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.

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.

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

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

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<th>MAJOR PROGRAMS</th>
<th>FORMULARY AND ACCESS RESTRICTIONS</th>
<th>USER COSTS</th>
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<td><strong>MEDITAID</strong></td>
<td>Virtually all FDA-approved drugs are covered. States can restrict access based on medical need, such as through prior authorization.</td>
<td>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.</td>
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<tr>
<td><strong>MEDITCARE</strong></td>
<td>Part B can have regional variations in what is covered. Part D must cover &quot;all or substantially all&quot; 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.</td>
<td>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.</td>
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<tr>
<td><strong>RYAN WHITE HIV/AIDS PROGRAM (RWHAP)</strong></td>
<td>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.</td>
<td>Cost sharing (e.g., office visit copays) in Ryan White programs is typically low and often on a sliding scale basis.</td>
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<td><strong>PRIVATE INSURANCE</strong></td>
<td>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).</td>
<td>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.</td>
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(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.


This Quick Take is a product of the Longer-Acting HIV Treatment and Prevention Policy Project of the O’Neill Institute for National and Global Health Law and was developed with support from Gilead Sciences, Inc. It was authored by Jeffrey S. Crowley and Kirk Grisham with input from community stakeholders. The views expressed are solely those of the authors.


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