DEPARTMENT OF HEALTH & HUMAN SERVICES
Joint HHS, CMCS, HRSA, and CDC Informational Bulletin

Opportunities to Improve HIV Testing, Prevention, and Care Delivery for Medicaid and CHIP Beneficiaries

January 15, 2025

PURPOSE

In the United States, Medicaid and the Ryan White HIV/AIDS Program (RWHAP) provide coverage and HIV care and treatment services for many individuals with HIV.[1] State Medicaid programs have an essential leadership role in working toward ending the HIV epidemic in the United States, and important opportunities to improve health outcomes. Medicaid provides health care coverage to an estimated 40% of nonelderly adults with HIV, with more than an estimated $18 billion in federal and state spending.

This informational bulletin builds on 2016 guidance issued by the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA),[2] providing state Medicaid agencies with updated guidance reflecting the latest scientific evidence.[3] Recent advances in HIV testing, prevention, care, and treatment, such as long-acting products that eliminate the need for daily oral medication and other strategies, have the potential to improve comprehensive and effective whole-person care. This informational bulletin identifies opportunities for state Medicaid programs to improve HIV prevention, outcomes, and population health in the context of these advances. Each section provides updates on clinical guidelines and innovation, followed by a summary of applicable federal requirements and strategies that state Medicaid programs may undertake. See Appendix A for a summary of strategies discussed in this informational bulletin.

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[1] A federal grant program administered by the Health Resource and Services Administration (HRSA) that provides a comprehensive system of HIV primary medical care, medication, and essential support services for people living with HIV who are uninsured or underinsured. For more information, please visit http://hab.hrsa.gov/.

[2] CMS. (2016, December 1). *Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries*. https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf.

[3] This document contains links to non-United States Government websites. We are providing these links because they contain additional information relevant to the topic(s) discussed in this document or that otherwise may be useful to the reader. We cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. We are providing these links for reference only; linking to a non-United States Government website does not constitute an endorsement by CMS, CDC, HRSA, HHS, or any of their employees of the sponsors or the information and/or any products presented on the website. Also, please be aware that the privacy protections generally provided by United States Government websites do not apply to third-party sites.

The information and recommendations provided in this guidance are consistent with the National HIV/AIDS Strategy for the United States (2022-2025), published in December 2021.[4] The Strategy focuses on four goals: 1) prevent new HIV infections; 2) improve HIV-related health outcomes for people with HIV; 3) reduce HIV-related disparities and health inequities; and 4) achieve integrated, coordinated efforts that address the HIV epidemic among all partners and entities. To monitor progress, the Strategy identifies eight core indicators, one stratified to measure progress in addressing HIV disparities in key populations, and five quality-of-life indicators for people with HIV. This informational bulletin also supports the goals of the Ending the HIV Epidemic in the U.S. (EHE) initiative.[5] Initially launched in 2019, EHE complements the National HIV/AIDS Strategy by focusing on scaling up proven strategies—to diagnose, treat, prevent, and respond. EHE aims to advance HIV care and outbreak response through coordinated efforts across the U.S. Department of Health and Human Services (HHS) agencies, targeting 57 priority areas where HIV transmission rates are highest in 26 states, the District of Columbia, and Puerto Rico.

This informational bulletin may assist states to address issues raised in two reports from the HHS Office of Inspector General (OIG), published in 2023 and 2024.[6,7] These reports highlight opportunities to strengthen care coordination and improve viral load suppression monitoring through data integration. By using existing Medicaid authorities, such as managed care contracts, section 1115 demonstrations, and state plan amendments, states can address identified gaps while promoting whole person care.

RECENT CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) POLICY MILESTONES IN HIV SERVICE PROVISION

Improving care for people with HIV requires a comprehensive, multi-program approach. In administering Medicaid, the Children's Health Insurance Program (CHIP), Medicare, and Health Insurance Marketplaces, CMS policy has adapted to new clinical developments and emerging best practices to improve HIV-related health outcomes. These efforts to improve coverage and strengthen the full continuum of care for people with HIV are particularly important given an increasing number of individuals with HIV who are insured by Medicare. This informational bulletin aligns with CMS's broader efforts to enhance care and expand access across its programs. See Appendix B for a summary of recent CMS policy actions related to services for individuals with or at risk for contracting HIV.

[4] The White House. (2021). *National HIV/AIDS Strategy for the United States: 2022-2025*. https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf.
[5] Office of Infectious Disease and HIV/AIDS Policy, HHS. (2024, December 12). *EHE overview*. HIV.gov. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview.
[6] Office of Inspector General, HHS. (2023, August). *One quarter of Medicaid enrollees with HIV may not have received critical services in 2021*. https://oig.hhs.gov/documents/evaluation/2949/OEI-05-22-00240-Complete%20Report.pdf.
[7] Office of Inspector General, HHS. (2024, September). *Systemic and operational challenges hinder efforts to ensure HIV care for Medicaid enrollees*. https://oig.hhs.gov/documents/evaluation/10002/OEI-05-22-00242.pdf

HIV EPIDEMIOLOGICAL TRENDS AND DATA IN THE UNITED STATES

The CDC estimates that approximately 1.2 million people in the United States were living with HIV at the end of 2022, with about 13% unaware of their status.[8] Early detection through routine testing is critical to linking individuals to care, reducing transmission, and improving long-term health outcomes. Equally important is access to safe, appropriate, and high-quality treatment and support services, which are essential for managing HIV, achieving viral suppression, and enhancing overall quality of life.

However, the impact of HIV is not evenly distributed across the U.S. In 2022, the Southern U.S. experienced approximately 52% of new HIV diagnoses, despite representing only 38% of the national population.[9] Racial and ethnic minorities are disproportionately affected, with Black/African American individuals, who make up about 12% of the U.S. population, accounting for 37% of new HIV infections.[10] Similarly, Hispanic/Latino individuals, comprising 18% of the population, represented 33% of new HIV infections.[11] Men who have sex with men (MSM) continue to be the most impacted group, accounting for 67% of new HIV infections in 2022, with young MSM aged 13-24 comprising 26%.[12]

These disparities highlight the urgent need to address localized patterns of HIV transmission, particularly in areas and among populations experiencing the highest rates of new cases. HIV clusters and outbreaks signal that specific people and places are experiencing rapid transmission. Public health authorities detect nearly 100 HIV clusters and outbreaks each year in the U.S. Such clusters have transmission rates 8–11 times the national rate.[13] Thus, when HIV clusters and outbreaks occur, it is particularly essential for public health programs to partner with Medicaid and other payers to respond to improve HIV testing, care, and prevention services and address rapid HIV transmission among affected populations.

According to the Social Determinants of Health Among Adults with Diagnosed HIV Infection, 2019 report, many adults with HIV face significant socioeconomic challenges, including low income, limited education, and unstable housing.[14] Similarly, the CDC's Medical Monitoring Project, United States 2021 Cycle (June 2021–May 2022) reveals disparities in healthcare access, viral suppression rates, and retention in care, emphasizing that individuals with lower socioeconomic status experience greater barriers to consistent treatment and care.[15]

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[8] Centers for Disease Control and Prevention. (2024, May). Estimated HIV incidence and prevalence in the United States, 2018–2022. *HIV Surveillance Supplemental Report* 2024;29 (No. 1). https://www.cdc.gov/ hiv-data/nhss/estimated-hiv-incidence-and-prevalence.html.

[9] CDC. (2024, May). Diagnoses, deaths, and prevalence of HIV in the United States and 6 territories and freely associated states, 2022. *HIV Surveillance Report, 2022*; vol. 35. http://www.cdc.gov/hiv-data/nhss/hiv-diagnoses-deaths-prevalence.html.

[10] CDC. (2024, May). Estimated HIV incidence and prevalence in the United States, 2018–2022 (see footnote 22).

[11] Ibid.

[12] Ibid.

[13] CDC. (2024, October 30). *Cluster detection and response guidance for health departments*. https://www.cdc.gov/hivpartners/php/cdr/health-department-guidance.html

[14] CDC. (2022, March). Social determinants of health among adults with diagnosed HIV infection, 2019. *HIV Surveillance Supplemental Report* 2022;27 (No. 2). http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html.

[15] CDC. (2024, April). *Individual-level Social Determinants of Health and Quality of Life Among Persons With Diagnosed HIV Infection—Medical Monitoring Project, United States, 2021 Data Cycle (June 2021–May 2022)*. HIV Surveillance Special Report 36. https://www.cdc.gov/hiv/library/reports/ hiv-surveillance.html.

These findings underscore the critical role of public health coverage programs like Medicaid and CHIP in providing essential coverage for individuals with lower incomes. Expanding access to these programs and aligning covered benefits with clinical and social needs—addressing social determinants of health (SDOH) that impact access to care—is critical to reducing inequities, improving health outcomes, and advancing national HIV prevention and care goals.

TESTING (DIAGNOSIS)

HIV testing functions as an entry point to prevention and care services. Those who test negative but face factors that increase their vulnerability to acquiring HIV can be connected to prevention services, including pre-exposure prophylaxis (PrEP). Similarly, those who test positive for HIV should be promptly linked to HIV medical care and initiated on antiretroviral therapy (ART). Early diagnosis and treatment not only improve length and quality of life but also significantly reduce the potential for new HIV transmissions.[16,17,18]

Screening Recommendations

HIV testing guidelines continue to evolve as advancements in testing technology and outreach methods improve access to these critical services. Presently, the U.S. Preventive Services Task Force (USPSTF) recommends all persons between the ages of 15 and 65 be screened at least once for HIV infection, regardless of risk (Grade A recommendation).[19] The USPSTF also recommends more frequent screening for disproportionately affected populations, including men who have sex with men, individuals who inject drugs, and those engaged in transactional or commercial sex work, regardless of age. Clinicians may wish to screen more frequently (e.g., every 3 or 6 months) depending on associated risk factors, local HIV prevalence, and local policies. USPSTF also recommends that all pregnant persons be screened for HIV, including those who present in labor or at delivery whose HIV status is unknown.[20] Presently, the USPSTF is developing a research plan to be used in the review and possible update of existing HIV screening recommendations for those 13 years of age or older.[21]

In December 2024, CDC published draft *Recommendations for HIV Screening in Clinical Settings* as an update to previous guidelines.[22] These recommendations propose at least one HIV

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[16] Farnham PG, Gopalappa C, Sansom SL, Hutchinson AB, Brooks JT, et al. (2013). Updates of lifetime costs of care and quality-of-life estimates for HIV-infected persons in the United States: late versus early diagnosis and entry into care. *Journal of Acquired Immune Deficiency Syndromes, 64*(2), 183-189. DOI: 10.1097/QAI.0b013e3182973966.

[17] The INSIGHT START Study Group. (2015). Initiation of antiretroviral therapy in early asymptomatic HIV infection. *The New England Journal of Medicine, 373*(9), 795-807. DOI: 10.1056/NEJMoa1506816

[18] Jacobson EU, Li Z, Bingham A, Farnham PG, & Sansom SL. (2023). Assessing the individual benefits of reducing HIV diagnosis delay and increasing adherence to HIV care and treatment. *AIDS Care, 35*(7), 1007-1013. DOI: 10.1080/09540121.2022.2147478.

[19] U.S. Preventive Services Task Force. (2019, June 11). *Final recommendation statement: Human immunodeficiency virus (HIV) infection: Screening*. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening#fullrecommendationstart.

[20] Ibid.

[21] USPSTF. (2024, February 16). *Final research plan: Human immunodeficiency virus (HIV): Screening*. https://www.uspreventiveservicestaskforce.org/uspstf/draft-update-summary/human-immunodeficiency-virus-hiv-infection-pregnant-nonpregnant-adults.

[22] CDC. (2024, December 3). *Draft CDC's recommendations for HIV screening in clinical settings*. https://www.regulations.gov/docket/CDC-2024-0100/document.

test in a lifetime for all persons 15 years of age or older, removing any upper age limit. This change seeks to normalize HIV screening as a routine, lifelong practice, reducing stigma and supporting earlier diagnosis and treatment. The guidance encourages implementation strategies such as using clinical decision support tools (e.g., automated HIV test laboratory orders to implement HIV screening), adopting general consent processes consistent with other routine diagnostic tests, and ensuring anyone requesting an HIV test receives one.

Opt-Out and Self Testing

Risk-based screening may fail to identify some people with HIV. As a result, some people with HIV are diagnosed only after developing advanced HIV or AIDS. Routine, opt-out screening in hospital emergency departments and other healthcare settings has proven highly effective by decreasing stigma, facilitating earlier diagnoses and treatment, and supporting cost-effective care.[23] Notably, state laws on HIV testing vary, with some requiring healthcare providers to offer voluntary (opt-out) HIV testing to all patients.[24]

HIV self-testing programs provide another critical tool to identify undiagnosed individuals. These programs empower individuals to test themselves, enable earlier diagnoses for historically underserved and marginalized populations, and bring linkage-to-care services closer to those in communities with limited access to care.[25,26] Rapid self-tests can deliver results within 20 minutes in the privacy of one's home or another convenient location. For beneficiaries facing barriers to traditional testing, various federal, state, and community-driven initiatives offer FDA-approved rapid test kits at no cost, including CDC's Together TakeMeHome program.[27]

Medicaid Strategies and Opportunities

State Medicaid programs play a critical role in ensuring access to HIV testing services for beneficiaries with or at increased chance of acquiring HIV. States are encouraged to adopt testing coverage policies that remove cost-sharing barriers, expand access to appropriately certified providers, and ensure services reach populations disproportionately affected by HIV.

State Medicaid programs are also encouraged to implement policies that would help to ensure that HIV testing is integrated as part of routine care delivery, to enable use of tools like automated laboratory orders and electronic health record reminders, and to explore strategies that support self-testing initiatives. Some states have expanded the list of provider types who can be reimbursed for HIV testing and other services to increase access opportunities. For example, states may pay additional provider types, such as community health workers, disease intervention specialists, and pharmacists, to screen for HIV and provide related services. (See

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[23] Soh QR, Oh LY, Chow EP, Johnson CC, Jamil MS, et al. (2022). HIV testing uptake according to opt-in, opt-out or risk-based testing approaches: A systematic review and meta-analysis. *Current HIV/AIDS Reports, 19*(5), 375-383. DOI: 10.1007/s11904-022-00614-0

[24] https://www.cdc.gov/hivnexus/hcp/diagnosis-testing/index.html

[25] Freeman AE, Sullivan P, Higa D, Sharma A, MacGowan R, et al. (2018). Perceptions of HIV self-testing among men who have sex with men in the United States: A qualitative analysis. *AIDS Educ Prev., 30*(1), 47-62. DOI: 10.1521/aeap.2018.30.1.47.

[26] Lippman SA, Moran L, Sevelius J, Castillo LS, Ventura A, et al. (2016). Acceptability and feasibility of HIV self-testing among transgender women in San Francisco: A mixed methods pilot study. *AIDS Behavior, 20*(4), 928-38. DOI: 10.1007/s10461-015-1236-2.

[27] Together TakeMeHome (TTMH) is a collaborative program between Emory University, Building Healthy Online Communities, NASTAD, OraSure, Signal, and the CDC. TTMH mails free oral HIV self-tests. For more information, please visit https://together.takemehome.org/.

Pharmacist Engagement under the Treatment Section, and Community Health Workers and Patient Navigators under the Program Coordination and Integration section for more information.)

There are multiple coverage requirements and opportunities for states related to preventive services that are recommended by the USPSTF. The Affordable Care Act (ACA) required most private health plans (including those offered through the Health Insurance Marketplace®[28]), and state Medicaid alternative benefit plans (ABPs) (through which states must provide Medicaid coverage to the Medicaid expansion population and through which states can opt to provide coverage to other Medicaid populations) to provide coverage of Essential Health Benefits (EHB). EHB includes covering the following preventive services 1) items and services that have in effect an "A" or "B" rating from the USPSTF;[29] 2) immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the CDC; and 3) preventive care and screenings for women, infants, children, and adolescents as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).[30] In 42 CFR Part 440, Subpart C, CMS codified and implemented the requirement that Medicaid ABPs include EHB, and in 45 CFR 156.115(a)(4), CMS codified that the EHB coverage requirements include coverage of these preventive services. These requirements thus apply to most individual and small group market coverage (including Qualified Health Plans (QHPs) sold through the Health Insurance Marketplace®), and also apply to ABPs offered to Medicaid populations.

Section 4106 of the Affordable Care Act established a one percentage point increase in the federal medical assistance percentage (FMAP) effective January 1, 2013 for states that cover, without cost-sharing, certain services, including preventive services assigned a grade of A or B by the USPSTF. The one percentage point FMAP increase applies to state expenditures for certain services, including clinical preventive services assigned a grade of A or B by the USPSTF (described in section 1905(a)(13)(A) of the Act). Of note, effective October 1, 2023, statutory amendments made by the Inflation Reduction Act (IRA) modified the requirements for claiming

[28] Health Insurance Marketplace® is a registered service mark of the U.S. Department of Health & Human Services.
[29] On March 30, 2023, the United States District Court for the Northern District of Texas issued a final judgment in the case *Braidwood Management Inc. v. Becerra*, Civil Action No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023) holding that the USPSTF's recommendations operating in conjunction with PHS Act section 2713(a)(1) violate the Appointments Clause of Article II of the United States Constitution. The district court decision in *Braidwood* vacated any and all actions taken by the Departments to implement or enforce PHS Act section 2713(a)(1)'s preventive service coverage requirements in response to an "A" or "B" recommendation by the USPSTF on or after March 23, 2010, and enjoined the Departments from implementing or enforcing PHS Act section 2713(a)(1)'s preventive service coverage requirements in response to an "A" or "B" rating from the USPSTF in the future. The district court also concluded that the requirement under PHS Act section 2713(a)(1) to cover pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy for persons who are at high risk of HIV acquisition, consistent with a June 11, 2019, USPSTF recommendation, violated the rights of some of the plaintiffs before the court under the Religious Freedom Restoration Act. On appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's judgment to the extent that it enjoined the Departments from enforcing the USPSTF's recommendations under PHS Act section 2713(a)(1) with respect to the named plaintiffs; reversed the district court's judgment to the extent it imposed a nationwide injunction; and remanded to the district court for further proceedings. *See* 104 F.4th 930 (5th Cir. 2024), *petition for cert. filed*, (U.S. Sept. 19, 2024) (No. 24-316). On August 28, 2024, the district court entered a stay pending proceedings in the Supreme Court. On January 10, 2025, the Supreme Court of the United States granted the government's petition for certiorari. *Becerra v. Braidwood Mgmt. Inc.*, cert. granted, No. 24-316, 2025 WL 65913 (Jan. 10, 2025).
[30] Coverage of Certain Preventive Services Under the Affordable Care Act, 80 FR 41317 (July 14, 2015).

the one percentage point FMAP increase and changed how that increase applies with respect to adult vaccination services described in section 1905(a)(13)(B) of the Act. Effective October 1, 2023, states that opt to cover preventive services described in section 1905(a)(13)(A) of the Act without cost sharing receive the FMAP increase for Medicaid expenditures for these services and for the tobacco cessation services for pregnant individuals described in section 1905(a)(4)(D) of the Act, notwithstanding the changes to how this FMAP increase applies with respect to vaccination services described in section 1905(a)(13)(B) of the Act.[31]

PREVENTION

Certain antiretroviral medications significantly reduce the risk of HIV acquisition when taken by individuals without HIV. This approach, known as pre-exposure prophylaxis (PrEP), has been validated through several large, randomized controlled trials, which indicate that taking PrEP as prescribed reduces the risk of acquiring HIV through sexual contact by about 99% and lowers the risk among persons who inject drugs by at least 74%.[32] Currently, two oral medications are approved for daily use as PrEP: emtricitabine and tenofovir disoproxil fumarate (Truvada®) and emtricitabine and tenofovir alafenamide (Descovy®).[33] In addition to these, multiple generic formulations equivalent to Truvada are now available in the United States. Expanding beyond oral medications, the FDA approved cabotegravir extended-release injectable suspension (Apretude) in December 2021.[34] This intramuscular injection, administered once every two months, provides an alternative to daily oral PrEP.

In 2014, the U.S. Public Health Service (USPHS) released the first comprehensive clinical practice guidelines for PrEP – *Preexposure Prophylaxis for HIV Prevention in the United States - 2014: A Clinical Practice Guideline.*[35] These guidelines include criteria for determining HIV risk and indications for PrEP use; recommendations for regular clinical follow-ups; emphasis that PrEP is one of several HIV risk-reduction options and its use does not obviate the importance of, or need for, other risk-reduction approaches (e.g., using condoms); and clarification that PrEP is not intended as a lifelong commitment, as individuals may discontinue its use due to changes in their life circumstances.

In 2019, the USPSTF issued a recommendation with an "A" rating that clinicians offer PrEP with effective antiretroviral therapy to persons at high risk for HIV acquisition.[36] In 2023, the

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[31] See State Medicaid Director Letter #13-002 "Affordable Care Act Section 4106 (Preventive Services) and State Health Official Letter #23-003 "Mandatory Medicaid and Children's Health Insurance Program Coverage of Adult Vaccinations under the Inflation Reduction Act" for more information.

[32] CDC. (2024, August 20). *Clinical guidance for PrEP*. https://www.cdc.gov/hivnexus/hcp/prep/index.html.

[33] Ibid.

[34] FDA. (2021, December 20). *FDA approves first injectable treatment for HIV pre-exposure prevention*. https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention.

[35] U.S. Public Health Service. (2014). *Preexposure prophylaxis for the prevention of HIV infection in the United States – 2014: A clinical practice guideline*. https://stacks.cdc.gov/view/cdc/79935.

[36] USPSTF. (2019, June 11). Recommendation statement: Preexposure prophylaxis for the prevention of HIV infection. *JAMA, 2019; 321*(22), 2203-2213. DOI: 10.1001/jama.2019.6390.

USPSTF broadened the recommendation to include persons at increased risk and reviewed newer formulations, such as long-acting injectable PrEP.[37]

In December 2021, CDC published an updated Clinical Practice Guideline for Preexposure Prophylaxis for HIV Prevention and Clinical Providers' Supplement.[38,39] The updated guideline and supplement reflect the latest science and are intended to help physicians effectively prescribe all FDA-approved PrEP medications to patients and increase PrEP use among all people who could benefit. Importantly, the guideline showcases how PrEP can serve as a gateway to improved access to clinical care. During initiation or maintenance appointments, providers are encouraged to address primary care needs while also screening for sexually transmitted infections (STIs), mental health disorders, tobacco/nicotine use, and alcohol or other substance use disorders (SUDs). Key revisions to the guideline include:

- A new recommendation for providers to inform all sexually active adults and adolescents about PrEP. This is intended to increase awareness of PrEP more broadly.
- A recommendation that, in addition to taking a very brief history to identify persons with indications for PrEP, providers prescribe PrEP to anyone who requests it, even if they do not report specific HIV risk behaviors. This recommendation is intended to make PrEP available to people who may be apprehensive about sharing potentially stigmatized HIV risk behaviors with their provider.
- A new section on prescribing bimonthly intramuscular injections of cabotegravir (CAB) for sexually active men and women who could benefit from PrEP.

Post-Exposure Prophylaxis

Post-exposure prophylaxis (PEP) involves the use of antiretroviral medication to prevent HIV in a person without HIV who may have recently been exposed. Specifically, PEP is intended for individuals who seek care within 72 hours following an isolated sexual or injection-related HIV exposure.[40] It requires completing a 28-day course of medication. Current CDC guidelines recommend that individuals who seek one or more courses of PEP and possess increased risk factors for ongoing HIV exposures should be evaluated for possible PrEP use.[41]

Doxycycline Post-Exposure Prophylaxis (Doxy PEP)

Co-infections involving HIV, syphilis, and other STIs are common, as the presence of one infection increases the likelihood of acquiring or transmitting another.[42] Research indicates that

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[37] USPSTF. (2023, August 22). *Final recommendation statement: Prevention of acquisition of HIV: Preexposure prophylaxis*. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

[38] USPHS. (2021). *Preexposure prophylaxis for the prevention of HIV infection in the United States – 2021 update: A clinical practice guideline*. https://snapshot2024.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

[39] USPHS. (2021). *Preexposure prophylaxis for the prevention of HIV infection in the United States – 2021 update: Clinical providers' supplement*. https://snapshot2024.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf.

[40] CDC. (2024, May 7). *Clinical guidance for PEP*. https://www.cdc.gov/hivnexus/hcp/pep/index.html.

[41] CDC. (2016). *Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV – United States, 2016*. https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf.

[42] Spach DH. (2023, November 29). *Sexually transmitted infections*. National HIV Curriculum. https://www.hiv.uw.edu/go/co-occurring-conditions/sexually-transmitted-diseases-infections/core-concept/all#additional-topics.

doxycycline post-exposure prophylaxis (doxy PEP) can reduce the risk of acquiring STIs—including syphilis, chlamydia, and, in some studies, gonorrhea—among men who have sex with men (MSM) and transgender women.[43] CDC guidelines recommend beneficiaries receiving doxy PEP should be appropriately screened for HIV and STIs, both at the time of initial prescription and during follow-up visits (e.g., every 3 to 6 months).[44]

Medicaid Strategies and Opportunities

Federal requirements and opportunities for states related to USPSTF-recommended preventive services are discussed under the Medicaid Strategies and Opportunities section under Testing. On October 21, 2024, the Departments of Labor, HHS, and the Treasury issued FAQs clarifying that most private health plans and insurers must cover specified oral and long-acting injectable formulations of PrEP without cost-sharing and that medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another are not permitted.[45] The guidance also reiterated that these payers must cover specified baseline and monitoring services that are essential to the efficacy of PrEP without cost-sharing, and it addressed ways health plans and insurers can mitigate common coding and claims processing issues for PrEP and other recommended preventive services to ensure that individuals are not improperly charged cost-sharing for important preventive care. This also applies to Medicaid ABPs which must provide USPSTF "A" and "B" recommended preventive services without cost-sharing. While these requirements do not apply to all other sources of coverage, health care payers should consider that comprehensive coverage of PrEP and PEP can reduce new HIV infections, which in turn helps to prevent HIV-related downstream health care utilization and expenditures.

State Medicaid programs are encouraged to assess and enhance the implementation of tools such as coverage for PEP, doxy PEP, and related STI testing in coordination with HIV and PrEP screening services. For example, Washington's state Medicaid program facilitates access to these testing services by covering regular HIV and STI testing in multiple settings, such as family planning clinics, local health departments, and primary care offices. Medicaid programs are encouraged to ensure that testing is covered across a variety of accessible settings. In addition, there is evidence that PrEP access can be expanded to those who would benefit from it most through the involvement of community pharmacies, pharmacists, telehealth, mobile units, street programs, and other non-clinic-based delivery systems. State Medicaid programs are encouraged to partner with community-based organizations to expand access locations for PrEP services.

Additional PrEP products, such as monthly oral medications and longer-acting formulations, are expected to become available. These advances hold the potential to improve adherence and persistence in PrEP use among diverse populations. States are encouraged to proactively adapt their coverage policies and delivery systems to accommodate these new modalities to ensure Medicaid beneficiaries can benefit from these products. For instance, clinics may need to adjust

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[43] CDC. (2024, December 5). *Doxy PEP for bacterial STI prevention*. https://www.cdc.gov/sti/hcp/doxy-pep/index.html.

[44] Bachmann LH, Barbee LA, Chan P, et al. (2024, June 6). CDC clinical guidelines on the use of doxycycline postexposure prophylaxis for bacterial sexually transmitted infection prevention, United States, 2024. *MMWR Recomm Rep 2024;73* (No. RR-2): 1-8. http://dx.doi.org/10.15585/mmwr.rr7302a1.

[45] CMS. (2024, October 21). *FAQs about Affordable Care Act and Women's Health and Cancer Rights Act implementation part 68*. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-68.pdf

workflows and billing procedures to handle patients receiving injections instead of oral medications dispensed by pharmacies.

There are many clinical resources state Medicaid programs can share with providers to increase awareness of PrEP advances. With the rapid pace of innovation in PrEP medications, CDC and multiple HIV and providers organizations offer and regularly update, a variety of free Continuing Medical Education (CME), Continuing Education (CE), Continuing Pharmacy Education (CPE), and other learning programs for health care providers to build and maintain their skills across the HIV prevention and care continuum.[46] This includes the CDC and HRSA-funded National HIV PrEP Curriculum, providing health care professionals fundamental skills to assess, initiate, and monitor PrEP.[47] Additional clinical recommendations can be obtained through respective PEP and PrEP hotlines via the National Clinician Consultation Center.[48,49]

TREATMENT

The primary goal of HIV treatment is to achieve and maintain viral suppression, where the viral load becomes undetectable. A robust body of clinical evidence has confirmed that individuals with HIV who are on treatment and maintain a viral load below 200 copies/mL not only experience improved health but also cannot sexually transmit the virus, a principle known as Undetectable Equals Untransmittable (U=U).[50,51,52,53,54,55] This underscores the critical importance of treatment adherence and the need for a systematic approach that ensures access to care and treatment for all individuals with HIV. Achieving these outcomes requires comprehensive services, including early diagnosis, timely linkage to care, sustained retention in care, medically appropriate treatment, and long-term viral suppression. These sequential steps, from diagnosis to achieving and maintaining viral suppression, are collectively known as the HIV care continuum. The HIV care continuum is essential for optimizing health outcomes for people with HIV.[56] It also provides policymakers and service providers with a valuable

[46] CDC trainings and guidance can be accessed through "HIV Nexus" at https://www.cdc.gov/hivnexus/hcp/.
[47] National HIV PrEP Curriculum resources and modules can be found at https://www.hivprep.uw.edu/.
[48] The NCCC PEP hotline number is (888) 448-4911. Hours and additional information can be found at https://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/.
[49] The NCCC PrEP hotline number is (855) HIV-PrEP [448-7737] and operates Monday – Friday from 9 AM to 8 PM ET. Additional information can be found at https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/.
[50] Eisinger RW, Dieffenbach CW, Fauci AS. (2019). HIV viral load and transmissibility of HIV infection: Undetectable equals untransmissible. *JAMA, 321*(5), 451-452. DOI: 10.1001/jama.2018.21167.
[51] LeMessurier J, Traversy G, Varsaneux O, Weekes M, Avey MT, et al. (2018). Risk of sexual transmission of human immunodeficiency virus with antiretroviral therapy, suppressed viral load and condom use: A systematic review. *CMAJ, 190*(46), E1350-E1360. DOI: 10.1503/cmaj.180311.
[52] Vernazza P, Hirschel B, Bernasconi E, Flepp M. (2008). Les personnes seropositives ne souffrant d'aucune autre MST et suivant un traitement antiretroviral efficace ne transmettent pas le VIH voie sexuelle. *Bulletin des medecins suisses, 89*(5), 165-169. DOI: 10.4414/bms.2008.13252.
[53] Cohen MS, Chen YQ, McCauley M, et al; HPTN 052 Study Team. (2011). Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med. 2011, 365*(6), 493-505. DOI: 10.1056/NEJMoa1105243.
[54] Cohen MS, Chen YQ, McCauley M, et al; HPTN 052 Study Team. (2016). Antiretroviral therapy for the prevention of HIV-1 transmission. N Engl J Med., 375(9), 830-839. DOI: 10.1056/NEJMoa1600693.
[55] Rodger A, Cambiano V, Brunn T, et al. *Risk of HIV transmission through condomless sex in MSM couples with suppressive ART: the Partners2 Study extended results in gay men*. Presented at: 22nd International AIDS Conference; July 25, 2018; Amsterdam, the Netherlands.
[56] Cheever LW. (2007). Engaging HIV-infected patients in care: Their lives depend on it. Clinical Infectious Diseases, 44(11), 1500-1502. https://doi.org/10.1086/517534.

framework to identify service gaps, design targeted strategies, and support individuals along their treatment journey.

Advances in HIV treatment have significantly improved the long-term health and quality of life for people with HIV. These scientific developments include the Food and Drug Administration's (FDA) approval of the first long-acting injectable ART regimens, which offer an alternative to daily fixed-dose combination pills. Modern ART is highly effective, well-tolerated, and capable of maintaining viral suppression, providing people with HIV more options tailored to their needs. Selecting the appropriate ART regimen requires considering factors such as antiretroviral history, previous toxicities or intolerances, adherence patterns, and resistance testing. Adjustments may be necessary for individuals experiencing adverse effects, drug interactions, stigma, cost barriers, or for those who are pregnant or planning to become pregnant.

Early ART Initiation and Rapid Start Programs

Timely initiation of ART is also critical to these efforts. Longitudinal research demonstrates that starting ART early, when the immune system is still strong, leads to better long-term health outcomes compared to delaying treatment.[57,58,59,60] Interruptions in treatment can result in viral rebound, worsening immune function, and increased morbidity and mortality.[61] Routine HIV care should include counseling to address barriers to ART adherence, which is crucial for maintaining health, preserving treatment options, and preventing community-level transmission.

Rapid start programs, which initiate ART within seven days of an HIV diagnosis or re-engagement in care, ideally on the same day, are essential for quickly connecting people with HIV to treatment. This approach minimizes the risk of losing individuals to care and accelerates positive health effects. Early ART initiation is strongly recommended by leading health organizations, including the National Institutes of Health, International Antiviral Society-USA, and World Health Organization. Rapid start programs, such as those implemented in HRSA's Ryan White HIV/AIDS Program (RWHAP), have demonstrated increased rates of medication uptake, viral suppression, retention in care, and client satisfaction.

Long-Acting Injectables (LAIs)

In 2021, the FDA approved the first complete long-acting monthly injectable ART regimen, cabotegravir (CAB) and rilpivirine (RPV) for adults with HIV who are on ART, with HIV viral load <50 copies/mL, no history of treatment failure, and no known or suspected resistance to CAB or RPV.[62] In a randomized trial, CAB/RPV was superior in suppressing HIV replication compared to daily oral ART in people who had been unable to maintain viral suppression

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[57] Lundgren JD, Babiker AG, Sharma S, Grund B, Phillips AN, et al. (2023). Long-term benefits from early antiretroviral therapy initiation in HIV infection. *NEJM Evidence, 2*(3), 1-19. DOI: 10.1056/evidoa2200302.
[58] Danel C, Moh R, Gabillard D, Badje A, Le Carrou J, et al. (2015). A trial of early antiretrovirals and isoniazid preventive therapy in Africa. *NEJM, 373*(9), 808-822. DOI: 10.1056/NEJMoa1507198.
[59] Ford N, Migone C, Calmy A, Kerschberger B, Kanters S, et al. (2018). Benefits and risks of rapid initiation of antiretroviral therapy. *AIDS, 32*(1), 17–23. DOI: 10.1097/QAD.0000000000001671.
[60] Pilcher CD, Ospina-Norvell C, Dasgupta A, Jones D, Hartogensis W, et al. (2017). The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. *Journal of Acquired Immune Deficiency Syndromes, 74*(1), 44–51. DOI: 10.1097/QAI.0000000000001134.
[61] El-Sadr WM, Lundgren JD, Neaton JD, et al. (2006). CD4+ count-guided interruption of antiretroviral treatment. *N Engl J Med., 355*(22), 2283-2296. DOI: 10.1056/NEJMoa062360.
[62] https://www.fda.gov/news-events/press-announcements/fda-approves-first-extended-release-injectable-drug-regimen-adults-living-hiv

through an oral daily regimen, [63] and a pilot study also found CAB/RPV suppressed HIV among people with unstable housing, mental illnesses, substance use disorders.[64]

In 2022, the FDA approved twice-yearly lenacapavir (LEN), a first-in-class HIV capsid inhibitor, to be used in combination with other antiretrovirals (ARVs) for the treatment of heavily treatment-experienced adults with multidrug-resistant HIV.[65] Both long-acting regimens require doses of the oral formulation of the drug prior to or at the time of initiation, the details of which differ by ARV. The safety and efficacy of CAB/RPV and LEN have not been formally evaluated in pregnant people.

Advances in HIV treatment have improved long-term outcomes, providing better viral suppression, fewer side effects, and simplified dosing. FDA approval of LAIs heralded a new era of HIV treatment.[66] These new therapies provide a discreet and long-acting alternative to daily oral medication, which can enhance adherence and reduce stigma associated with HIV treatment.

Vertical HIV Transmission

ART effectively prevents vertical HIV transmission during pregnancy, childbirth, and breastfeeding.[67] ART regimens should be tailored to the individual's ARV history and clinical needs. Inclusion of pregnant individuals in research has significantly expanded the evidence base and guidelines on ART use in people who are pregnant or of reproductive potential. For instance, dolutegravir (DTG), a first-line ARV initially for individuals of reproductive potential, was initially associated with elevated fetal neural tube defects, but has undergone extensive study and is now considered safe throughout conception, pregnancy, childbirth, and breastfeeding.[68] A Phase 3 international clinical trial demonstrated that DTG-containing regimens have a superior safety profile compared to efavirenz.[69] Additionally, long-term follow-up from the Botswana birth outcomes surveillance study, which initially reported elevated neural tube defects associated with DTG, found no significant difference in NTD prevalence between DTG-containing regimens and non-DTG regimens.[70]

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[63] Rana *et al*. Long-acting Injectable CAB/RPV is Superior to Oral ART in PWH with adherence challenges: ACTG A5359. Conference on Retroviruses and Opportunistic Infections in Denver, Colorado. Wednesday, March 6, 2024.

[64] Gandhi M, Hickey M, Imbert E, Grochowski J, Mayorga-Munoz F, Szumowski JD, Oskarsson J, Shiels M, Sauceda J, Salazar J, Dilworth S, Nguyen JQ, Glidden DV, Havlir DV, Christopoulos KA. Demonstration Project of Long-Acting Antiretroviral Therapy in a Diverse Population of People With HIV. Ann Intern Med. 2023 Jul;176(7):969-974. doi: 10.7326/M23-0788. Epub 2023 Jul 4. PMID: 37399555; PMCID: PMC10771861.

[65] https://public4.pagefreezer.com/content/FDA/30-06-2023T13:23/https://www.fda.gov/news-events/press-announcements/fda-approves-new-hiv-drug-adults-limited-treatment-options

[66] https://aidsrestherapy.biomedcentral.com/articles/10.1186/s12981-022-00477-w

[67] Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal

[68] R Zash, J Makhema, RL Shapiro. Neural-tube defects with dolutegravir treatment from the time of conception. N Engl J Med, 379 (2018), pp. 979-981.

[69] Lockman S et al. Efficacy and safety of dolutegravir with emtricitabine and tenofovir alafenamide fumarate or tenofovir disoproxil fumarate, and efavirenz, emtricitabine, and tenofovir disoproxil fumarate HIV antiretroviral therapy regimens started in pregnancy (IMPAACT 2010/VESTED): a multicentre, open-label, randomised, controlled, phase 3 trial. Lancet. 2021 Apr 3;397(10281):1276-1292. doi: 10.1016/S0140-6736(21)00314-7. PMID: 33812487; PMCID: PMC8132194.

[70] Zash R et al. *Update on neural tube defects with antiretroviral exposure in the Tsepamo study, Botswana*. 24th International AIDS Conference, Montreal, abstract PELBB02, 2022.

Medicaid Strategies and Opportunities

For state Medicaid programs, strengthening the HIV care continuum involves ensuring access to necessary services, removing barriers to care, and fostering coordination with other programs like the RWHAP. States have used multiple policy mechanisms to expand access to care for individuals with HIV. For example, Maine has a Medicaid 1115 demonstration that expands healthcare coverage to HIV-positive individuals with incomes at or below 250% of the federal poverty level (FPL).[71] Through this demonstration, Maine offers a limited yet comprehensive service package, including antiretroviral therapies, to support early and effective HIV treatment. The program works in coordination with the state's AIDS Drug Assistance Program (ADAP).[72]

Outpatient prescription drug coverage is an optional benefit that all state Medicaid programs currently provide.[73] Given that adherence to ART is a critical prerequisite to realizing both individual and public health benefits, states are reminded of the statutory requirement to cover all covered outpatient drugs of manufacturers with agreements described in section 1927(b) of the Act, including single-tablet ART regimens. States can also, and are strongly encouraged to, go farther to support access and adherence to effective treatments for people with HIV. States should design their prescription drug formularies to minimize potential barriers so that Medicaid and CHIP beneficiaries with HIV can readily access regimens described for potential use (including those labeled as "Recommended", "Alternative", and "Other") in the HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV ("HHS Guidelines").[74] For state Medicaid programs, integrating rapid start programs aligns with the mission to deliver timely, high-quality care and improve health outcomes for beneficiaries with HIV. This strategy also can reduce long-term healthcare expenditures by preventing complications from delayed treatment.[75] By ensuring coverage policies do not serve as barriers to accessing LAIs and by addressing other potential barriers to care, state Medicaid programs can improve health outcomes for populations disproportionately affected by HIV and advance public health efforts to end the epidemic.

For example, Nevada has established regulations[76] that prevent the Medicaid program preferred prescription drug list from limiting access to medically necessary single-tablet regimens (STRs) and ART drugs for HIV/AIDS treatment and prevention. This policy helps ensure that Medicaid enrollees receive uninterrupted access to life-saving medications, supporting better health outcomes and advancing the state's HIV prevention efforts.

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration, and the RWHAP are vital components of the HIV care system, complementing Medicaid by supporting access to essential care for vulnerable populations. Specifically, the

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[71] https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81876.

[72] Under HRSA's Ryan White HIV/AIDS Program (RWHAP) Part B, the AIDS Drug Assistance Program (ADAP) offers FDA-approved medications to low-income individuals with HIV. For more information on ADAP visit https://ryanwhite.hrsa.gov/about/parts-and-initiatives/part-b-adap.

[73] Section 1905(a)(12) of the Social Security Act.

[74] Panel on Antiretroviral Guidelines for Adults and Adolescents, HHS. *Guidelines for the use of antiretroviral agents in adults and adolescents with HIV*. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf.

[75] Benson C, Emond B, Romdhani H, et al. Long-Term Benefits of Rapid Antiretroviral Therapy Initiation in Reducing Medical and Overall Health Care Costs Among Medicaid-Covered Patients with Human Immunodeficiency Virus. *J Manag Care Spec Pharm*. 2020;26(2):117-128. doi:10.18553/jmcp.2019.19174

[76] Nevada Revised Statute 422.4025

340B Drug Pricing Program provides safety-net providers with savings from discounted purchases of HIV medication, which enables expanded access to comprehensive services, such as substance use treatment, mobile clinics, and dental care, especially in underserved and rural areas.

Medicaid Strategies and Opportunities: ***Supplemental Rebates and Value-Based Purchasing***
State Medicaid programs face the dual challenge of managing rising drug costs while ensuring access to high-quality care for individuals with or vulnerable to HIV. Supplemental rebates and value-based purchasing (VBP) agreements offer innovative opportunities to achieve both goals. Supplemental rebates are discounts beyond the federal statutory rebates received by Medicaid programs through the Medicaid Drug Rebate Program and can be negotiated either by individual state programs or through a multi-state purchasing pool.

Manufacturers that offer supplemental rebates assist states in reducing the net cost of high-cost medications like ART and PrEP. These rebates are often tied to the inclusion of specific drugs on state Medicaid preferred drug lists, ensuring patient access to the negotiated drugs while controlling spending. For example, states can negotiate supplemental rebates to lower the net cost to the Medicaid program of long-acting injectable PrEP or cutting-edge HIV treatments, helping states expand access to these products that foster better adherence and reduce new HIV transmissions.

Value-based purchasing (VBP), or value-based payment, agreements take this negotiated approach a step further by linking payments for medications or healthcare services to measurable health outcomes. For people with HIV, VBP agreements can include benchmarks such as achieving viral suppression, reducing hospitalizations, or improving treatment adherence rates. If the outcomes are not met, manufacturers could be required to provide additional rebates or discounts to offset expenditures for drugs that have not met health outcome benchmarks. This model shifts the focus from volume to value and clinical outcomes, incentivizing manufacturers and providers to prioritize effectiveness. Some states have used VBP agreements to implement a subscription model of sorts for purchasing key pharmaceuticals. VBP agreements can help Medicaid programs encourage the use of evidence-based care while ensuring financial sustainability.

Medicaid Strategies and Opportunities: ***Pharmacist Engagement***
It is important that Medicaid and CHIP beneficiaries can access HIV-related services at times and locations that are convenient for them. With an estimated 70% of rural residents living within 15 miles of a pharmacy and 90% of urban residents within 2 miles, pharmacies are well-positioned to help improve testing accessibility and identify individuals with undiagnosed HIV.[77] States may submit state plan amendments (SPAs) proposing to designate pharmacists and pharmacies as qualified health care providers and settings for critical prevention services, including ordering and administering HIV screening tests and providing HIV PrEP and PEP medications. For example, under 42 CFR 440.60, states can cover services provided by a licensed pharmacists within their authorized scope of practice as defined under state law.

[77] Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, et al. (2022). Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. *Journal of the American Pharmacists Association, 62*(6), 1816-1822. https://doi.org/10.1016/j.japh.2022.07.003.

For example, Colorado's Medicaid program pays pharmacists for medically necessary services that are part of a statewide protocol or collaborative practice agreement and not duplicative of existing pharmacy benefits.[78] This includes services associated with the prescribing of HIV PrEP and PEP medications. Pharmacists receive payment at 100% of the physician fee schedule for these services, supporting expanded access to critical HIV prevention care.[79]

Since 2023, Virginia law requires the Medicaid program to pay for clinical services provided by a pharmacist, pharmacy technician, or pharmacy intern that are performed pursuant to a statewide protocol or a collaborative practice agreement and consistent with the terms of a managed care contract.[80] Pharmacists can be paid for any of the services outlined in the Virginia Board of Pharmacy Protocols, including HIV PrEP and PEP.[81]

Considerations for Certain Populations

The HHS Guidelines provide comprehensive insights into ART's effects across the lifespan, addressing factors such as weight gain following ART initiation or regimen changes, the impact of menopause on ART adherence, and how these factors influence quality of life. The guidelines also highlight the unique challenges faced by adolescents, young adults, and transgender individuals, particularly regarding ART adherence and stigma. For adolescents and young adults, state Medicaid and CHIP programs are encouraged to promote seamless access to care as they transition from pediatric to adult HIV services, as well as to support coordinated care for individuals with unique health needs.

HIV and Aging

In 2022, more than half (53.7%) of all people with HIV in the United States were aged 50 or older, and about 15.4% percent of new diagnoses occurred in this age group.[82] Older people with HIV face unique challenges and have a higher risk of certain comorbidities, such as neurocognitive decline, cardiovascular disease, and some cancers.[83] State Medicaid programs can support integrated care models that address these conditions alongside HIV treatment to improve health outcomes for older adults. People with HIV aged 50 and older face similar health and social issues as the general aging population, including: multiple chronic conditions, medication management, polypharmacy, changing physical and cognitive abilities, and social isolation and loneliness. However, they experience age-related conditions 10-15 years sooner and with more complexity than the general population.[84] Similarly, people diagnosed with HIV

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[78] Code of Colorado Regulations: State Board of Pharmacy, 3 CCR 719-1. https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=11189&fileName=3%20CCR%20719-1.

[79] Colorado Department of Health Care Policy & Financing. (2024, October 16). *Pharmacist Services Billing Manual*. https://hcpf.colorado.gov/pharm-serv.

[80] An amendment to § 32.1-325 of the Code of Virginia was introduced through Virginia Senate bill 1538, which was approved March 23, 2023. Full text can be read at https://legacylis.virginia.gov/cgi-bin/legp604.exe?231+ful+CHAP0412.

[81] Virginia Department of Health Professions: Board of Pharmacy. https://www.dhp.virginia.gov/Boards/Pharmacy/PractitionerResources/StatewideProtocols/.

[82] CDC. (2024, May). Diagnoses, deaths, and prevalence of HIV in the United States and 6 territories and freely associated states, 2022 (see footnote 23).

[83] Budak JZ. (2024, February 14). *HIV in older adults*. National HIV Curriculum. https://www.hiv.uw.edu/go/key-populations/hiv-older-patients/core-concept/all.

[84] Guaraldi, G., Orlando, G., Zona, S., et al. (2011). Premature age-related comorbidities among HIV-infected persons compared with the general population. *Clinical Infectious Diseases, 53*(11), 1120-1126. https://doi.org/10.1093/cid/cir627.

at birth or in childhood were exposed to the virus when their immune systems were not yet fully developed, which may accelerate the rate at which their immune system ages.[85]

Factors such as age, gender identity, race, ethnicity, and socioeconomic status also contribute to disparities in health outcomes. Affected populations may include: older adults (people with HIV aged 50 and older); long-term survivors (adults who acquired HIV prior to the availability of ART); and/or life-term survivors (adults who acquired HIV at birth or as young children). The health care landscape for people with HIV aged 50 and older, and long-term and life-term survivors, is constantly evolving. HHS issued new considerations for older people with HIV in the guidelines for the use of ARVs in adults and adolescents.[86] State Medicaid programs should promote coordination among Medicaid, Medicare, and the RWHAP, and area agencies on aging, to ensure comprehensive, integrated care for individuals managing HIV and associated co-morbidities.

PROGRAM COORDINATION AND INTEGRATION

Effective program coordination is essential for reducing administrative burden, ensuring continuity of care, and improving health outcomes for people with HIV. Data sharing and information integration between Medicaid and HIV care systems can enhance a community's ability to coordinate services, address gaps, and evaluate program effectiveness. Streamlined health care coverage eligibility determinations are particularly crucial for newly diagnosed individuals, those currently in care, and those needing re-engagement. Simplifying these processes for both providers and clients helps maintain individuals in care, reconnect those who have fallen out of care, and link newly diagnosed individuals to the services and support they need.

Specifically, collaboration between Medicaid and the RWHAP is vital for these efforts. Data sharing and integration, such as streamlining income verification processes, can reduce barriers to care and improve engagement, retention, and service quality. Effective care coordination requires organizations and planning bodies to work together to deliver comprehensive services that meet identified needs. State Medicaid programs are encouraged to collaborate with providers, including RWHAP recipients, to ensure services are complementary rather than duplicative.[87] This approach supports seamless, coordinated care for people with HIV.

For example, Virginia's Medicaid program aligned its preferred drug list for antiretrovirals with the state's ADAP formulary. This alignment ensures a smoother transition for people with HIV when they enroll in Medicaid or lose Medicaid coverage and move to ADAP. If Medicaid beneficiaries lose coverage, Virginia's RWHAP Part B, including ADAP, can step in to cover essential HIV care services. This coordinated approach between Medicaid and RWHAP

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[85] Gianesin, K., Noguer-Julian, A., Zanchetta, M., et al. (2016). Premature aging and immune senescence in HIV-infected children. *AIDS, 30*(9), 1363-1373. https://doi.org/10.1097/QAD.0000000000001093.

[86] Panel on Antiretroviral Guidelines for Adults and Adolescents, HHS. *Guidelines for the use of antiretroviral agents in adults and adolescents with HIV* (see footnote 70; "HIV and the Older Person" (p. I-44)). https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/special-populations-hiv-and-older.

[87] Bradley H, Viall AH, Wortley PM, Dempsey A, Hauck H, & Skarbinski J. (2016). Ryan White HIV/AIDS Program Assistance and HIV Treatment Outcomes. *Clinical Infectious Diseases, Volume 62*(1), 90–98. https://doi.org/10.1093/cid/civ708.

programs, including drug coverage and provider network alignment, helps prevent treatment interruptions and supports continuity of HIV care when individuals transition between sources of coverage.

Syndemics of HIV

A system-wide syndemic approach to HIV prevention, care and treatment can improve the health of persons with or those with increased vulnerability to acquiring HIV, and related health outcomes, as well as tackling health disparities that exacerbate disease burden. A syndemic arises when two or more health conditions interact within a population, amplifying negative health outcomes due to overlapping biological, social, and environmental factors.[88] In the context of HIV, common syndemics include co-occurring conditions such as substance use disorders, mental health challenges, STIs, and hepatitis C, all of which disproportionately impact vulnerable communities.[89,90,91,92] These conditions are further compounded by SDOH such as poverty, stigma, discrimination, and limited access to healthcare, creating significant barriers to care and worsening health outcomes.

In 2023, more than 2.4 million cases of syphilis, gonorrhea, and chlamydia were reported nationwide, highlighting the urgent need for expanded public health efforts to reduce STI incidence.[93] State Medicaid programs are encouraged to ensure beneficiaries with HIV receive routine and comprehensive screening, timely diagnoses, and appropriate treatments for STIs, viral hepatitis, and other conditions aligned with public health guidelines.

Medicaid plays a pivotal role in addressing syndemics by supporting integrated care models that deliver whole person care. Through mechanisms such as Medicaid demonstrations, managed care authorities and flexibilities, and state plan amendments, states can expand coverage for essential services such as behavioral health care, harm reduction programs, and care coordination. For example, Colorado's Medicaid 1115 demonstration includes increasing access to harm reduction services including access to STI, HIV, and hepatitis C virus (HCV) testing and syringe exchange for people who inject drugs.[94] A whole person approach to syndemics not only

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[88] Shelke A, Shelke S, Acharya S, & Shulka S. (2023). Synergistic epidemic or syndemic: An emerging pattern of human diseases. *Cureus, 15*(11). DOI: 10.7759/cureus.48286.

[89] Hartzler B, Dombowski JC, Crane HM, Eron JJ, Geng EH, et al. (2017). Prevalence and predictors of substance use disorders among HIV care enrollees in the United States. *AIDS and Behavior, 21*, 1138-1148. https://doi.org/10.1007/s10461-016-1584-6

[90] Perlman DC, & Jordan AE. (2018). The syndemic of opioid misuse, overdose, HCV and HIV: Structural-level causes and interventions. *Current HIV/AIDS Reports, 15*(2), 96-112. DOI: 10.1007/s11904-018-039

[91] Patel YS, & Lipps AA. (2024). The syndemic of HIV and sexually transmitted infections. *Infectious Diseases in Clinical Practice, 32*(4), E1379. DOI: 10.1097/IPC.0000000000001379

[92] Talman A, Bolton S, & Walson JL. (2013). Interactions between HIV/AIDS and the environment: Toward a syndemic framework. *American Journal of Public Health, 103*(2), 253-261. https://doi.org/10.2105/AJPH.2012.300924

[93] CDC. (2024, November 8). *STI fact sheet*. https://www.cdc.gov/sti/media/pdfs/2024/11/Syndemic-Infographic-11-08-2024.pdf.

[94] Colorado Department of Health Care Policy & Financing. (2020, December 18). *Colorado substance use disorder section 1115 waiver implementation plan*. Available at https://hcpf.colorado.gov/sites/hcpf/files/Colorado%20SUD%20Implementation%20Plan%20Approval%20and%20CMS%20Letter%20January%202021_0_0.pdf

improves viral suppression rates and reduces new HIV transmissions but also promotes long-term health equity and sustainability in treatment outcomes.[95]

Mental Health and Substance Use Disorders

People with HIV experience higher rates of depression, anxiety, and other mental health (MH) challenges due to the stress of managing a chronic condition, stigma, and discrimination.[96,97,98] Substance use disorders (SUDs) are also highly prevalent among people with HIV and significantly contribute to poor health outcomes.[99,100] Risk behaviors such as injection drug use not only increase the likelihood of acquiring or transmitting HIV but also create barriers to engaging and retaining individuals in treatment. SUDs can accelerate disease progression, hinder adherence to ART, and perpetuate behaviors that increase the risk of onward HIV transmission.[101,102]

Effectively addressing MH and SUD is essential to ending the HIV epidemic. Medicaid and CHIP can provide coverage for a full array of services and supports for people with MH conditions and SUDs, including services and supports that generally are not covered by other health care programs or plans. Collaboration between HIV care and SUD programs can strengthen services for people with HIV by pooling resources, expertise, and infrastructure. Integrated care models that co-locate HIV care, SUD treatment, mental health services, and psychosocial supports—such as case management, resource referrals, system navigation, and recovery assistance—can improve engagement in HIV treatment and enhance overall health outcomes.[103,104] Co-locating these services and collaborating with agencies like the Substance Abuse and Mental Health Services Administration (SAMHSA) enhances comprehensive treatment programs, improving long-term recovery and reducing HIV transmission rates.

Improving access to medications for SUD treatment within HIV clinics has been shown to reduce opioid use, increase ART adherence, elevate the quality of HIV care, and improve quality

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[95] https://www.cdc.gov/nchhstp/about/syndemic.html

[96] Remien RH, Stirratt MJ, Nguyen N, Robbins RN, Pala AN, et al. (2019). Mental health and HIV/AIDS: The need for an integrated response. *AIDS*, *33*(9), 1411-1420. DOI: 10.1097/QAD.0000000000002227.

[97] Lang R, Hogan B, Zhu J, McArthur K, Lee J, Zandi P, et al. (2023). The prevalence of mental health disorders in people with HIV and the effects on the HIV care continuum. *AIDS*, *37*(2), 259-269. DOI: 10.1097/QAD.0000000000003420.

[98] Hobkirk AL, Towe SL, Lion R, & Meade CS. (2016). Primary and secondary HIV prevention among persons with severe mental illness: Recent findings. *Current HIV/AIDS Reports, 12*(4), 406-412. DOI: 10.1007/s11904-015-0294-4.

[99] Substance Abuse and Mental Health Services Administration. (2021). Treating substance use disorders among people with HIV. *Advisory*. https://store.samhsa.gov/sites/default/files/pep20-06-04-007.pdf

[100] Hartler B, Dombrowski JC, Crane HM, Eron JJ, Geng EH, et al. (2018). Prevalence and predictors of substance use disorders among HIV care enrollees in the United States. *AIDS Behavior*, *21*(4), 1138-1148. DOI: 10.1007/s10461-016-1584-6

[101] Carrico, Adam W PhD et al. Psychiatric Risk Factors for HIV Disease Progression: The Role of Inconsistent Patterns of Antiretroviral Therapy Utilization. JAIDS Journal of Acquired Immune Deficiency Syndromes 56(2):p 146-150, February 1, 2011. | DOI: 10.1097/QAI.0b013e318201df63

[102] Memiah, P., Nkinda, L., Majigo, M. et al. Mental health symptoms and inflammatory markers among HIV infected patients in Tanzania. BMC Public Health 21, 1113 (2021). https://doi.org/10.1186/s12889-021-11064-5

[103] Remien RH, et al. (2019). Mental health and HIV/AIDS: The need for an integrated response. *AIDS 33*(9), 1411-1420. DOI: 10.1097/QAD.0000000000002227

[104] Walkup J, et al. (2008). The impact of mental health and substance abuse factors on HIV prevention and treatment. *Journal of Acquired Immune Deficiency Syndromes 47*, S15-S19. DOI: 10.1097/QAI.0b013e3181605b26

of life.[105] State Medicaid programs are encouraged to prioritize policies and investments that support integrated care models. By co-locating HIV care, SUD services, mental health care, and psychosocial supports, Medicaid programs can more effectively address the complex needs of individuals with HIV and SUDs, fostering better health outcomes and reducing transmission rates. Additionally, coordination and collaboration with the SAMHSA can enhance the development and implementation of integrated care models, ensuring that evidence-based approaches are widely adopted and that resources are maximized to address the intersection of HIV and substance use.[106]

CMS has made several changes to improve access to behavioral health services in Medicare, and state Medicaid programs could take steps to align with these changes. Starting in 2024, CMS began enrolling Marriage and Family Therapists and Mental Health Counselors in Medicare and paying for their behavioral health services, paying for Intensive Outpatient Program services, increased payment for behavioral health services such as psychotherapy, and paying for principal illness navigation services provided by peer support workers as part of a patient's treatment plan. Starting in 2025, CMS has created new coding and payment for safety planning interventions for individuals at high risk of overdose or suicide, and expanded the spectrum of services provided by Opioid Treatment Programs. CMS, along with the Departments of Labor and the Treasury, also recently updated regulations implementing the Mental Health Parity and Equity Addiction Act that are intended to further that law's purpose of ensuring that group health plans and health insurance issuers that offer group or individual health insurance coverage do not impose greater restrictions on mental health and substance use disorder benefits than those imposed on medical/surgical benefits.[107]

Community Health Workers and Patient Navigators

Community health workers (CHWs) and patient navigators play essential roles in HIV treatment and prevention. CHWs serve as trusted liaisons between communities and healthcare systems. Their work emphasizes health education, community engagement, and addressing social determinants of health. Within HIV care, CHWs are a bridge between HIV clinics and support service agencies and health care organizations.[108] Patient navigators focus on linking people with HIV to primary care, ensuring retention in care, enhancing adherence to medication, and guiding clients through complex healthcare systems. They work closely with care teams to help clients achieve viral suppression and improve health outcomes.

Services of CHWs may be covered and paid under Medicaid in several different benefit categories, as long as the services CHWs provide and the CHWs themselves meet the federal requirements under the respective benefit category. Potential benefit categories include

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[105] West, Brooke S., et al. "HIV status and substance use disorder treatment need and utilization among adults in the United States, 2015–2019: Implications for healthcare service provision and integration." *Journal of Substance Use and Addiction Treatment* 164 (2024): 209440.

[106] Funded by the Substance Abuse and Mental Health Services Administration (SAMHSA), the National Council for Mental Wellbeing's Center of Excellence offers support, resources, and training to advance integrated care models addressing mental health, substance use, and physical health. For more information, visit: Center of Excellence.

[107] 89 FR 77586.

[108] Boston University Center for Innovation in Social Work and Health. The Community Health Worker Role on the HIV Care Continuum (2020). Available at: https://targethiv.org/sites/default/files/Community_Health_Worker_Role_on_the_HIV_Care_Continuum_Fact_Sheet.pdf.

preventive services, services of other licensed practitioners, physician services, and rehabilitative services.

States and managed care plans can also design and implement managed care payment strategies to encourage managed care plans to consider specific CHW initiatives, such as:

- States can create pay-for-performance incentive arrangements for Medicaid managed care plans, subject to the requirements in 42 CFR 438.6(b)(2), to incentivize specific CHW activities or CHW contracting.
- States can also utilize Medicaid managed care state directed payments in accordance with 42 CFR 438.6(c) to contractually require that managed care plans implement specific payment arrangements with CHWs.

Additionally, CMS has finalized coding and Medicare payment for community health integration (CHI) and principal illness navigation (PIN) services, which went into effect January 1st, 2024, which pay for services performed by CHWs, patient navigators, and peer support specialists. While these types of health care support staff have been able to serve as auxiliary personnel to perform covered services incident to the services of a Medicare-enrolled billing physician or practitioner, the finalized codes are the first that are specifically designed to describe services involving CHWs, care navigators, and peer support specialists. CHI and PIN services involve a person-centered assessment to better understand the patient's life story, care coordination, contextualizing health education, building patient self-advocacy skills, health system navigation, facilitating behavioral change, providing social and emotional support, and facilitating access to community-based social services to address unmet SDOH needs. CHI services are to address unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems. PIN services are to help patients who are diagnosed with high-risk conditions (for example, HIV and AIDS) identify and connect with appropriate clinical and support resources. State Medicaid programs have the flexibility to adopt these codes.

Medicaid Health Homes

States have the option to cover Medicaid health home services for Medicaid beneficiaries with chronic conditions, and can receive a temporary enhanced federal matching percentage of 90% for their expenditures on these services for the first eight quarters from the effective date of the state plan amendment authorizing this coverage.[109] This optional health home benefit includes a range of services designed to help manage care for those who are chronically ill, such as comprehensive care management and care coordination. States can choose to focus coverage of health home services on several chronic conditions, including HIV. As of December 2024, 33 health homes had approval in 19 states and DC.[110] Among these, two states (Washington and Michigan) included HIV among other qualifying conditions for enrollment into the health home and one state, Wisconsin, designed a health home specifically for enrollees with HIV and AIDS. State Medicaid programs are encouraged to explore the potential for coverage of the optional health home benefit to help ensure tailored, integrated care for people with HIV, and help to improve health outcomes and enhance care coordination.

Primary Care Associations (PCAs)

[109] Section 1945(c)(1) of the Act.

[110] Updated quarterly under, "Resources" found at: https://www.medicaid.gov/resources-for-states/medicaid-state-technical-assistance/health-home-information-resource-center/index.html

Primary Care Associations (PCAs), funded by HRSA's Bureau of Primary Health Care, are state and regional nonprofit organizations that provide technical assistance and training to health centers. They support health centers in increasing access to primary care, fostering a strong healthcare workforce, advancing clinical quality, and enhancing emergency preparedness and response. PCAs maintain strong relationships with state governments and agencies, including Medicaid programs, offering a comprehensive, state-wide perspective on healthcare challenges. PCAs can be valuable partners in developing strategies to address public health priorities, such as HIV prevention and care integration.

QUALITY MEASUREMENT AND IMPROVEMENT

The Medicaid and CHIP Child and Adult Core Sets are sets of standardized health care quality measures that CMS and states use to measure the quality of care and improve quality and health outcomes. CMS supports quality improvement in the care for people with HIV through the quality measure "HIV Viral Load Suppression" on the Medicaid Adult Core Set, and through a project with HRSA and CDC, "Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set." The HIV Viral Load Suppression measure is voluntarily reported by states, and while there have not yet been enough states reporting for CMS to report results publicly, the number of states reporting has grown each year. These data are a critical lever for Medicaid to improve the quality of care for enrollees with HIV and to reduce inequities in health outcomes. Coordination and collaboration among state Medicaid programs, HIV surveillance programs, and RWHAP recipients are essential to achieving accurate reporting and leveraging this data to improve outcomes. The following are examples of state strategies:

- **Louisiana:** The Louisiana Office of Public Health and the Bureau of Health Services Financing have established a data-sharing agreement that enables the calculation of viral suppression rates and care retention for Medicaid enrollees with HIV. This collaboration allowed Louisiana Medicaid to adopt the HIV viral suppression measure as a core performance indicator for its managed care plans. Additionally, sharing client-level enrollment data with the state's HIV surveillance program has enabled the health department to identify individuals with HIV who are out of care or not virally suppressed and conduct targeted outreach efforts to re-engage them in treatment and supportive services.

- **Maryland:** Maryland's HIV Surveillance and Medicaid Programs partnered to establish a data sharing agreement, methodology to share and match data between HIV surveillance and Medicaid, calculate the viral suppression performance measure, and report the data to Centers for Medicare and Medicaid's Annual Adult Core Set Reporting. Maryland's approach has become a model for other states pursuing collaborative relationships across HIV and Medicaid and using the viral suppression data to retain clients in care and achieving viral suppression.

- **Washington:** The Washington (WA) State Department of Health's RWHAP Part B established data-sharing agreements with the WA State Department of Social and Health Services and the WA State Health Care Authority. These agreements streamline eligibility certification/recertification by centralizing eligibility verification for RWHAP Parts A and B, ADAP, and the state's PrEP Drug Assistance Program (DAP), while also

confirming Medicaid status. WA Department of Health eligibility specialists can access Medicaid verification data to meet RWHAP requirements for residency, income, and health coverage, including Medicare, simplifying and improving client services.

eClinical Quality Measures (eCQMs)

eCQMs are standardized performance measures that use data from electronic health records and health information technology systems to evaluate and improve healthcare quality. HIV-related eCQMs, such as HIV screening, Viral Load Suppression, Annual Retention in HIV Care, and Sexually Transmitted Disease Screening (e.g., for chlamydia, gonorrhea, and syphilis), are important tools for tracking progress and improving outcomes for people with HIV. State Medicaid programs are encouraged to adopt nationally recognized eCQMs into program requirements. This approach allows states to meaningfully evaluate policy impacts, benchmark performance against national standards, and minimize reporting burdens on providers by streamlining and standardizing data collection practices.

SOCIAL DETERMINANTS OF HEALTH AND WHOLE PERSON CARE

As emphasized in the National HIV/AIDS Strategy, addressing SDOH is essential for improving the health and quality of life of people vulnerable to and with HIV, including those affected by clusters and outbreaks of rapid HIV transmission. Housing instability is associated with poorer health outcomes, including lower rates of viral suppression.[111,112] Coordination with the Housing Opportunities for Persons with AIDS (HOPWA) program[113] enhances the delivery of comprehensive support services. Proper nutrition is critical for maintaining a strong immune system, helping people with HIV manage their condition more effectively.[114,115]

The CDC estimates that 1 in 8 people with HIV are unaware of their status.[116] According to transmission modeling, most new HIV transmissions occur from people who are either undiagnosed or diagnosed and out of care.[117,118] It is estimated that 220,000 people with HIV are

[111] Concerning RWHAP clients, the highest percentage of viral suppression was among people experiencing stable housing in 2023 (91.6%). This is contrasted by those experiencing temporary (85.2%) or unstable (79.7%) housing; Health Resources and Services Administration. (2024). *Ryan White HIV/AIDS Program Annual Data Report 2023*. https://ryanwhite.hrsa.gov/data/reports.

[112] Milloy MJ, Marshall BD, Montaner J, & Wood E. (2013). *Current HIV/AIDS Reports, 9*(4), 364-374. DOI: 10.1007/s11904-012-0137-5.

[113] HOPWA is administered by the U.S. Department of Housing and Urban Development (HUD) and is the only federal program dedicated to addressing the housing needs of people living with HIV/AIDS. The HOPWA program provides grants to local communities, States, and nonprofit organizations for projects that benefit low-income persons living with HIV/AIDS and their families. For more information, please visit https://www.hudexchange.info/programs/hopwa/.

[114] Duggal S, Chugh TD, & Duggal AK. (2012). HIV and malnutrition: Effect on immune system. *Clinical and Developmental Immunology*. https://doi.org/10.1155/2012/784740

[115] Mehta S, & Finkelstein JL. (Ed.). (2018). *Nutrition and HIV: Epidemiological evidence to public health*. CRC Press. https://www.ncbi.nlm.nih.gov/books/NBK572225/

[116] CDC. *Estimated HIV incidence and prevalence in the United States 2018–2022. HIV Surveillance Supplemental Report 2024*;29(1). Accessed July 2024.

[117] Centers for Disease Control and Transmission Vital Signs: HIV Transmission Along the Continuum of Care — United States, 2016. https://www.cdc.gov/mmwr/volumes/68/wr/mm6811e1.htm.

[118] Out of care" refers to individuals who are diagnosed with HIV but are not receiving consistent or appropriate medical care, such as routine health monitoring or antiretroviral therapy.

out of care.[119] People with HIV who are not engaged in care tend to have more complex needs than those that remain engaged.[120] Multiple studies indicate that those retained in care are more likely to achieve viral suppression compared to those not engaged in regular care.[121,122] Populations with multiple needs, including those who have been out of care; those who have co-morbidities such as mental health challenges, substance use disorders, or are experiencing homelessness or at risk of homelessness; and those affected by clusters and outbreaks of rapid HIV transmission, remain at increased risk of not meeting optimal viral suppression.[123]

While SDOH are broad environmental conditions, health-related social needs (HRSN) are specific to an individual and when unmet, these individual-level adverse social conditions contribute to poor health outcomes. These needs, when unmet, can drive lapses in coverage and access to care, higher downstream medical costs, worse health outcomes, and perpetuation of health inequities, particularly for children and adults at high risk for poor health outcomes, and individuals in historically underserved communities.[124]

Medicaid Strategies and Opportunities

By addressing HRSN, state Medicaid and CHIP programs can help their beneficiaries, including those with HIV, stay connected to coverage and access needed health care services. CMS supports states in addressing HRSN through multiple Medicaid and CHIP authorities and mechanisms, described in an updated Center for Medicaid and CHIP Services (CMCS) Informational Bulletin issued in December 2024.[125] As indicated in a letter to State Health Officials (SHO) on January 7, 2021,[126] states can address HRSN through a variety of Medicaid authorities, including state plan authorities, section 1915 home and community-based services (HCBS) waivers and state plan programs, managed care in lieu of services and settings (ILOSs) and section 1115 demonstrations, as well as CHIP Health Service Initiatives (HSIs). For example, the housing and nutrition supports provided under HCBS authorities have served as an important precedent for helping individuals stay connected to coverage and needed care, and in connecting eligible individuals to additional services necessary to meet their comprehensive health needs. Since the publication of the January 2021 SHO, CMS has issued additional HCBS

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[119] Dawson L, Kates J. (2023, June 26). *What do we know about people with HIV who are not engaged in regular HIV care?* KFF. https://www.kff.org/hivaids/issue-brief/what-do-we-know-about-people-with-hiv-who-are-not-engaged-in-regular-hiv-care/.

[120] Bouabida K, Chaves BG, & Anane E. (2023). Challenges and barriers to HIV care engagement and care cascade: Viewpoint. *Frontiers in Reproductive Health*. DOI: 10.3389/frph.2023.1201087

[121] Yehia BR, French B, Fleishman JA, Metlay JP, Berry SA, et al. Retention in care is more strongly associated with viral suppression in HIV-infected patients with lower versus higher CD4 counts. *J Acquir Immune Defic Syndr., 65*(3), 333-339. DOI: 10.1097/QAI.0000000000000023

[122] "Retained in care" refers to individuals who regularly attend medical appointments and adhere to treatment plans as part of their ongoing HIV care. There are other definitions of this term used for other purposes, such as that described by CDC in *Understanding the HIV Care Continuum*, published July 2019: https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf.

[123] O'Connor J, Smith C, Lampe FC, Johnson MA, Chadwick DR, et al. (2017). Durability of viral suppression with first-line antiretroviral therapy in patients with HIV in the UK: an observational cohort study. *Lancet HIV, 4*(7), e295-e302. https://doi.org/10.1016/S2352-3018(17)30053-X.

[124] https://aspe.hhs.gov/reports/building-evidence-base-social-determinants-health-interventions

[125] https://www.medicaid.gov/federal-policy-guidance/downloads/cib12102024.pdf

[126] https://www.medicaid.gov/sites/default/files/2022-01/sho21001_0.pdf

guidance in a continued effort to improve health equity and outcomes for Medicaid beneficiaries by addressing HRSN.[127,128]

CMS has also described ways in which state Medicaid and CHIP programs may cover services and supports addressing HRSN for specific populations not traditionally eligible for HCBS programs. On January 4, 2023, CMS published a State Medicaid Director Letter that describes innovative options states may consider employing in Medicaid managed care programs to address HRSN through the use of ILOSs.[129,130] In 2022, CMS also announced a section 1115 demonstration opportunity to support states in addressing HRSN,[131] and as of early January 2025, CMS has approved section 1115 demonstrations in 18 states that cover certain evidence-based housing and nutritional services designed to mitigate the negative health impacts of unmet HRSN.[132] These types of efforts can support better medication adherence, reduce health disparities, and promote long-term well-being for people with HIV.

For example, Texas Medicaid requires that its managed care plans have a process in place to identify Members with Special Health Care Needs (MSHCN). Texas Medicaid has designated individuals with serious ongoing illness or chronic complex conditions including HIV or AIDS as MSHCN. Managed care plans must have service coordination programs and procedures for MSHCN. As part of service coordination, managed care plans are responsible for working with MSHCNs, their health care providers, and their families/legal guardians to develop a seamless package of care. That package of care may include involvement of community-based organizations to address issues such as food insecurity, transportation, and housing.

Multiple states have used Medicaid home- and community-based services waivers to improve the care of individuals with HIV. For example, Illinois has a section 1915(c) HCBS waiver program that serves people with HIV and AIDS at risk of requiring nursing facility care, enabling them to remain at home while receiving essential services.[133] It covers a range of supports, including adult day services, respite, home health aides, nursing care, various therapies, personal emergency response system, and home delivered meals. Iowa also has a section 1915(c) HCBS waiver program allowing people with HIV who meet a hospital or nursing facility level of care to receive services in their homes and communities including adult day care, homemaker and respite services, home delivered meals and self-directed community support and employment

[127] https://www.medicaid.gov/sites/default/files/2022-04/mfp-supplemental-services-notice.pdf
[128] https://www.medicaid.gov/medicaid/section-1115-demonstrations/health-related-social-needs/index.html
[129] Additional Guidance on Use of In Lieu of Services and Settings in Medicaid Managed Care. https://www.medicaid.gov/sites/default/files/2023-01/smd23001.pdf.
[130] ILOSs are authorized in accordance with 42 CFR § 438.3(e)(2).
[131] https://www.medicaid.gov/sites/default/files/2023-01/addrss-hlth-soc-needs-1115-demo-all-st-call-12062022.pdf.

[132] See examples: https://www.medicaid.gov/sites/default/files/2022-06/ca-calaim-ext-appvl-12292021.pdf
https://www.medicaid.gov/sites/default/files/2022-09/or-health-plan-09282022-ca.pdf
https://www.medicaid.gov/sites/default/files/2022-09/ma-masshealth-ca1.pdf
https://www.medicaid.gov/sites/default/files/2022-10/az-hccc-ca-10142022.pdf
https://www.medicaid.gov/sites/default/files/2022-11/ar-arhome-ca-11012022_0.pdf
https://www.medicaid.gov/sites/default/files/2023-03/nj-1115-cms-exten-demnstr-aprvl-03302023.pdf
https://www.medicaid.gov/sites/default/files/2023-06/wa-medicaid-transformation-ca-06302023.pdf
[133] Illinois' approved waiver application and accompanying factsheet can be found at https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/Waiver-Descript-Factsheet/81546.

among others.[134] In addition, South Carolina offers a section 1915(c) HCBS waiver program that provides case management, companion care, home accessibility adaptations and environmental modifications, home delivered meals, pest control, and other services to Medicaid enrollees with HIV who meet a hospital level of care.[135]

Transportation

Reliable transportation is essential for accessing healthcare services, including routine medical appointments, pharmacy visits, and supportive services such as mental health counseling. Transportation barriers can delay care, disrupt treatment plans, and hinder medication adherence for people vulnerable to and with HIV. State Medicaid plans are required to ensure necessary emergency and non-emergency medical transportation to and from providers for eligible Medicaid beneficiaries.[136] More information is available in the Medicaid Transportation Coverage Guide, which was issued in September of 2023.[137]

Language Access

Language barriers can hinder access to HIV-related care and services for individuals with limited English proficiency (LEP), contributing to disparities in health outcomes. Medicaid programs can address this by ensuring compliance with the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care and must also comply with applicable requirements of Section 1557 of the Affordable Care Act, and the requirements of Title VI of the Civil Rights Act of 1964.[138,139,140]

Stigma and Discrimination

Stigma and discrimination deter individuals from seeking care, adhering to treatment, and disclosing their status. Under federal law, HIV may be considered a disability, and programs that discriminate against individuals with HIV may violate the Americans with Disabilities Act (ADA), Section 504 of the Rehabilitation Act of 1973, and Section 1557 of the Affordable Care Act, which prohibit disability-based discrimination.[141] In addition to complying with applicable

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[134] Additional information can be found at https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/81686.

[135] Further information can be accessed at https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/Waiver-Descript-Factsheet/83136.

[136] See section 1902(a)(4)(A) of the Social Security Act and 42 CFR 431.53

[137] https://www.medicaid.gov/federal-policy-guidance/downloads/smd23006.pdf

[138] Office of Minority Health, HHS. *National standards for culturally and linguistically appropriate services (CLAS) in health and health care*. https://thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf.

[139] *See* Section 1557 of the Patient Protection and Affordable Care Act (42 U.S.C. § 18116 and its implementing regulation at 45 C.F.R. § 92). The relevant Section 1557 regulations are found at 45 C.F.R. §§ 92.8 (covered entities must maintain language access procedures), 92.11 (covered entities must provide notice of the availability of language assistance services), 92.201 (covered entities must provide meaningful access for individuals with LEP). Additional Section 1557 information can be found at: https://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html. Title VI (42 U.S.C. § 2000d and its implementing regulation at 45 C.F.R. § 80) contains language access requirements based on national origin. *See also* HHS Office for Civil Rights, *Language Access Provisions of the Final Rule Implementing Section 1557 of the Affordable Care Act* (Dec. 4, 2024).

[140] *See* HHS Office for Civil Rights, *Ensuring Language Access for Limited English Proficient (LEP) Individuals and Effective Communication for Individuals with Disabilities During the States' Unwinding of the Medicaid Continuous Enrollment Condition* (Apr. 4, 2023), https://akaprod-www.hhs.gov/sites/default/files/medicaid-unwinding-letter.pdf.

[141] *See* 28 C.F.R. § 35.108; 45 C.F.R. § 84.4; 45 C.F.R. § 92.4 (Providing the definitions of disability under Title II of the ADA, Section 504 Part 84, and Section 1557).

federal and state civil rights laws, state Medicaid programs can mitigate these barriers by funding culturally competent care, requiring nondiscrimination clauses in managed care contracts, and promoting provider education programs focused on reducing HIV-related stigma.

Community Engagement

Achieving equitable health outcomes for people vulnerable to and with HIV requires active community involvement. Medicaid programs can collaborate with community-based organizations and public health agencies to design and implement policies that reflect the lived experiences of those most affected. Initiatives such as community health worker programs, peer navigation services, and advisory councils can ensure that care models are inclusive, culturally competent, and focused on reducing barriers to care.

For additional information about this information bulletin or to request technical assistance, please contact: Dr. Jessica Lee, CMCS Chief Medical Officer, at Jessica.Lee@cms.hhs.gov for CMS; NCHHSTPpolicy@cdc.gov for CDC; or HABOAA@hrsa.gov for HRSA.

Comprehensive List of Acronyms

ACA:	Affordable Care Act
ACIP:	Advisory Committee on Immunization Practices
ADA:	Americans with Disabilities Act
ADAP:	AIDS Drug Assistance Program
AHA:	American Heart Association
ART:	Antiretroviral Therapy
ARV:	Antiretrovirals
CAB:	Cabotegravir
CCM:	Chronic Care Management
CDC:	Centers for Disease Control and Prevention
CE:	Continuing Education
CHIP:	Children's Health Insurance Program
CHWs:	Community Health Workers
CLAS:	Culturally and Linguistically Appropriate Services
CMCS:	Center for Medicaid and CHIP Services
CME:	Continuing Medical Education
CMS:	Centers for Medicare & Medicaid Services
CPE:	Continuing Pharmacy Education
DAP:	Drug Assistance Program
DIS:	Disease Intervention Specialists
DTG:	Dolutegravir
eCQMs:	Electronic Clinical Quality Measures
EHB:	Essential Health Benefits
EHE:	Ending the HIV Epidemic Initiative
FDA:	Food and Drug Administration
FMAP:	Federal Medical Assistance Percentage
FPL:	Federal Poverty Level
HCV:	Hepatitis C Virus
HCBS:	Home- and Community-Based Services
HHS:	U.S. Department of Health and Human Services
HOPWA:	Housing Opportunities for Persons With AIDS
HRSA:	Health Resources and Services Administration
HRSN:	Health-Related Social Needs
HUD:	U.S. Department of Housing and Urban Development
ILOS:	In-Lieu-of-Services
IRA:	Inflation Reduction Act
LEP:	Limited English Proficiency
LEN:	Lenacapavir
MH:	Mental Health

MSHCN:	Members with Special Health Care Needs
MSM:	Men Who Have Sex with Men
NCD:	National Coverage Determination
NEMT:	Non-Emergency Medical Transportation
PCAs:	Primary Care Associations
PEP:	Post-Exposure Prophylaxis
PIN:	Principal Illness Navigation
PrEP:	Pre-Exposure Prophylaxis
POS:	Place of Service
RPV:	Rilpivirine
RWHAP:	Ryan White HIV/AIDS Program
SAMHSA:	Substance Abuse and Mental Health Services Administration
SDOH:	Social Determinants of Health
SPAs:	State Plan Amendments
STIs:	Sexually Transmitted Infections
STRs:	Single-Tablet Regimens
SUDs:	Substance Use Disorders
USPHS:	U.S. Public Health Service
USPSTF:	U.S. Preventive Services Task Force
VBP:	Value-Based Purchasing
VLS:	Viral Load Suppression

Appendix A: Summary of Opportunities for State Medicaid Programs

Testing (Diagnosis)	• Cover USPSTF-recommended HIV screening without cost sharing for all Medicaid and CHIP beneficiaries. • Integrate HIV testing as part of routine care delivery, using tools like automated laboratory orders and electronic health record reminders. • Cover HIV screening services when provided by providers that meet qualifications established by the state • Explore strategies to support self-testing initiatives, including coverage for test kits.
Prevention	• Cover all FDA-approved PrEP options, including oral and injectable forms. • Ensure that utilization management techniques are not designed or implemented in ways that limit access to PrEP among persons for whom it is indicated. • In addition to PrEP formulations, cover PrEP services, including HIV testing, STI and viral hepatitis testing, as recommended in USPHS Guidelines. • Promote education programs to raise awareness of PrEP availability and benefits. • Assess and enhance the implementation of tools such as PEP, doxy PEP, and related STI testing in coordination with HIV and PrEP screening services.
Treatment	• Cover all ART regimens and associated laboratory tests recommended in HHS Guidelines, including long-acting injectables. • Implement rapid start programs to initiate ART within seven days of diagnosis. • Design and implement utilization management techniques that promote adherence.
Program Coordination and Integration	• Coordinate benefits with other programs that support access to HIV services (e.g., Medicare, Ryan White HIV/AIDS Program). • Include HIV infection among the chronic conditions targeted through coverage of the state Medicaid Health Home benefit.

	• Collect and report to CMS results for the HIV Viral Load Suppression measure.
Social Determinants of Health and Whole Person Care	• Design and implement innovative policy to address health-related social needs for people with and at risk of contracting HIV. • Use targeted case management services as part of integrated care models to coordinate and improve access to medical, behavioral, and social services. • Align eligibility and benefits with other federal programs to ensure seamless access to care and support services, including case management, housing assistance, and transportation, coordinating to ensure that Medicaid program benefits do not supplant existing social services and housing assistance.

Appendix B: Key CMS Policy Actions Related to Services for Individuals with or At Risk of Contracting HIV

- On January 1, 2009, CMS issued a National Coverage Determination (NCD) to include HIV screening as "additional preventive services" based on a Grade "A" or "B" ratings from the U.S. Preventive Services Task Force (USPSTF).[142] This recommendation applied to individuals with Medicare aged 15 to 65, younger and older individuals with increased vulnerability, and all pregnant individuals.

- On June 6, 2011, the Center for Medicaid and CHIP Services (CMCS) issued a letter to State Medicaid Directors outlining opportunities to expand Medicaid coverage for people with HIV through other mechanisms such as health homes, section 1915(c) home and community-based services waivers, and section 1915(i) or 1915(k) Medicaid State Plan options in addition to section 1115 authority.[143]

- On May 1, 2013, CMCS and HRSA issued a joint Informational Bulletin emphasizing coordination between Medicaid and the Ryan White HIV/AIDS Program. The bulletin clarified that the Ryan White Program serves as the payer of last resort, covering services and benefits not provided by Medicaid.

- On November 27, 2013, CMS released an Informational Bulletin clarifying changes to the Medicaid preventive services benefit under 42 CFR 440.130(c), allowing states to cover services recommended by licensed practitioners but delivered by qualified non-licensed professionals, such as community health workers (CHWs) or Disease Intervention Specialists (DIS)[144]. This flexibility enables states to expand access to preventive care, including screenings and health education, in community settings, improving public health outcomes and reducing barriers for Medicaid beneficiaries.

- On January 1, 2015, CMS introduced Chronic Care Management (CCM) Services as a billable service under the Medicare Physician Fee Schedule.[145] Providers can bill for non-face-to-face care coordination services for patients with multiple chronic conditions,

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[142] CMS. (2009, January 1). *Screening for the human immunodeficiency virus (HIV) infection*. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=335&ncdver=1&.
[143] CMS. (2011, June 6). *Re: Coverage and service design opportunities for individuals living with HIV*. https://www.medicaid.gov/Federal-Policy-Guidance/downloads/11-005.pdf.
[144] CMS. (2013, November 27). *CMCS Informational Bulletin: Update on preventative services initiatives*. https://www.medicaid.gov/federal-policy-guidance/downloads/CIB-11-27-2013-Prevention.pdf.
[145] Medicare Program; Revision to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015, 42 C.F.R. pts. 403, 405, 410, 411, 412, 413, 414, 425, 489, 495, and 498. (2014). https://www.govinfo.gov/content/pkg/FR-2014-11-13/pdf/2014-26183.pdf.

including HIV. This includes medication management, care planning, and patient education—all essential for managing HIV.

- On April 13, 2015, CMS updated its HIV screening National Coverage Determination (NCD) to include HIV screening for individuals with Medicare aged 15 to 65, and for those outside this age range who are considered vulnerable to HIV, ensuring broader access to preventive services.[146]

- On December 1, 2016, CMCS, HRSA, and the Centers for Disease Control and Prevention (CDC) issued a joint Informational Bulletin.[147] The bulletin advised state Medicaid agencies on important advances in HIV prevention, care, and treatment, highlighting opportunities to improve access, quality, cost-efficiency, and the population-level impact of HIV-related services for Medicaid beneficiaries.

- On July 19, 2021, the Departments of Labor, HHS, and the Treasury issued FAQs clarifying that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must cover without cost sharing PrEP for HIV prevention, including baseline and monitoring services (such as screenings and lab tests) that are essential to the efficacy of PrEP.[148] The guidance also addresses the use of reasonable medical management techniques with respect to PrEP.

- On January 5, 2023, CMS issued guidance clarifying Medicaid and CHIP coverage and payment policies for interprofessional consultations[149]. This policy expands access to specialized care, enabling more Medicaid patients with HIV and AIDS to receive expert clinical support.

- On October 1, 2023, CMS introduced Place of Service (POS) code 27 (Outreach Site/Street), which may be used to facilitate payment for street medicine services, such as those provided to individuals with HIV and AIDS who are experiencing homelessness.[150] This code applies to non-permanent locations in street or found environments where

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[146] CMS. (2015, April 13). *Screening for the human immunodeficiency virus (HIV) infection*. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=335&ncdver=2.
[147] CMS. *Opportunities to improve HIV prevention and care delivery to Medicaid and CHIP beneficiaries* (see footnote 2).
[148] CMS. (2021, July 19). *FAQs about Affordable Care Act implementation part 47*. https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf.
[149] CMS. (2023, January 5). *Re: Coverage and payment of interprofessional consultation in Medicaid and the Children's Health Insurance Program (CHIP)*. https://www.medicaid.gov/federal-policy-guidance/downloads/sho23001.pdf.
[150] CMS. (2024, May 2). *Place of Service code set*. https://www.cms.gov/medicare/coding-billing/place-of-service-codes/code-sets.

healthcare providers deliver preventive, screening, diagnostic, and treatment services to unsheltered, homeless patients.

- Starting in 2024, CMS created new coding and payment for principal illness navigation, which pays for services for patients with a high-risk condition like HIV or AIDS. The services involve health system navigation, person-centered planning, identifying or referring the patient or caregiver to supportive services, practitioner, home, and community-based care coordination or communication, patient self-advocacy promotion, community-based resources facilitation. These services can be especially important to make sure that patients with HIV or AIDS do not fall through the cracks of our health care system.

- On April 22, 2024, CMS issued landmark regulations aimed at removing barriers to coverage and improving care quality for Medicaid beneficiaries with HIV. The Ensuring Access to Medicaid Services and Medicaid and CHIP Managed Care Access, Finance, and Quality final rules enhance transparency, standardize data and monitoring, and increase state accountability.[151,152] These regulations also create new opportunities for states to promote active beneficiary engagement, advancing comprehensive, person-centered care.

- On September 30, 2024, CMS announced a National Coverage Determination (NCD) under Medicare Part B, covering PrEP medications and related services without cost-sharing for individuals at increased risk for HIV[153]. This includes coverage of FDA-approved oral and injectable PrEP medications (including supplying or dispensing of these drugs and administration of injectable PrEP), counseling sessions, HIV screenings, and a hepatitis B virus screening.

- On October 21, 2024, the Departments of Labor, HHS, and the Treasury issued FAQs clarifying that oral and long-acting injectable formulations of PrEP specified in the USPSTF's "A" rated recommendation for PrEP must be covered without cost sharing and that medical management techniques to direct individuals prescribed PrEP to utilize one

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[151] CMS. (2024, April 22). *Ensuring access to Medicaid services final rule (CMS-2442-F)*. https://www.cms.gov/newsroom/fact-sheets/ensuring-access-medicaid-services-final-rule-cms-2442-f.
[152] CMS. (2024, April 22). *Medicaid and Children's Health Insurance Program managed care access, finance, and quality final rule (CMS-2439-F)*. https://www.cms.gov/newsroom/fact-sheets/medicaid-and-childrens-health-insurance-program-managed-care-access-finance-and-quality-final-rule.
[153] CMS. (2024, September 30). *Preexposure prophylaxis (PrEP) using antiretroviral therapy to prevent human immunodeficiency virus (HIV) infection*. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=310.

specified formulation over another are not permitted.[154] The guidance also reiterated that specified baseline and monitoring services that are essential to the efficacy of PrEP must be covered without cost-sharing, and it addressed ways health plans and insurers can mitigate common coding and claims processing issues for PrEP and other recommended preventive services to ensure that individuals are not improperly charged for important preventive care.

[154] CMS. (2024, October 21). *FAQs about Affordable Care Act and Women's Health and Cancer Rights Act implementation part 68*. https://www.cms.gov/files/document/faqs-implementation-part-68.pdf