

July 17, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
200 Independence Avenue, SW
Washington DC 20201

Subject: Request for Updated USPSTF PrEP Guidance & Issuer Compliance

We, the undersigned 63 organizations dedicated to the fight to end HIV, write to request CMS issue *updated* guidance in order to ensure issuer compliance with the most recent, *updated* United States Preventive Services Task Force (USPSTF) recommendation for HIV Pre-Exposure Prophylaxis (PrEP). As community-based organizations, advocacy groups, clinical providers, and public health practitioners working with people and communities affected by HIV, we know the urgency of ensuring broad and equitable access to PrEP free of insurance barriers.

The USPSTF's most recent A-grade recommendation for PrEP, finalized on August 22, 2023, is not drug specific and includes new medications that significantly expand the HIV prevention toolkit, including the first long-acting PrEP drug. This is an injection administered every two months, which demonstrated superior efficacy in preventing HIV in clinical trials compared to daily oral PrEP. New plans must soon come into compliance with the USPSTF recommendation. Additionally, revolutionary new long-acting PrEP formulations, including a biannual injectable, are in the drug development pipeline and show tremendous, game-changing promise.

Ensuring Access to All FDA-Approved PrEP Medications

Section 2713 of the Affordable Care Act requires non-grandfathered commercial insurance plans to cover all USPSTF-recommended preventive services without cost-sharing. It is imperative that CMS issue updated guidance that recognizes that all FDA-approved PrEP medications are incorporated in the USPSTF recommendation so that PrEP users do not experience years of delay before they can access each novel PrEP formulation. As you have done for contraception, this guidance should ensure that all individuals at increased risk of HIV can access any FDA-approved PrEP medication prescribed by their healthcare provider without financial barriers.

Despite the availability of effective PrEP medications, uptake remains insufficient, particularly among populations most at risk for HIV. Only 36 percent of those who can benefit from PrEP are using PrEP. Black individuals constitute 39 percent of new HIV diagnoses but only 14 percent of PrEP users. Hispanic individuals represent 31 percent of new diagnoses but only 18 percent of PrEP users. Women account for 19 percent of new HIV diagnoses, but only 8 percent

of PrEP users. Turning to regional disparities, 53 percent of HIV diagnoses are in the South, but only 39 percent of PrEP users. Addressing these disparities by enabling all communities to benefit from no-cost, barrier-free access to PrEP is critical to ending the HIV epidemic.

Coverage of Clinical Visits and Laboratory Testing

Comprehensive PrEP care includes not only the medication itself but also the necessary clinical visits and laboratory tests as recommended by the CDC. Insurance plans must cover these ancillary services without cost-sharing, as they are an integral part of PrEP. We urge CMS to reaffirm in updated guidance that all required clinical and laboratory services for PrEP, including those specific to new PrEP medications, must be covered without cost-sharing.

Removing Utilization Management Barriers

Utilization management processes, such as prior authorization and step therapy, create significant barriers to PrEP access. These processes can delay or deny access to PrEP, increasing the risk of HIV acquisition. Research has shown that Black and Hispanic individuals are more likely to encounter a prior authorization denial, and we hear frequently from providers that it is far easier to provide PrEP to the uninsured than to the insured because of prior authorizations. It is essential that CMS guidance prohibit such barriers for PrEP to ensure timely and uninterrupted access to this life-saving prevention method.

Federal and State Precedents

Several states, including California, Colorado, Maine, New Jersey, and New York, have already implemented policies to eliminate cost-sharing for all PrEP medications. California and New York have prohibited prior authorization for PrEP. We urge CMS to make sure these critical protections are available to ensure equity throughout the United States. At the federal level, CMS has proposed a National Coverage Determination for PrEP in Medicare, which would remove cost-sharing for all PrEP formulations—including future forms of PrEP—through Part B. These precedents underscore the feasibility and necessity of removing PrEP access barriers at the federal level.

Enforcement

We continue to hear from PrEP users that they are being charged cost-sharing for PrEP drugs and associated services. Recent studies have shown that about a third of commercial insurance claims for PrEP (medications, including the generic, required laboratory testing, and provider visits) are associated with cost-sharing, demonstrating the urgent need for enforcement actions from insurance regulators. We urge you to take proper enforcement actions against issuers that continue to violate the law.

Ensuring no-cost access to all PrEP medications and associated services is vital for increasing PrEP uptake and reducing HIV incidence, particularly among marginalized populations. We urge CMS to act swiftly to implement and enforce this guidance and protect the health of individuals vulnerable to HIV.

Sincerely,

Act Now: End AIDS (ANEA)
ADAP Advocacy Association
Advocates for Youth
AIDS Action Baltimore
AIDS Alabama
AIDS Foundation Chicago
AIDS United
Aliveness Project
Alliance Community Healthcare Inc.
American Academy of HIV Medicine
APLA Health
CAEAR Coalition
Community Access National Network
Community Resource Initiative (CRI)
DotHouse Health
Duffy Health Center
Equality California
Equitas Health
Fast-Track Cities Institute
Fenway Health
Five Horizons Health Services
Georgia AIDS Coalition
Georgia Equality
GLBTQ Legal Advocates & Defenders
Health Imperatives
HealthHIV
HIV Dental Alliance
HIV Medicine Association
HIV+Aging Research Project—Palm Springs
HIV+Hepatitis Policy Institute
Human Rights Campaign
International Association of Providers of AIDS Care
JRI Program RISE
Latino Commission on AIDS
Latinos Salud
NASTAD
National Coalition for LGBTQ Health
National Coalition of STD Directors
National Family Planning & Reproductive Health Association
National Health Law Program
National Working Positive Coalition
NMAC
North Carolina AIDS Action Network
Outreach LGBTQ+ Community Center
PFLAG National
PlusInc
Resource Center, Dallas TX
Rhode Island Public Health Institute

San Francisco AIDS Foundation
Shoals Diversity Center
Silver State Equality
The AIDS Institute
The Center for HIV Law & Policy (CHLP)
The Pride Center at Equality Park
The Reunion Project
Thrive Alabama
Treatment Action Group
Upham's Community Care
U.S. People Living with HIV Caucus
Vivent Health
Waves Ahead Puerto Rico Corp.
We Are Family
Whitman-Walker Health

cc: Ellen Montz, Deputy Administrator, CMS, and Director, CCIIO
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ADM Rachel Levine MD, Assistant Secretary for Health, HHS
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Employee Benefits Security Administration, DOL
Francisco Ruiz, Director, Office of National AIDS Policy, White House Domestic Policy
Council