

QUICK TAKE

EQUITABLE ACCESS TO NEW HIV TREATMENT AND PREVENTION OPTIONS IS NEEDED ACROSS PAYERS

NEW PRODUCTS FOR HIV TREATMENT AND PREVENTION are available or in development. Sometimes called longer-acting (LA) treatment or LA pre-exposure prophylaxis (PrEP), they offer new options for individuals unable to take their medication every day. These innovations are potentially transformative, but for this promise to be realized, they must be available, affordable,

and readily accessible. Once the Food and Drug Administration (FDA) determines that a product is safe and effective and approves it for use, health care payers (i.e., insurance companies or public programs such as Medicaid) make coverage decisions about whether and when to make a product available and under what conditions. Equitable access to these products for consumers, regardless of payer, is essential to achieve national public health goals.

THE US HEALTH CARE LANDSCAPE IS COMPLEX

In the U.S., the major health care payers for HIV treatment and prevention are Medicaid and Medicare, as well as private insurance that is typically provided through employers or Affordable Care Act (ACA) marketplaces. Additionally, the Ryan White HIV/AIDS Program provides HIV primary care services to uninsured and underinsured people with HIV; the largest component of this program is the AIDS Drug Assistance Program (ADAP). ADAP covers ART for uninsured people with HIV and provides supplementary support for persons with insurance coverage when cost-sharing is a barrier to accessing treatment. Because not all states have expanded Medicaid and because of funding limitations in the Ryan White HIV/AIDS Program, assistance is not always available for all people with HIV. Further, there is no analogous federal program to assist with financial and other barriers to PrEP. In 2022, President Biden requested that Congress establish a National PrEP Program, but it is unclear whether this program will be enacted into law.

POLICY PLANNING MUST START NOW

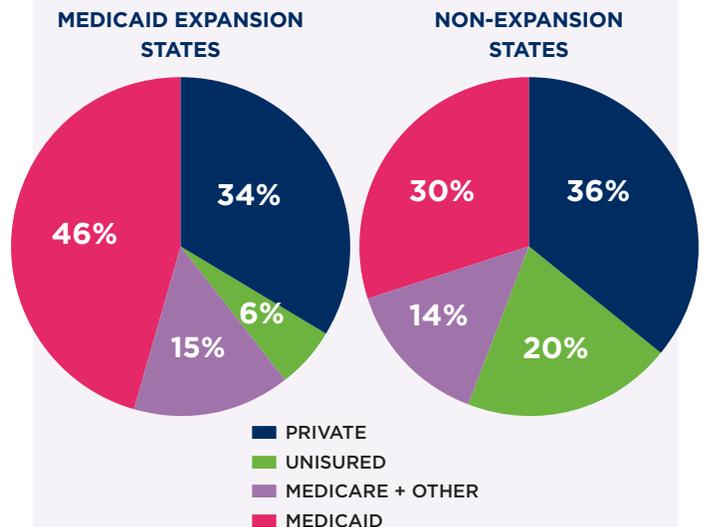
As new LA products become available, we must pro-actively plan for their rollout to avoid confusion, low uptake, and unequal access. Key stakeholders must plan ahead for the emergence of a broader array of products for HIV treatment and prevention:

FEDERAL AGENCIES AND STATE AND LOCAL HEALTH DEPARTMENTS: The Centers for Medicare and Medicaid Services (CMS) that administers Medicaid and Medicare and oversees ACA marketplaces should remind states and health plans of their coverage obligations and provide the evidence for the effectiveness of new products at improving outcomes. They also should provide guidance for how to evaluate new products in the context of existing treatment and PrEP medications. The National Institutes of Health

LONGER-ACTING MEDICATIONS: WHY THEY MATTER

For a variety of reasons, many individuals with acute and chronic health concerns do not take their medications daily, including people living with HIV on antiretroviral therapy (ART) and people who are using pre-exposure prophylaxis (PrEP). Longer-acting (LA) medications do not require daily pill taking and are generally effective for a month or longer, requiring less frequent administration. These types of products are widely available for contraception and mental health conditions. LA options are becoming available for ART as treatment and for prevention as PrEP.

INSURANCE COVERAGE AMONG ADULTS WITH HIV, 2018



Source: Lindsey Dawson & Jennifer Kates, *Insurance Coverage and Viral Suppression Among People with HIV, 2018*, KAISER FAMILY FOUND. (September 2020), <https://www.kff.org/hiv/aids/issue-brief/insurance-coverage-and-viral-suppression-among-people-with-hiv-2018/>.

THE U.S. HEALTH SYSTEM HAS A COMPLEX MIX OF PROGRAMS

MAJOR PROGRAMS

MEDICAID

Traditional Medicaid covers low-income children, parents, seniors, and people with disabilities. Medicaid expansion (available in 38 states + Washington, DC) covers people with income up to 138% of poverty.

MEDICARE

Covers seniors age 65 and up and working age people with disabilities.

Part B provides physician services and covers drugs administered in a physician's office. Part D is the outpatient prescription drug benefit.

RYAN WHITE HIV/AIDS PROGRAM (RWHAP)

AIDS Drug Assistance Programs (ADAPs) and other parts of the program can cover antiretroviral drug and administration costs for uninsured clients, as well as premium, deductible, or co-payment support for insured people with HIV meeting state eligibility criteria.

PRIVATE INSURANCE

Roughly half of Americans are covered by employer-sponsored insurance or purchase coverage from ACA marketplaces.

FORMULARY AND ACCESS RESTRICTIONS

Virtually all FDA-approved drugs are covered. States can restrict access based on medical need, such as through prior authorization.

Part B can have regional variations in what is covered. Part D must cover "all or substantially all" ART medications, but it is unclear whether all new products will be covered. Manufacturer copay assistance programs generally cannot be used for Part B or Part D covered services.

While ADAPs are only required to cover at least one drug from each class of antiretroviral medications, all have robust formularies and many are establishing policies and practices for covering longer-acting injectables.

Plans generally have broad flexibility in setting coverage policies. Some states may establish enhanced protections for plans not covered by the Employee Retirement Income Security Act (ERISA).

USER COSTS

For persons with income below 150% of the poverty level, cost-sharing must be nominal (i.e., for preferred drugs up to \$4 and non-preferred drugs, up to \$8). For higher income persons, costs can be up to 20% of the cost of the drug.

Part B beneficiaries pay 20% of the cost of physician-administered drugs. Part D has significant protections for persons with income below 150% of poverty and modest assets. Some people, however, are at-risk for much higher Part D out-of-pocket costs.

Cost sharing (e.g., office visit copays) in Ryan White programs is typically low and often on a sliding scale basis.

Cost-sharing can vary dramatically and can be quite high. ACA plans and many other private plans are subject to annual limits. Manufacturer copay assistance programs, independent charity organizations, and the RWHAP can help cover out-of-pocket medication costs.

(NIH) has a critical role in supporting research on the benefits of new options beyond safety and effectiveness, most critically, by funding implementation science research to increase access among key populations. The Health Resources and Services Administration (HRSA) that administers the Ryan White HIV/AIDS Program and the Health Centers Program, the Centers for Disease Control and Prevention (CDC), and the HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP), along with state and local health departments, have essential roles in educating their grantees, providers, and community stakeholders on the development of and need for new options for HIV treatment and PrEP.

HEALTH CARE PAYERS: Transparent and evidence-based industry standards should be developed to minimize access barriers as more products become available. The USPSTF PrEP recommendation requires most private plans and all Medicaid expansion programs to fully cover medically necessary PrEP products. Research shows that for key populations, higher costs for HIV prevention can be cost-effective (Schackman et al., *Medical Care*, 2015).

PROFESSIONAL ORGANIZATIONS: Physician and other professional organizations play a critical role in establishing practice guidelines about the need for

and benefits of new therapeutic options. They also have a critical role in evaluating evidence and making recommendations for which products should be covered and under what clinical standards.

LA products create exciting new opportunities to increase engagement in HIV treatment and prevention. To realize their potential, however, proactive efforts are needed to partner with affected communities, address community concerns, and overcome financial and other barriers to access.

TO LEARN MORE

See other July 2022 Quick Takes and our 2018 series of briefs prepared for amfAR, Long-Acting HIV Treatment and Prevention are Coming: Preparing for Potential Game-Changers, at the link below.

Kates, J. et al, "Insurance coverage and financing landscape for HIV treatment and prevention in the USA," *Lancet*, February 18, 2021, available at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00397-4/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00397-4/fulltext).

See various longer-acting materials produced by AVAC at <https://www.avac.org>.