are some steps that you can take to help protect your patients from PrEP cost sharing:

- Follow the recommended ICD-10-CM codes for PrEP-related services outlined in the document “Recommended ICD 10 - CM Codes PrEP (pre-exposure prophylaxis) and PEP (post-exposure prophylaxis)”, developed by the New York State Department of Health and the New York City Department of Health and Mental Hygiene.

- Follow the recommended CPT code and use ‘modifier 33’ as outlined in the document “Billing Coding Guide for HIV Prevention,” developed by the National Alliance of State & Territorial AIDS Directors (NASTAD).

- Share this letter widely with your colleagues and throughout your practice.

* In December 2021, the FDA approved long-acting injectable cabotegravir (CAB LA; brand name Apretude) for HIV PrEP. At this time, coverage and payment options for injectable PrEP are still in development. The USPSTF is expected to reconvene in the coming months to address this topic.
Make sure that your patients and all staff in your practice, including reception staff, understand the information contained in this letter and these two important points:

1. Patients should never have any PrEP-related out of pocket costs. This includes no co-pays being collected at the front desk.

2. Patients have a right to file a complaint if they do receive a bill. Protocols for submitting a complaint vary depending on the type of insurance involved:
   - **Commercial Insurance and HMOs**: submit complaints to the NYS Department of Financial Services (DFS) by using the DFS Secure Portal Link: Consumer Complaint - DFS Portal (ny.gov).
   - **Medicaid Managed Care or Fee-For-Service**: call the Medicaid Helpline at 1-800-541-2831. Also, different agencies may be able to help file the complaint. See the NYSDOH List of government agency complaint contacts.
   - **Medicare**: Use the Medicare Complaint Form or follow the instructions from individual plan membership materials to submit a complaint.

Be aware of these helpful resources and share them widely within your networks:

- The newly released Billing & Coding guidance from the American Academy of HIV Medicine provides helpful coding information for long-acting PrEP.
- The Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis (PrEP) document outlines important information regarding health coverage and New York State Department of Health sponsored programs (including Fee-for-Service Medicaid and Medicaid Managed Care), medication assistance programs, additional resources, and further details for filing a complaint when an insurer provides insufficient coverage of PrEP.
- The How to verify if PrEP is a covered Preventive Service handout developed by the National Alliance of State & Territorial AIDS Directors (NASTAD) provides clear, step by step guidance for consumers to verify that PrEP costs will be covered by a health plan.
- The NYS Medicaid Coverage for HIV Pre-Exposure Prophylaxis (PrEP) Related Services chart outlines the PrEP services covered by Medicaid in NYS, including coding suggestions.
- New York State of Health Insurance Navigators provide enrollment assistance to individuals, families, small businesses, and their employees who would like help applying for health insurance through the Marketplace. These navigators could assist an individual in choosing an insurance that will cover PrEP with no out of pocket expenses.
- The PrEP Assistance Program (PrEP-AP) covers costs of clinical visits and lab testing for uninsured and underinsured individuals. Services include HIV and STI/STD testing, counseling, and supportive primary care services consistent with clinical guidelines for PrEP. PrEP medication is not covered by PrEP-AP, but
manufacturer’s patient assistance programs can help. See details in the Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis (PrEP) document.

Since 2014, The New York State Department of Health (NYSDOH) has strongly endorsed PrEP as a safe and effective evidence-based biomedical intervention for the prevention of HIV. Our commitment to reduce barriers to and increase uptake of PrEP remains unwavering. Thank you for joining in our efforts to ensure that those we serve have access to PrEP and are protected from unfairly incurring out-of-pocket costs.

Sincerely,

Charles John Gonzalez, M.D.
Medical Director, AIDS Institute
New York State Department of Health