

# **Issue Brief**

# **Leveraging Medicaid Financing and Coverage Benefits to Deliver PrEP Intervention Services**

By Naomi Seiler, JD

# **Key Messages**

- The Medicaid program is an important vehicle for increasing access to pre-exposure prophylaxis, or PrEP, for HIV prevention
- States Medicaid financing policies, including managed care payment rates and payment models already in place, could be adapted to better reflect and encourage PrEP uptake.
- A number of existing Medicaid benefits could be leveraged to encourage and support uptake of medication and the corresponding clinical services recommended by CDC
- Within the Medicaid program, there are a range of levers available to improve PrEP delivery performance, at both the managed care plan and provider levels.
- Medicaid can play a role in efforts to increase PrEP use through specific providers, settings, and modalities.

# Introduction

Pre-exposure prophylaxis, or PrEP, is a highly effective intervention to prevent HIV, and a key pillar of plans to confront the HIV epidemic in the U.S. PrEP entails the use of a medication by people who are at high risk of acquiring HIV to reduce the risk of seroconversion, along with ongoing clinical services including monitoring of STIs and HIV status. Trials have demonstrated that with adequate adherence, effectiveness of over 90 percent for consistent use among those at risk of sexual transmission, and over 70 percent for people who inject drugs.

However, in the fourth quarter of 2017, PrEP was being used by fewer than 10 percent of people who were candidates for its use, with even lower uptake among eligible African-Americans. (see Appendix for list of populations for whom CDC recommends considering PrEP as a prevention option). Among people with prescriptions for PrEP medication, evidence suggests that some may not be receiving the full set of PrEP clinical services recommended by the CDC.

Medicaid's role as insurance for low-income Americans makes it a crucial vehicle for addressing these challenges. Medicaid is currently the largest payer for HIV care in the United States. Since passage of the Affordable Care Act, Medicaid expansions in 33 states and DC have significantly increased rates of insurance coverage overall and among populations relevant to PrEP, including LGBT people and young adults. The Medicaid program reflects an opportunity to reach people with key HIV prevention services like PrEP, and stands to benefit from reduced HIV infections and treatment costs.

This issue brief outlines how stakeholders in Medicaid agencies, Medicaid managed care organizations (MCOs) and public health departments can work to identify current barriers to PrEP medication and high-quality PrEP clinical services, and identify opportunities to leverage benefit design and financing approaches to support PrEP. State Medicaid programs vary in many ways, creating different challenges and opportunities for using Medicaid benefits and financing mechanisms to support PrEP utilization. This issue brief offers a range of options for state Medicaid agencies, MCOs, and public health stakeholders to consider within the context of their own programs.

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# **State-Level Financial Policies**

Several key state-level financing decisions have implications for access to PrEP medication and clinical care within the Medicaid program.

Capitation Rates and Risk Adjustment: State Medicaid agencies typically pay MCOs a monthly fee per enrollee, based in part on historical cost data. As PrEP uptake increases and is reflected in utilization data, the cost of the drugs and clinical services will be reflected in the capitated rate that state Medicaid agencies pay MCOs. Until then, to ensure that MCOs receive enough funding to cover PrEP medication and services, the impact of scaled-up PrEP use on rates could be projected by actuaries and factored into future rates. For example, rate setting for HIV-negative people enrolling in New York's HIV Special Needs Plans (SNPs) was based on added costs of PrEP drugs and clinical services, incorporating a projected trended uptake model that estimated the portion of HIV-negative enrollees who would use PrEP. Similarly, states can develop models to reflect PrEP use or indications in the risk adjustment factors that are used to reflect variation in actual plan enrollment across MCOs.

Medicaid Carveouts: States can elect to "carve out" certain services from MCO contracts, continuing to cover them on a fee-for-service (FFS) basis. Carveouts can facilitate MCO enrollee access to services by taking financial responsibility away from the MCOs. Of the 39 states with comprehensive MCOs in 2017, only four carve pharmacy entirely out of MCO contracts; another three carve out HIV drugs. In these carveout states, MCOs do not have financial responsibility for PrEP medication, and therefore may be less concerned about the implications of the drug costs.

Even where PrEP medication is carved out, MCOs would retain responsibility for PrEP clinical services. One important question is whether in any state it might be advantageous to carve PrEP medication and clinical services out of MCO contracts entirely. This could potentially improve access if enrollees in MCOs are facing barriers to PrEP, though carveouts could also hinder integration of services. If appropriate, a state could consider initially carving out PrEP medication and services, then reversing this policy once the costs and uptake of PrEP within a state are more clearly established and can be incorporated directly into rates.

State-Level Value-Based Payment Mechanisms: States can consider building on recent alternative ways of paying for care in Medicaid to support improved provision of PrEP care. The majority of states have at least some Medicaid beneficiaries in a Medicaid Patient-Centered Medical Home (PCMH) model, and the ACA authorized additional federal funding to support Medicaid Health Homes, a model that builds on the PCMH concept for beneficia-

ries with chronic conditions. Medicaid health homes offer certain wraparound services that could help support PrEP use, including care coordination and health promotion services, patient support, and referral to community and social support services. Meanwhile, nearly half of states have or are pursuing Medicaid Accountable Care Organization models, and 31 jurisdictions are currently participating in the Centers for Medicare and Medicaid Services' (CMS) Accountable Communities for Health Model for Medicare and Medicaid, using shared-risk models to target social determinants of health. The shared savings and risk inherent to these models could incentivize providers and communities to connect eligible patients to PrEP medication and high quality clinical services, while addressing social and structural barriers to access.

# **Leveraging Medicaid Benefits to Support PrEP**

While some Medicaid benefit categories are mandatory, state Medicaid agencies and Medicaid MCOs have discretion to design their benefit packages in ways that support access to PrEP services.

Aligning PrEP Coverage Across a State Medicaid Program: In some states, it may be feasible to specifically write PrEP medication and service standards into MCO contracts. Even if a state's contracts with MCOs do not explicitly mention PrEP, a state Medicaid agency can reach out to MCOs to discuss bringing their policies into alignment. For example, in California, even though HIV medication is carved out of managed care contracts, claims analysis identified that in some MCOs, fewer enrollees than expected were receiving PrEP. The Medi-Cal program reached out to MCOs, typically with each plan's medical director, to discuss making coverage of PrEP comparable to the FFS benefit. These conversations tended to result in increased PrEP uptake among the plans' enrollees. Similarly, public health officials in Louisiana were able to educate Medicaid MCOs that multisite STI test claims were neither repeat tests nor errors, but a recommended component of PrEP intervention services (see "STI Testing and Treatment" for further discussion).

State Medicaid agencies, public health agencies and providers can work together to determine approaches to aligning coverage policies across the state program to support comprehensive coverage of PrEP services.

Medication: All states currently cover Truvada – the only PrEP medication on the market to date – under the national Medicaid National Drug Rebate Agreement. However, states can apply utilization management tecÚiques, such as prior authorization (PA), for FFS enrollees. Of 16 states responding to an informal Academy-Health survey of Medicaid Medical Directors, 12 reported having no PA or other utilization management requirements on Truvada for PrEP within their FFS programs. A brief PA requirement, such

as requiring a physician to confirm that the patient is HIV-negative, may be medically reasonable and not unduly burdensome. However, lengthy or burdensome PA requirements could hinder use of PrEP. State Medicaid agencies can work with contracted providers and other stakeholders to assess whether any PA requirements for PrEP medication serve as useful clinical tools or as unnecessary barriers to care.

Medicaid MCOs must provide access to the same drugs as the FFS program, but in most states, MCOs can place different controls on utilization of covered medications. State Medicaid programs can consider whether to require MCOs to adhere to a uniform coverage policy for PrEP medication to improve access and provide consistency for providers.

The U.S. Preventive Services Task Force and PrEP: In November 2018, the U.S. Preventive Services Task Force (USPSTF) issued a draft "Grade A" recommendation for PrEP for HIV. If finalized, this recommendation will trigger a statutory requirement that PrEP medication be covered without cost-sharing by nearly all private issuers, as well as for Medicaid expansion enrollees. While cost sharing in Medicaid must be "nominal," reducing the cost sharing for PrEP medication to zero may help promote access. Any financial barriers to PrEP clinical services not included in the final recommendation may still need to be addressed.

STI Testing and Treatment: Medicaid FFS programs typically cover some STI testing as well as the other clinical components of the PrEP intervention, such as HIV screening, pregnancy testing, and other lab tests. However, programs may not formally cover testing on a quarterly basis and may not always cover the multisite STI testing (e.g. genital, rectal, and pharyngeal) required for some PrEP users. Medicaid agencies or MCO payment systems may reject multiple claims for tests for the same disease for the same person on the same day.

State Medicaid agencies and their MCOs can assess their lab reimbursement protocols for STIs to identify and address any barriers to reimbursement of PrEP-associated labs. Under CMS's 2019 *National Correct Coding Initiative Policy Manual for Medicare Services*, a special modifier is not necessary for up to three of the same chlamydia or gonorrhea tests (CPT codes 87491 and 87591 respectively) ordered in a day; for 4 or more, special modifiers can be used. However, Medicaid and private coding systems may differ from this national approach, and can be reviewed to assess consistency with PrEP clinical recommendations.

Medicaid Family Planning Expansions: States have the option to create Medicaid family planning expansion programs that offer certain family planning benefits to people who are not otherwise eligible for Medicaid. These programs can reach people with certain PrEP clinical services, including HIV and STI testing and visits, while connecting people to the manufacturer assistance program for the medication.

Family planning expansions can be particularly important for PrEP clinical services in states that have not expanded their overall Medicaid programs. Even in states with Medicaid expansions, Medicaid family planning programs often cover people up to higher income thresholds. As of June 2017, 26 states had expanded Medicaid eligibility for family planning services. In 22 of these states, eligibility is based on income, usually set at a threshold around 200 percent of the federal poverty level (FPL). The majority include coverage of STI testing and lab services as well as HIV testing, and most extend eligibility to both men and women.

Leveraging a Family Planning Expansion for PrEP: Mississippi has not expanded its overall Medicaid program under the ACA, but the state does have a family planning expansion program. The Open Arms Healthcare Center in Jackson has approximately 200 patients on PrEP. For patients who are uninsured, a staff person submits an application to the Medicaid family planning program, which covers up to four visits a year as well as labs, including STI testing and treatment, all of which are key components of the PrEP intervention.

Condoms: CDC's PrEP guidelines emphasize that "[t]he importance of using condoms during sex, especially for patients who decide to stop taking their medications, should be reinforced." The majority of states' Medicaid programs cover condoms with a prescription. Efforts to increase provider awareness of this benefit, as well as appropriate procedures for issuing condom prescriptions, can increase access to and use of this important complementary HIV and STD prevention option.

# Case Management, Care Coordination, and Peer Support:

Services to help coordinate and support care for PrEP users can be implemented as a state benefit or as an "additional" service covered by an MCO. For example, Targeted Case Management (TCM), an optional Medicaid benefit, allows states to cover enhanced case management services to help certain categories of beneficiaries access medical and other services. A number of states' Medicaid programs include TCM for people living with HIV. Rhode Island has expanded this concept to allow TCM to be available for certain beneficiaries at high risk of HIV, creating a reimbursement mecha-

nism for services around linking people to PrEP and encouraging their adherence to PrEP clinical services.

Similarly, State Medicaid agencies can work with other stakeholders to identify existing policies regarding reimbursement of non-licensed support providers and discuss potential reimbursement of PrEP peer supports, navigators, or case managers.

MCOs can provide care coordination services beyond what is included in a state plan or waivers. Currently, most Medicaid MCOs report using a range of strategies to promote coordinated care, including peer support specialists and home visits. MCOs can determine whether and how care coordination for PrEP could be integrated into existing or emerging strategies.

Non-Emergency Medical Transportation: For some potential PrEP users, particularly in rural areas, transportation to PrEP-related visits may be a barrier. Non-emergency medical transportation is a Medicaid benefit that covers transportation to non-emergency, Medicaid-covered care; its coverage and scope vary by state. Where this benefit is available, information should be shared with PrEP-eligible enrollees and included in PrEP outreach materials.

Coding and Billing for PrEP: The National Alliance of State and Territorial AIDS Directors has prepared a detailed guide for providers seeking to bill Medicaid and other payers for PrEP clinical services. The guide details procedure codes and diagnosis codes for billing key elements of the intervention.

# **Performance Improvement**

In the Medicaid program, the quality of PrEP care covered by MCOs and delivered by providers could be improved through a range of performance incentive programs and projects as explained below.

Available measures: At any level, using performance measures to improve PrEP care requires valid measures. The CDC's 2017 PrEP guidelines include five "Potential Practice Quality Measures." While none have been tested and validated according to commonly endorsed standards, they may represent a useful starting point for states interested in evaluating the performance of providers and MCOs in offering PrEP medication and clinical services. As an initial step, states and MCOs could base incentives on simpler metrics, such as provider participation in PrEP training.

**Incentives for Plan-Level Quality Improvement:** In FY17, the majority of managed care states reported using one or more types of quality improvement approaches for MCOs, including "pay for performance" bonuses for reaching performance thresholds; "capi-

tation withholds" or penalties for plans *not* meeting performance thresholds; and requirements for data collection and reporting. In addition to financial incentives, states can reward high-performing MCOs with priority for auto-assignment of enrollees who do not select a plan. State Medicaid agencies can consider building specific incentives into their contracts with MCOs to encourage the provision of PrEP medication and clinical services.

States can also require Medicaid MCOs to engage in targeted Performance Improvement Projects, or PIPs, on their own or collaboratively. A PIP focused on PrEP coverage and engagement could give MCOs an opportunity to examine the delivery of PrEP services to their enrollees and identify necessary changes.

Incentives for Providers: In states with significant FFS enrollment, state Medicaid agencies can undertake a range of financing policies to influence provider behavior regarding PrEP. Medicaid agencies and public health officials can identify any existing provider incentive initiatives in their states' FFS programs and determine if PrEP medication and clinical services could be integrated into the model.

Similarly, in nearly all states, MCOs are using various alternative payment models to improve the quality of care. In FY17, 93 percent of plans surveyed reporting using "pay for performance"; 38 percent reported using bundled payments (such as episode-based or global, per member/per month payments); and 44 percent reported using other shared-savings or risk arrangements. Such approaches could be tailored to encourage appropriate provision of PrEP clinical services within plans' networks.

# Lessons from MCO Support of Medication-Assisted Treatment for Opioid Addiction

A recent report for the Association for Community Affiliated Plans details strategies some Medicaid MCOs are using to support and engage primary care physicians in prescribing Medication-Assisted Treatment (MAT) for opioid use disorder. Similar strategies could be explored for supporting PrEP delivery, including:

- performance-based payments for providers who meet multiple MAT-related quality indicators;
- payment for out of office MAT training time;
- financial incentives to primary care providers who are willing to take MAT referrals and conduct specific monitoring activities;
   and
- bundled payment for MAT prescribers to reduce provider administrative burden.

# Increasing Access to PrEP: Networks, Settings, and Providers

States and MCOs can promote PrEP access by ensuring participation of PrEP providers, facilitating patient access through telehealth, and supporting providers and settings – including local health departments, community-based organizations, and pharmacies – that can serve important roles in the PrEP intervention suite.

Access to PrEP Providers: It is important to ensure that PrEP providers are participating in the Medicaid program and accepting new Medicaid patients. For managed care enrollees, Medicaid MCOs contract with a specific network of providers – including clinicians, health care facilities, and laboratories – to provide care to their enrollees. Current federal law regarding Medicaid MCO "network adequacy" does not address the specific issue of PrEP provision, but states can choose to develop further standards. MCOs can also proactively evaluate their networks to ensure they include enough PrEP providers to meet their members' HIV prevention needs.

The website https://preplocator.org is a searchable directory of clinics and providers who offer PrEP. It is not exhaustive, but can inform first steps in determining a state program or MCO network's adequacy with regard to PrEP. More broadly, ensuring that state Medicaid programs and MCO networks include STI clinics, other public health clinics, and infectious disease doctors would give access to a slate of providers who may be more likely to offer PrEP services.

After initial consultation with a prescribing provider, some ongoing PrEP services and visits could be conducted by Registered Nurses (RNs)." However, visits with *only* a registered nurse are not reimbursable in all states or settings. Reimbursement of RN visits can be assessed at the state level to determine whether and how PrEP clinical services could be supported under this model.

Telehealth: PrEP can be offered via telehealth services, in which the patient and the practitioner are communicating in real time over a telecommunications system. For example, the New York State AIDS Institute identified rural counties with limited PrEP access and worked with a Federally Qualified Health Center (FQHC) in the region that had engaged in HIV treatment by telehealth to establish a system for PrEP telehealth, with local providers present in the room with the patients as a training opportunity. Louisiana recently launched a Tele-PrEP program that uses a HIPAA compliant video platform to connect patients using a computer, tablet, or smartphone with a nurse practitioner located in New Orleans; a tele-PrEP navigator provides care coordination and support and connects the patients to lab services.

As of spring 2018, 49 states and DC provide for Medicaid reimbursement of some form of live video telehealth services. Roughly half of states specify the set of facilities that can serve as "originating sites" where the patient may be; only ten states permit a patient's home to be the originating site. In addition, some multi-state Medicaid MCOs provide their enrollees with free access to national telehealth service providers, like Teladoc. These policies could be leveraged or modified to provide reimbursement for PrEP telehealth services.

Supporting Partnerships with Local Health Departments and Community-Based Organizations: State Medicaid agencies and MCOs can support local health department STD or primary care clinics or community-based organizations that offer PrEP services for Medicaid enrollees.

Health-department-run clinics, including STD clinics, can be important sites for initiating PrEP medication and clinical services or, for some clinics, maintaining patients on PrEP. State Medicaid agencies and MCOs can explore approaches to Medicaid reimbursement for health department provision of PrEP and related clinical care.

For non-clinical CBOs, State Medicaid agencies and MCOs can develop contracts or agreements to support PrEP services. For example, AIDS Foundation of Chicago (AFC) contracts with two Medicaid MCOs to provide outreach to members deemed "unable to locate," to connect and re-engage them with primary care providers. Members assigned to AFC include some who are HIV-positive as well as others who are at high risk of HIV. AIDS United has developed a set of webinars and resources to support CBOs in approaching MCOs.

#### **CBO Contributions to PrEP Access**

Open Arms Health Care Center in Jackson, Mississippi, which offers PrEP prescriptions and care, is affiliated with My Brother's Keeper, a CBO with satellite sites in Hattiesburg and near the Coast. Patients can go to My Brother's Keeper for rapid HIV tests and bloodwork, combined with a telehealth visit with a provider at Open Arms. This reduces transportation time and costs for patients.

At the Medical University of South Carolina (MUSC), the Department of Family Medicine partners with Palmetto Community Care in the provision of PrEP. Palmetto Community Care refers patients to MUSC, where providers can conduct initial assessments and prescribe the medication. Patients can then return to Palmetto for regular lab services, the results of which are shared with the prescribing provider. This relationship makes lab services and PrEP adherence support more accessible for patients, while relieving MUSC of some of the work of ongoing monitoring.

Pharmacies and Pharmacists: Pharmacies and pharmacists can play key roles not only in dispensing PrEP medication but also in supporting adherence to PrEP and to PrEP clinical services through various models. The benefits of pharmacy engagement in PrEP include the possibility of evening and weekend hours and pharmacists' ability to monitor refill gaps to address non-adherence. Typically, Medicaid reimburses for drugs and pays pharmacists a dispensing fee. In some states, Medicaid can reimburse pharmacists for enhanced medication therapy management, or MTM services. MTM eligibility could be extended to persons on PrEP and include enhanced counseling and reminders about renewals.

Some pharmacies may also be able to provide PrEP services directly, depending on the practice arrangements permitted under state law. For example, in Seattle, the Kelley-Ross Pharmacy runs a "One-Step PrEP" clinic under a collaborative drug therapy agreement. Pharmacists conduct initial meetings, sexual histories, lab testing, and education, in addition to dispensing medication. In Iowa, collaborative practice agreements between physicians and pharmacists allow the pharmacists to provide expanded PrEP services. Providers conduct an initial PrEP visit through either telehealth or an LGBTQ+ clinic, and pharmacists conduct monitoring and follow-up visits.

#### Federally-Qualified Health Centers and Rural Health Centers:

As community-based providers of comprehensive and coordinated primary care services, Federally Qualified Health Centers (FQHCs) are an important locus for the provision of PrEP medication and clinical services. For example, as highlighted in text box, Whitman-Walker Health, an FQHC in Washington DC, provides PrEP intervention services to approximately 2,000 people, an estimated 30-35 percent of whom are Medicaid enrollees.

FQHCs' unique Medicaid reimbursement structure creates both opportunities and challenges for provision of PrEP medication and clinical services. Under federal law, state Medicaid programs pay FQHCs under a prospective payment system (PPS), using a set, per-visit rate based either on cost reporting or on local averages. This per-visit rate includes all services provided during a visit with a licensed provider, encompassing not only the primary encounter but, for example, any nurse or lab services provided in the visit. Under federal law, similar Medicaid payment provisions apply to Rural Health Centers, which are certain facilities in "non-urbanized," underserved areas.

FQHC reimbursement rates can vary by state and by facility. In general, because PPS rates are only negotiated every few years, they are often not reflective of current year expenses, and may not reflect the costs of newer services like PrEP. Local and state public health agencies can determine if FQHCs are providing PrEP and work to identify any barriers, including those related to Medicaid reimbursement.

# **FQHCs and PrEP Access: Whitman-Walker Health**

While the majority of Whitman-Walker's PrEP patients see a Medicaid-reimbursable provider during their visits, Whitman-Walker has also been able to establish a specific PrEP clinic which to date has seen approximately 200 of their PrEP patients. The patients see both a nurse and phlebotomist in a brief visit to streamline their receipt of PrEP clinical services. These patients do not otherwise come to the center frequently for other medical care (though the patients do see a clinical provider at least once per year, for annual wellness visits, per 340B program requirements). Other than the lab services, these streamlined visits are not reimbursable by Medicaid or other insurance because the patients do not see a Medicaid-reimbursable clinical provider in the visit. However, Whitman-Walker reports that it is worth it to use clinic funds to support this immediate PrEP access option so that this subset of patients receive PrEP adherence support and STI testing on demand.

# **Developing Actuarial Models and ROI for PrEP**

For the Medicaid program to effectively cover PrEP for FFS and managed care enrollees, decision makers need information about the costs, uptake, and projected utilization trends for PrEP medication and clinical services. This information can help inform capitation rates for Medicaid MCOs, as well as budget estimates for state- and MCO-level planning.

In addition, return on investment (ROI) data on PrEP can help inform benefit and financing discussions. ROI can be conceptualized at two levels: the ROI for PrEP overall, and the marginal ROI for optimal PrEP care that includes all recommended clinical services. The former is important for consideration of overall PrEP uptake; the latter may be useful in promoting policy changes to specifically ensure that Medicaid programs and MCOs are covering STI labs and other clinical PrEP services. An important factor to consider in PrEP ROI is that a high proportion of PrEP users are likely to be "expansion enrollees" for whom the vast majority of Medicaid costs are borne by the federal government. Overall, the financial ROI for PrEP may evolve over time, particularly as generics become available.

## Conclusion

Scaling up the full PrEP intervention suite is a crucial component of combating the HIV epidemic. The Medicaid program offers important opportunities to explore whether benefits design and financing mechanisms are being leveraged to reach many of the people who could most benefit from PrEP. The approaches outlined in this paper can help inform new or ongoing efforts to take advantage of these opportunities at the state level.

# **About this Brief**

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As part of its work to address the underutilization of PrEP, the CDC's National Center for HIV, Hepatitis, STD and TB Prevention, with collaboration between the Division of HIV/AIDs Prevention and the Division of STD Prevention, supported the Medicaid Strategies to Implement Comprehensive Pre-exposure Prophylaxis (PrEP) Intervention Services project (the Medicaid PrEP Project), led by Academy Health and ChangeLab Solutions, to identify ways to improve care and delivery of PrEP medication and clinical services to the Medicaid population.

To inform this project, researcher Naomi Seiler, J.D., developed two white papers identifying Medicaid benefits and financing mecha-

nisms that could be used to improve uptake and comprehensive delivery of PrEP medication and clinical care, and describing further ways to leverage the Medicaid program to engage patients and providers. The papers were based on semi-structured interviews with experts in Medicaid, PrEP, and patient and provider engagement, as well as peer-reviewed and "gray" literature on Medicaid, PrEP, and Medicaid financing mechanisms. In January 2019, ChangeLab Solutions and Academy Health convened state Medicaid officials, Managed Care Organizations (MCOs), public health officials, and other stakeholders to consider which of the approaches discussed may be appropriate for their policy environments. This issue brief summarizes the findings of the first white paper on benefit and financing mechanisms.

Potential conflicts of interest: CDC and individual employees involved in the guideline development process are named in US government patents and patent applications related to methods for HIV prophylaxis.

# **Appendix**

## Summary of US Public Health Service PrEP Guidelines: Indications for PrEP and Providing PrEP Clinical Services

CDC recommends PrEP be considered as one prevention option for the following people at substantial risk of HIV infection:

# Men Who Have Sex with Men (including those who inject drugs)

- HIV-positive sexual partner
- Recent bacterial STI (Gonorrhea, chlamydia, syphilis)
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work

## **Persons Who Inject Drugs**

- HIV-positive injecting partner
- Sharing injection equipment

# Heterosexual Women and Men (including those who inject drugs)

- HIV-positive sexual partner
- Recent bacterial STI (Gonorrhea, syphilis)
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work
- In high HIV prevalence area or network

# CDC recommends the following clinical services with PrEP use:

#### At initiation:

- An HIV test (which should be documented as negative);
- An assessment to rule out signs or symptoms of acute HIV infection; a renal function test (estimated creatinine clearance);
- Assessment of current medications to rule out contraindications.
- Documentation of Hepatitis B infection and vaccination status is also recommended.

#### For PrEP users:

- A follow-up visit at least quarterly for an HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, and STI symptom assessment.
- Renal function testing at 3 months and every 6 months thereafter.
- Bacterial STI testing every 3-6 months for both sexually active men and women. The CDC recommends nucleic acid amplification (NAAT) STI testing at sites of potential sexual exposure including pharyngeal and rectal testing for men who have sex with other men (MSM), as well as rectal testing for women who report engaging in anal sex.
- Offer of pregnancy tests and discussion of pregnancy intent as appropriate every six months.
- PrEP users who inject drugs should have access to clean needles and drug treatment services.

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