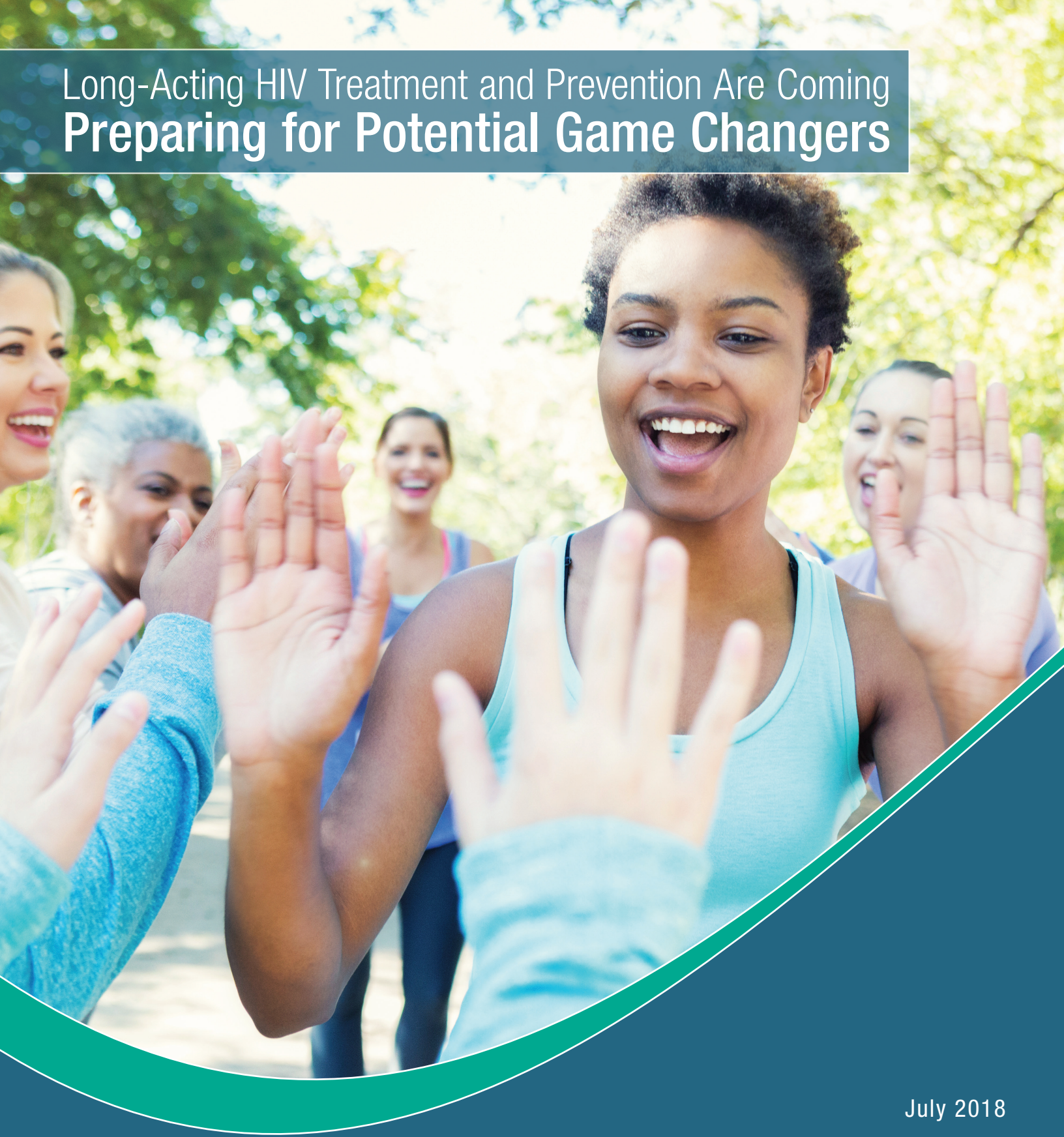
# Long-Acting HIV Treatment and Prevention Are Coming
# Preparing for Potential Game Changers



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## ASSESSING THE PAYER LANDSCAPE

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Innovative products for treating and preventing HIV infection are under development. Sometimes called long-acting agents, such products may take different forms ranging from injections to implants to oral medications. If determined to be safe and effective, what could make these new products transformative is that they would not require daily dosing. Some products may require monthly dosing and others may require administration only a few times a year. Taking an idea and turning it into a desirable, effective, affordable, and accessible product is a long and difficult process. To facilitate the analysis and policy decisions needed to advance the process, we describe here some of the issues that must be considered to make durable new HIV treatment and prevention options available for individuals.

## ASSESSING THE PAYER LANDSCAPE

Several pharmaceutical manufacturers are actively engaged in developing innovative new products both to treat and prevent HIV infection. If successful, new long-acting products that do not require daily dosing could become available within the next few years. Once a product is approved by the Food and Drug Administration (FDA), payers — meaning the public and private programs that pay for health care, such as Medicaid, Medicare, the Ryan White HIV/AIDS Program, private insurance, and other programs — will have various levels of discretion to determine whether and when to make these products available. Consumer access and costs may vary dramatically. Different payers and programs have different standards for introducing and pricing new products. To ensure appropriate access to new products and relatively consistent application of unfolding scientific knowledge across programs, policy work will be needed to inform payer coverage policies.

Whereas the FDA evaluates new products for safety and effectiveness, coverage policies by payers typically relate to whether a therapy is "reasonable and necessary." What is reasonable is a highly subjective standard, but the focus of

### Long-Acting HIV Treatment and Prevention: Navigating Coverage Policies in Public and Private Health Care Programs

To achieve the benefits of innovative products, payers (Medicaid, Medicare, private insurers, the Ryan White HIV/AIDS Program, and others) must be engaged with clinicians, researchers, and consumers to consider how to deploy new technologies.

Payers have a range of tools to manage (i.e., restrict or promote) access to prescription drugs. Program rules and policies will impact access along with the price paid for drugs both by consumers and payers. Coverage policies could vary dramatically depending on the payer and the specific product.

Policy planning should begin now:

- **Federal agencies should prepare payers for prospective long-acting HIV treatment and prevention options.**
- **Professional organizations should plan to develop guidance to shape professional practice, especially when products are new and definitive data are not available.**
- **Payers should consider how to respond to potential emerging situations, such as a greater role for Medicare Part B, which has higher consumer cost-sharing and provides no low-income cost-sharing assistance.**

payers typically is on whether a product or service is "medically necessary." Medical necessity determinations often have multiple components, including whether an intervention is needed for a specific condition (e.g., to treat HIV infection or to prevent HIV acquisition), and whether better or cheaper products are already available. There are related costs that must be covered in addition to the medication, such as administration and monitoring by a health care provider, along with associated laboratory tests. If a product involves physician administration, this could add significantly to the overall cost of the therapy beyond the cost of the drug itself.

### Components of Payer Costs for Long-Acting Products

The cost to a payer or health plan is not limited to the price of a drug. Total cost includes:

**Drug Cost:** Amount paid for the drug product minus any rebates or discounts and consumer cost-sharing

**Dispensing Cost:** Fee paid to a pharmacy, physician office, or hospital for procuring, storing, and providing the drug; more complex products may result in higher dispensing fees

**Administration:** Payment for a provider to administer a product and for supplies (e.g., syringes for injectables)

**Management and Monitoring:** Cost for follow-up visits with a provider and other monitoring expenses

**Laboratory Services:** Lab fees for regular monitoring of the safety and effectiveness of a drug product

It is important to consider not only the standards that health plans use in setting their coverage policies, but also who is responsible for making decisions. Many health plans, often pursuant to payer requirements, establish Pharmacy and Therapeutics (P&T) Committees to review clinical data in order to make some of these decisions. In most cases, such committees consist almost entirely of treating clinicians and pharmacists with the expertise necessary to assess the veracity of research studies and make evidence-informed decisions. Payer requirements also may give consumers process guarantees and evidentiary standards intended to ensure that decisions are not driven solely by cost. Separately, once a P&T Committee has determined that a drug merits coverage, a health plan also may establish a separate Drug Utilization Review (DUR) Committee that establishes tiering, prior authorization, and other access policies (to be explained in more detail in the next section).

While some consumers may want to have the option to access all approved medications, the need to control costs in our health system creates an important role for health plans and payers to restrict access to products and services to when they are medically necessary. Indeed, a role of health plans, as a general matter, is to make the default practice to prescribe the least costly, yet safe and effective intervention. Therefore, establishing the standards by which payers determine whether a product or therapy is medically necessary for an individual is critically important, so that standards balance individual circumstances and preferences with the ability to make prudent decisions to conserve health care resources. Frequently lacking in health plan enrollment campaigns and plan materials, but critically important, are clear, transparent discussions of plan coverage policies so that health plan enrollees and prospective enrollees can determine whether a therapy or service they are seeking is likely to be covered. In some cases, it can be especially challenging for individuals to ascertain formulary information (including whether a drug is covered and at what cost).

## Prescription Drug Policies in the Major Health Programs

### Medicaid

Medicaid is the largest source of health coverage for people living with HIV in the U.S.[1] It operates under federal law, and while each state's participation in the program is voluntary, all states participate and retain significant discretion in the structuring of benefits, payment for services, and the operation of their programs. All states operate traditional Medicaid programs that cover low-income children, parents, seniors, and people with disabilities, though eligibility levels and service delivery models (such as fee-for-service or various forms of managed care) vary widely.

Historically, the greatest number of people living with HIV qualified on the basis of disability once their condition progressed to where they met the clinical criteria for an AIDS diagnosis. The Affordable Care Act (ACA) created a new optional Medicaid expansion group

that enables states to expand Medicaid coverage to all eligible persons with incomes below 138% of the poverty level, with the federal government paying the vast majority of the costs. As of July 2018, 33 states plus the District of Columbia had taken up the Medicaid expansion option.[2] At least 62% of the U.S. population of people living with HIV are estimated to reside in states that have expanded Medicaid, leaving less than 38% in states with more limited coverage options.[3] Whereas states have greater latitude in designing the prescription drug benefit for the expansion population, most states have chosen to align their benefits for all of their Medicaid beneficiaries (which means that enrollees have access to a broad range of treatments).

**Medicaid Coverage Policies:** States are not required to offer prescription drugs through Medicaid, but all states have elected to do so. Once a state opts to provide prescription drugs, however, they must comply with federal law, which effectively guarantees broad access to all FDA-approved medications. Indeed, the law requires pharmaceutical manufacturers that wish to sell their products to Medicaid to sign an agreement with the federal government that provides for rebates to be paid to Medicaid for purchased drugs, and guarantees (as a general standard) that Medicaid will get the "best price" for medications sold in the U.S.[4] Virtually all pharmaceutical manufacturers have signed rebate agreements with Medicaid. In exchange, manufacturers have a right to have all of their FDA-approved products made available to Medicaid beneficiaries.

### Medicaid

**Formulary Access:** Virtually all FDA-approved drugs are covered.

**Access Restrictions:** Extensive state variation possible; states have extensive tools to manage/restrict access based on "medical need."

**Payer Costs:** States guaranteed the Medicaid "best price," which is discounted compared to other payers; states can negotiate supplemental rebates.

**Consumer Costs:** Significant cost-sharing protections; not all states charge prescription drug cost-sharing.

States (and Medicaid Managed Care plans that operate under contract with a state) retain significant flexibility in setting payment levels and managing the pharmacy benefit. Utilization management is the term for the range of tools that health plans have to restrict access (e.g., step therapy or prior authorization) or to determine whether an individual meets their established clinical requirements for receiving a prescribed medication. States must provide prescription medications when they are medically necessary, but states (or health plans) define the standards for medical necessity. Prior authorization involves review by persons with clinical expertise

States have broad flexibility in establishing payment levels for physician services and laboratory services, and if set too low, this can impede access.

to establish the medical need for a product before payment is approved and before a medication is dispensed. States subject many prescription drugs to prior authorization, including drugs that may raise unique safety concerns or those that are high-cost products, both of which may apply to long-acting products. States also can establish step therapy or fail first requirements, which means that individuals cannot receive approval for a medication until they have first tried and failed an alternative therapy (typically a lower cost one).

States can set limits on the number of prescriptions a beneficiary can receive each month. Medicaid programs cannot, however, refuse to cover a medically necessary drug because of the cost, and in setting limits on coverage, they must ensure the "amount, duration, and scope" of the drug coverage is sufficient to reasonably achieve the medically indicated purpose of the medication. This prevents states from providing coverage in name only by, for example, covering a medication for only a few days if it is needed over a longer period of time. All of these policy tools can be used to ensure that drugs are only dispensed in a manner that is safe and appropriate, but they also are a primary tool for health plans to drive down use of drugs or drive patients towards lower-cost options, which can increase access barriers for patients or impede adherence to therapy.

States are guaranteed the Medicaid rebate price for prescription drugs, but they can (and often do) negotiate additional supplemental rebates from manufacturers. In some cases, this means that the state Medicaid program or plan would place a drug on the preferred drug list and provide easier access to the drug than other drugs in a class when a supplemental rebate has been negotiated. States have broad flexibility in establishing payment levels for physician services and laboratory services, and if set too low, this can impede access.[5]

**Medicaid Consumer Costs:** Medicaid law permits states to charge cost-sharing for items and services provided to Medicaid beneficiaries, though not all elect to do so. In 2017, about half (23) of states charged cost-sharing for prescription drugs to adults in the Medicaid expansion group.[6] Recognizing the low-income population served by Medicaid, however, the level of cost-sharing cannot be more than "nominal." Under federal rules, in 2017, cost-sharing for prescription drugs for adults could not be more than $4 for a preferred drug or $8 for a non-preferred drug for persons with income below 150% of the federal poverty level (FPL).[7] For adult beneficiaries with income above 150% of FPL, cost-sharing is limited to $4 for preferred drugs and 20% of the state cost for non-preferred drugs.[8] Even nominal cost-sharing has been shown to deter access for low-income individuals, and Medicaid beneficiaries with income below the poverty level cannot be denied an item or service, including prescription drugs, for failure to pay cost-sharing.[9]

## Medicare

Medicare is the second largest source of financing for HIV care after Medicaid.[10] People with HIV are relatively costly enrollees compared to the average Medicare beneficiary, and prescription drug spending is a significant driver of these costs. Average per capita spending for HIV-positive beneficiaries was $45,489 in 2014, more than half of which ($26,761, or 59%) was Part D drug spending. By contrast, average spending for all Medicare beneficiaries was $11,651, of which $1,821 (16%) was Part D drug spending.[11]

Medicare consists of several parts. All persons enrolled in Medicare receive Part A benefits, which cover hospital care. Part B is technically optional, but nearly all Medicare beneficiaries enroll in the Part B program. It covers physician services, outpatient care, and some home health and preventive services. Drugs that are administered in a physician's office are covered by the Part B program. Part C, called Medicare Advantage, is a voluntary managed care alternative to traditional Medicare coverage. Part D is the voluntary outpatient prescription drug benefit. Eighty-seven percent of Medicare beneficiaries have Part C or D prescription drug coverage.[12] Depending on the product and how it is administered, long-acting products for HIV treatment and prevention could be either Part B or Part D drugs, and potentially both. These parts of Medicare may have different coverage policies, and confusion over which part of the program is responsible could impede adoption of new products.

**Medicare Part B Coverage Policies:** Part B coverage decisions are guided by: 1) federal law; 2) national coverage determinations (NCDs) made by the Centers for Medicare and Medicaid Services (CMS) about whether something is covered (issuing an NCD is done at the discretion of CMS to ensure uniform national coverage and it should not be assumed such a determination would be made at all or would be made soon after any product is approved by the FDA); and 3) local coverage decisions made by companies in each state that process claims for Medicare (called

### Medicare Part B (Physician Services)

Covers physician administered drugs, such as some injectables and implants

**Formulary Access:** Regional variation is possible, especially as new products are introduced, unless and until the Centers for Medicare and Medicaid Services (CMS) issues a national coverage determination.

**Access Restrictions:** Past study found that only 80% of new FDA-approved Part B drugs and devices were covered, with restrictions placed most frequently on devices.

**Payer Costs:** Average Sales Price (ASP) + 6%; these payments to providers could create incentives for providers to prefer Part B long-acting products over self-administered Part D products.

**Consumer Costs:** Consumers pay 20% of the Medicare cost, which could create access barriers.

Because some long-acting products may be outpatient drugs (such as pills and certain injectables) and some may require physician administration (such as implants and some injectables), coverage, access, and costs in Medicare could vary dramatically by product.

Medicare claims processing contractors, these companies decide whether something is medically necessary and should be covered in their area). One study of national coverage determinations published in 2013 found that Medicare Part B covered FDA-approved drugs or devices 80% of the time.[13] It found, however, that Medicare often added conditions beyond FDA approval, particularly for devices, and often restricted access to persons with the most severe disease. Long-acting implantable products are under development that would be considered medical devices.

Payments for physician services to administer Part B drugs are controlled by the Physician Fee Schedule that is adjusted each year. It sets maximum allowable payments for physician services based on the intensity of the service and other factors, and is adjusted for geographic variation in the cost of health services. Medicare payment for Part B drugs is based on the Average Sales Price plus 6%, which is based on the manufacturer's sales of a drug to all purchasers in the U.S. The 6% additional payment is intended to compensate for the additional overhead costs associated with complex drugs and to adjust for differences in the actual acquisition costs paid by individual physician practices.

**Medicare Part B Consumer Costs:** Cost-sharing in Part B can be significant, as beneficiaries are responsible for 20% of the Medicare approved amount for the drug and the Part B deductible applies ($183 in 2018).[14] Unlike Part D, there is no program in Part B to provide cost-sharing relief to low-income beneficiaries. Physicians who administer Part B drugs must accept "assignment," which means they must accept the Medicare payment amount and are not permitted to charge beneficiaries more for the drug.

**Medicare Part D Coverage Policies:** The Medicare Outpatient Prescription Drug Program creates a right for Medicare beneficiaries to purchase drug coverage. Individuals who enroll in the Part C program can select a Part C plan that offers prescription drug coverage (most do). Individuals enrolled in regular, fee-for-service Medicare can select from a range of private insurance options. Each individual Part D health plan establishes its own formulary of covered drugs. Unlike Medicaid, which has an open formulary requiring nearly all FDA-approved drugs to be covered, Medicare Part D formularies can be closed, meaning that they can completely exclude certain drugs. The basic standard for Part D is that all plans must cover at least two drugs per class, although most formularies cover far more. Additionally, there is a special consumer protection for Part D formularies that applies to antiretroviral therapy (ART) medications as one of six "protected classes," and also includes oncology drugs, certain psychotropic drugs, anticonvulsant medications used to treat epilepsy, and immunosuppressants.[15] For these classes, Part D plans are required to cover "all or substantially all" drugs within the class. There is an additional protection for ART medications. Except for enfuvirtide injection (Fuzeon), ART drugs may not be subject to prior authorization.[16]

It cannot be assumed that new long-acting products will

### Medicare Part D (Outpatient Drugs)

Covers outpatient prescription drugs, including self-administered injectable products

**Formulary Access:** Plans must cover "all or substantially all" antiretroviral medications; new long-acting products potentially could meet an exception criterion, so full formulary coverage cannot be assumed.

**Access Restrictions:** Part D plans have extensive tools to manage/restrict access based on "medical need."

**Payer Costs:** Plans negotiate prices with manufacturers. Plans also may contract with pharmacy benefit managers (PBMs) to negotiate prices and control costs.

**Consumer Costs:** Significant cost-sharing is possible, up to a catastrophic limit with special protections for persons with income below 150% of poverty. Part D plans typically place drugs in different cost-sharing tiers; long-acting products are likely candidates for the highest cost "specialty" tier.

automatically be included on Part D formularies without prior authorization. When the Part D program was established, enfuvirtide injection was a new product and it was the most expensive ART available. It was never recommended as first-line therapy, was the only ART drug at the time administered by self-injection, and was dispensed by the manufacturer, not a retail pharmacy. Some of these types of circumstances may come into play with future long-acting products.

Part D plans, or pharmacy benefit managers (PBMs) under contract with a plan, negotiate drug prices with manufacturers. For drugs on the formulary, Part D plans can use many of the same tools as discussed for Medicaid to manage the benefit and restrict access.

The ACA (and the recent two-year budget deal) is playing a role in reducing beneficiary cost-sharing by phasing out the Medicare Part D coverage gap so that by next year, it will not exist.

This includes the use of prior authorization and step therapy requirements. In addition, because there are not the same out-of-pocket protections that exist in the Medicaid program, Part D plans have greater discretion in setting beneficiary cost-sharing levels. As a result, plans can either incentivize or disincentivize use of a particular product (and potentially impact adherence) when setting beneficiary out-of-pocket obligations.

**Medicare Part D Consumer Costs:** The Part D program has a complicated structure for beneficiary cost-sharing. First, there is the standard benefit, then the assistance offered through the low-income subsidy program for persons with limited income and assets. In 2018, the standard benefit has a $405 deductible and 25% coinsurance up to an initial coverage limit of $3,750 in total drug costs, followed by a coverage gap. During the gap, enrollees are responsible for a larger share of their total drug costs (up to 35% of drug costs in 2018) than in the initial coverage period, until their total out-of-pocket spending reaches $5,000. After enrollees reach the catastrophic coverage threshold, Medicare pays for most (80%) of their drug costs and enrollees pay either 5% of total drug costs or $3.35/$8.35 for each generic and brand-name drug, respectively.

Most plans have shifted to charging tiered copayments or varying coinsurance amounts for covered drugs rather than a uniform 25% coinsurance rate, and a substantial majority of prescription drug plans use specialty tiers for high-cost medications. In these cases, lower-tier drugs incur lower coinsurance and enrollees have to pay more than 25% of the cost of specialty-tier drugs. The ACA (and the recent two-year budget deal) is playing a role in reducing beneficiary cost-sharing by phasing out the coverage gap so that by next year, it will not exist.[17,18]

The low-income subsidy (LIS) program, also called "Extra Help," provides some out-of-pocket spending relief for beneficiaries with incomes below 150% of poverty and limited assets (less than $14,100 in 2018). Assistance levels vary both with Part D premiums and cost-sharing, but most Extra Help recipients (those with incomes up to 135% FPL or the full subsidy) pay only $3.35/$8.55 for each generic and brand-name drug, respectively, at any period (i.e., initial coverage period, coverage gap, and catastrophic level coverage). Those with slightly higher incomes (135-150% FPL), receiving a partial LIS subsidy, may be charged up to 15% of the cost of the drug.[19]

## Private Insurance

Private insurance provides coverage to an estimated 30% of people living with HIV nationwide.[20] This includes persons with group coverage typically offered through an employer, as well as individuals and families enrolled in ACA marketplace coverage.

**Private Insurance Coverage Policies:** Individual and small group health plans that operate under the ACA have broad flexibility in designing their prescription drug benefits. Prescription drugs are one of ten essential health benefits (EHBs) that all plans must cover. Plans must cover the greater of one drug per class or the same number of drugs in each category and class as the benchmark plan (subject to federal rules, each state selects a "benchmark plan" whose policies define minimum standards with respect to coverage of EHBs).

The ACA also includes civil rights protections that prohibit discrimination in benefit design and delivery of services. While the scope and meaning of the non-discrimination provisions of the law are often unclear, federal regulations state that plans cannot structure their drug benefits in ways that result in *de facto* discrimination, and they cite the placement of all ART medications on the highest cost tier as an example of a discriminatory practice. Early experience has

found that not all antiretroviral medications are covered in all health plans, with single tablet regimens among the products most likely to be excluded.[21] Private insurers that offer large group coverage (i.e., to employers) and non-grandfathered plans outside of ACA marketplaces have even more flexibility in deciding whether or not to cover prescription drugs and in structuring the benefit (but are often more generous).

Regulation of insurance is primarily a state responsibility and, as was the case prior to the ACA, states have taken a wide variety of approaches ranging from virtually no controls on private insurer practices to legislating benefit coverage requirements that may mandate the coverage of specific drugs or drug classes.[22] Prior to the ACA, most small and large group plans offered fairly comprehensive formulary coverage of antiretrovirals (ARVs).[23] The existence and growth of exclusions and adverse tiering (in which all ART medications are placed in the highest cost specialty tier) in ACA marketplace plans may lead to additional formulary restrictions for expensive new antiretroviral products in the future.

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Plans utilize many of the same tools as Medicaid and Medicare (e.g., prior authorization, step therapy, etc.) to manage the benefit.[24] Insurers negotiate drug prices directly with manufacturers. Private insurers, and in some cases payers such as employers, also may use PBMs to manage the pharmacy benefit. These entities often assert that they have more expertise to understand the latest science around pharmacy practices and can use technology to more effectively provide appropriate access. They also may be able to use bulk purchasing to obtain better drug prices than a single health plan.

**Private Insurance Consumer Costs:** Health plans in private markets have broad flexibility in structuring the pharmacy benefit, including establishing co-insurance in which enrollees must pay a fixed percentage of the drug's cost (e.g., 20 or 30%) or co-payments that require individuals to pay a fixed amount per drug. Co-insurance and/or co-payments typically vary by drug tiers, and issuers are free to create any number of drug tiers as part of a plan's benefit design. In fact, there has been some trend toward plans using an increasing number of tiers (and introducing specialty tiers) since the ACA's implementation. ACA marketplace plans have been observed to rely on tiering more than many other private insurers. While other programs can and do use tiering to vary the cost-sharing level for different drug products, this has been a common feature of ACA marketplace plans and many plans either exclude some ARVs or place all ARVs on the highest cost "specialty" level cost-sharing tier.[25]

An analysis by Avalere in 2015 found that only 16 percent of silver plans in ACA marketplaces covered all top HIV drug regimens with cost sharing less than $100 per month per regimen.[26] Silver plans are plans with midrange coverage based on actuarial value, and they are the level at which cost-sharing subsidies are provided for low-income individuals. While almost half of plans include all 10 of the most commonly used HIV regimens on their formularies, many

## Private Insurance

**Formulary Access:** ACA marketplace plans are required to cover only one drug per class and non-marketplace plans typically have even fewer coverage requirements, leading to potentially significant variation in coverage of ARVs. Therefore, there are no guarantees that private insurers will quickly incorporate new long-acting products on their formularies.

**Access Restrictions:** Plans have extensive tools to manage/restrict access based on "medical need": 10–12% of ACA marketplace plans place all ARVs on the specialty tier with the highest cost-sharing.

**Payer Costs:** Plans negotiate prices with manufacturers. Plans or employers also may contract with pharmacy benefit managers (PBMs) to negotiate prices and control costs.

**Consumer Costs:** These are few cost-sharing protections, except for lower-income persons enrolled in ACA marketplace plans. Even low-income persons can be subject to very high cost-sharing. The ACA has an annual out-of-pocket limit that caps consumer spending on deductibles and cost-sharing for covered services; limit also applies to most employer and non-ACA health plans.

plans charge higher out-of-pocket costs, and costs are often particularly high for single tablet regimens that can be important in supporting adherence.[27]

The ACA includes special assistance for lower- and moderate-income enrollees.[28] Advance Premium Tax Credits are available to persons with income from 100 to 400% of the poverty level who enroll in any metal ACA plan. Plans come in four levels: bronze, silver, gold, and platinum, reflecting the level of coverage provided by the plan. Further, persons with income from 100 to 250% of the poverty level also can enroll in special Cost Sharing Reduction (CSR) silver plans that provide for not only reduced premiums, but also lower deductibles and reduced cost-sharing. However, even with a CSR plan, an enrollee could still face relatively high out-of-pocket costs in certain circumstances. An analysis from 2016 found, for example, that the average cost-sharing for a specialty tier drug in a reduced cost-sharing plan was more than $200.[29]

The ACA has an annual out-of-pocket (OOP) limit that covers consumer spending on deductibles, co-insurance, and co-payments (but not premiums). Once the OOP limit for a year is met, the individual does not pay anything for cost-sharing for covered services (as long as those services are provided in-network or a plan specifically covers out-of-network care). In 2018, the maximum OOP limit is $7,350 for a single individual and $14,700 for a family, though issuers can set this limit at a lower level (and in many cases, must do so to meet actuarial value requirements).[30]

## Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP)

The Ryan White HIV/AIDS Program provides health services or financial assistance to more than 500,000 people living with diagnosed HIV, including persons who are both uninsured and underserved. The majority of individuals who rely on the program have insurance and turn to the program for supplemental assistance, including assistance with cost-sharing. It does not provide pre-exposure prophylaxis (PrEP) or prevention services to persons at risk for HIV infection. Its largest program is the AIDS Drug Assistance Program (ADAP), which allocates funds to states and territories to provide prescription drug coverage. State ADAPs can provide drugs directly, pay cost-sharing to remove access barriers to drugs provided by insurance coverage, or purchase comprehensive insurance coverage. ADAP is funded by an earmarked appropriation within the overall Ryan White HIV/AIDS Program budget, as well as rebates paid by manufacturers, supplemental funding allocated from other Parts of the Ryan White HIV/AIDS Program, and state general revenue funding allocations.

### Ryan White AIDS Drug Assistance Program (ADAP)

**Formulary Access:** State programs vary dramatically in coverage policies.

**Access Restrictions:** Extensive state variation possible; states have extensive tools to manage/restrict access based on "medical need."

**Payer Costs:** Many programs rely on the 340B drug pricing program to receive highly discounted prices; the ADAP Crisis Task Force seeks to negotiate supplemental rebates on behalf of ADAPs.

**Consumer Costs:** Significant variation in assistance provided from state to state, but since ADAPs assist with cost-sharing through other programs, they play a significant role in assuring affordable drug access for many people with HIV, including many with insurance coverage.

**ADAP Coverage Policies:** ADAPs are only permitted to purchase private insurance when it is cost-effective for the program (compared to the cost of directly providing prescription drugs) and when the coverage is at least as comprehensive as the ADAP program. Prior to the ACA's enactment, in 2009 43 ADAPs engaged in insurance purchasing, representing 10% of the total ADAP budget. By 2015, 47 states engaged in insurance purchasing, representing 17% of the total ADAP budget. This increase was driven in part by the new availability of insurance purchase options through the marketplaces, which made it easier to satisfy the cost-effectiveness requirement.[31]

**ADAP Consumer Costs:** The Health Resources and Services Administration (HRSA), the federal agency of the Department of Health and Human Services (HHS) that administers the Ryan White HIV/AIDS Program, requires that ADAPs ensure that clients receive treatment consistent with current HHS treatment guidelines; provide access to, and support for, appropriate medications; include at least one medication on their formularies from new antiretroviral classes within 90 days of inclusion in the HHS Guidelines; and include at least one medication from each antiretroviral class on their formularies.[32] Each state and territory operates its own program and determines what it will

cover within the scope of what is permitted by statute. There are no requirements that ADAPs cover any specific drug products, although all formularies are fairly comprehensive. As of 2017, only six ADAPs had open formularies in which all FDA-approved drugs were covered (with designated exceptions), and several more covered all drugs except for generics.[33] With limited resources, ADAPs are explicitly making formulary and coverage policy decisions to have the greatest impact. Therefore, one cannot assume that there will be quick or widespread adoption of coverage of new long-acting products. As a snapshot of state policies, as of 2015:

- Fifty-eight percent of ADAPs paid prescription drug cost-sharing for persons below poverty, while only 33% covered prescription drug cost-sharing for persons at or above 400% of poverty.

- Ninety-two percent of ADAPs assisted with Medicare Part D cost-sharing for the highest income beneficiaries, but fewer assisted with lower-income persons receiving Medicare Extra Help benefits with incomes below 135% of poverty (73% of states).

- Sixty percent of ADAPs assisted dual eligible, low-income persons receiving both Medicaid and Medicare with Part D cost-sharing assistance. Most states did not assist with Part B cost sharing.[34]

## Other Considerations

There are other agencies and programs that influence access to drug products. For example, the Centers for Disease Control and Prevention (CDC) has an important role to play in policy development and implementation. While it does not administer programs to provide drug access and it does not permit its funding to health departments to be used to purchase drugs, its Division of HIV/AIDS Prevention (DHAP) within the National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) funds important research that supports the implementation of PrEP and issues PrEP prescriber guidance. The CDC also publishes guidance on issues such as improving retention in HIV care, including adherence to prescribed treatment and promoting the prevention benefit of treatment to reduce new HIV infections. Thus the CDC has a role in guiding the health system and individual prescribers in incorporating new forms of long-acting prevention into practice.

The U.S. Preventive Services Task Force (USPSTF) is a federally appointed independent panel of national experts in prevention and evidence-based medicine that makes evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. Preventive services given an A or B rating (indicating that a high standard of clinical evidence supports the effectiveness of a service) are available to Medicare beneficiaries, Medicaid expansion enrollees, and ACA marketplace health plan enrollees without cost-sharing when medically necessary. These recommendations serve a normative function and the traditional Medicaid programs are encouraged to make these services available without cost-sharing. Private insurers also often adopt USPSTF recommendations.

The USPSTF is currently conducting a review of the evidence for PrEP in the prevention of HIV infection. In August 2017, the USPSTF published a final research plan that will guide its review.[35] Of note, this review is limited to oral PrEP regimens, including daily tenofovir-emtricitabine (the only PrEP regimen currently approved by the FDA). The evidence review also will assess daily tenofovir without emtricitabine, since several trials have evaluated this regimen and reported benefits similar to those of daily tenofovir-emtricitabine. Alternative dosing strategies, such as on demand or intermittent dosing regimens, which are actively being studied in the U.S. and other settings, also will be reviewed. If the USPSTF issues an "A" or "B" grade recommendation for PrEP, this would facilitate access to existing oral PrEP regimens without cost-sharing under many payer scenarios.

The CDC has a role in guiding the health system and individual prescribers in incorporating new forms of long-acting prevention into practice.

## Programs of Note

**340B Drug Pricing Program:** All ADAPs and many other Ryan White HIV/AIDS Program recipients, along with Health Centers and recipients of other federal programs, can participate in the 340B Drug Pricing Program. This is a program operated under federal

law, separate from the Ryan White HIV/AIDS Program and the Health Centers Program, but administered by HRSA. It requires pharmaceutical manufacturers to offer significant discounts on prescription drugs to eligible 340B program participants in order to participate in the Medicaid program.[36] ADAPs and other Ryan White HIV/AIDS Program recipients must apply to HRSA to participate in the program.

Once accepted, these "covered entities" can obtain drugs at prices that are always lower than the Medicaid rebate price and often significantly lower. Covered entities can obtain drugs for outpatient use, as well as for administration by a physician or other health care provider. Covered entities cannot resell or transfer drugs to other entities, and drugs must only be dispensed to eligible patients. These patients must have an established relationship with the covered entity, must receive care from an employee or professional operating under contract with the covered entity, and must receive health services from the covered entity that are consistent with the services for which grant funding was provided to the entity. Under the guidelines, an individual is not considered a patient of the covered entity if the only health care service received by the individual from the entity is the dispensing of a drug for subsequent self-administration or administration in the home setting, although ADAPs and ADAP clients are eligible and are exempted from this patient definition.[37]

In addition to providing the most deeply discounted prices for medications, an important advantage of the 340B program has been the ability of covered entities to bill payers (Medicaid, Medicare, private insurance, or ADAP) the regular reimbursement rates for drugs through these programs and receive reimbursement greater than their costs. For many clinics and programs, the difference between the price paid and the amount reimbursed is a significant revenue generator. This is permissible as long as this revenue is used consistent with the purpose of the Ryan White HIV/AIDS Program (or the other 340B qualifying program), such as to serve more low-income people living with HIV or provide more services.[38] Significant changes to the 340B program have been debated, and future legislation or pending rule making could create new restrictions on the program.

**Patient Assistance Programs:** Virtually all pharmaceutical manufacturers operate programs to provide free or lower cost medications to eligible individuals. Program rules vary by manufacturer and specific drug product. Typically, there are two types of assistance: co-pay assistance for persons whose insurance cost-sharing could be a barrier to access, and free or low-cost drugs for persons who are uninsured. These programs can provide an important last-ditch way for people to acquire prescribed medications. Past experience of these programs, notably in the context of implementing PrEP, is that while critically important, they typically do not cover all costs associated with obtaining treatment. For example, even if a person is able to access the drug product, he or she may have no way to pay for the physician administration costs or to obtain required laboratory monitoring.

## Policy Development Should Begin Now

The diversity of insurance and other health care programs and differing rules and policies make it virtually certain that adoption of new long-acting products will be uneven, especially when new products are first introduced. Early experience with implementing PrEP has demonstrated that without concerted efforts to overcome obstacles to access for populations and communities facing the largest barriers and who often stand to benefit most from innovative products and therapies, these new products could exacerbate rather than reduce health disparities both in terms of access and outcomes.

Three ways that program administrators, researchers, consumer advocates, and others can begin to lay the policy groundwork for a future with long-acting products are as follows:[39]

### 1. Federal programs should prepare payers for prospective long-acting HIV treatment and prevention options

HRSA, CMS, CDC, NIH, and other relevant agencies should begin to review their evidence standards for new coverage policies and consider how they can provide early guidance for purchasers, prescribers, and the public on how to implement potential new products. The first step may involve informing all interested parties that these products are in development and are generating significant interest. This should lead to creating opportunities for dialogue among payers, clinicians, and consumers to consider the numerous implications of these products in terms of cost, coverage, consumer demand, impact on health equity, and other factors in order to shape how such products are introduced within U.S. health care programs.

The HHS Panel on Antiretroviral Guidelines for Adults and Adolescents (a working group of the Office of AIDS Research Advisory Council at the NIH) and related groups for other populations develop HIV treatment guidelines that define the standard of care for HIV treatment in the U.S. The CDC issues guidelines for prescribers for the use of PrEP. Both of these sets of guidelines are evidence-based and likely will offer a clinical research perspective on the role of long-acting therapies.

CMS issues State Medicaid and CHIP Director (SMD) letters and other guidance on various topics. In some cases, these SMDs provide legally binding guidance to states on their obligations under the Medicaid law. In others, however, they inform states of unfolding scientific advances and offer guidance on how to respond to these developments. CMS, potentially working with the HRSA HIV/AIDS Bureau (which has the most extensive HIV clinical care expertise in the federal government), could work together to inform states about potential innovations in the research pipeline and assess state information needs for them to make coverage decisions about future products. This also may include examining, before products are available for marketing, clinical recommendations for how to combine long-acting products with existing therapies.

### 2. Professional guidance can lead the way

Payer policies in Medicaid and other programs also are heavily influenced by the best professional judgment of the appropriate treatment professionals. Therefore, ensuring that professional societies and relevant bodies are aware of the unfolding science around long-acting products and encouraging them to offer guidance is important. It may be especially important early on to encourage groups to offer interim guidance, recognizing that new developments may quickly force alteration of recommendations, as the absence of any "best professional judgment" may lead to bad policy and harm the interests of both consumers and payers.

In the case of HIV prevention and treatment, several organizations and bodies play important roles in guiding clinical practice. These include the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents (see above), the International Antiviral Society—USA (IAS-USA), the International Association of Providers of AIDS Care (IAPAC), the HIV Medicine Association, and the American Academy for HIV Medicine, all of which either have issued guidance in the past or have the prestige needed to help inform unfolding policy development in this area.

### 3. Consider program adaptations to respond to innovative long-acting products

If and when long-acting products become available, it will be imperative to consider how existing programs are able to assist people in accessing these products. This necessarily demands a separate review for programs that help people living with HIV access treatment services and programs that assist HIV-negative individuals in accessing preventive services.

## Access to Long-Acting HIV Treatment

ADAPs will likely become the quickest payers to adopt coverage policies and respond to these innovations. Decisions they make regarding whether and when to cover them will be influenced by numerous factors, including pricing of new products and the extent of rebates negotiated by the ADAP Crisis Task Force, which collectively negotiates discounts with manufacturers on behalf of ADAPs. Additionally, the prevailing economic and political climate will shape their decisions. If state budgets are tighter than normal, this could slow the adoption of new drugs on ADAP formularies. And if the uncertainty or anxiety over the future stability of the broader health insurance system is as acute as it is today, then states may be more conservative in deciding whether to add new products.

One issue that likely will confront ADAPs is demand that they assist clients with Medicare Part B cost-sharing. Given resource constraints, many ADAPs may be reluctant to assume this role, and current HRSA program guidance seems to preclude such assistance. Similar reticence may have existed prior to implementation of the Medicare Part D program, however, and soon after this program was established, ADAPs quickly stepped up to assist clients struggling to afford Part D medications. This issue is not only a financial question, but raises complex legal and regulatory questions over how to administer Medicare Part B cost-sharing assistance. Nonetheless, the high level of cost-

If the uncertainty or anxiety over the future stability of the broader health insurance system is as acute as it is today, then state ADAPs may be more conservative in deciding whether to add new products.

sharing that Medicare Part B would impose would effectively preclude access to these products and, therefore, HRSA and ADAPs should anticipate pressure to find a route to extending coverage to Part B. NASTAD, the national association that represents state AIDS directors, could begin convening its members to grapple with the policy and operational issues that taking on this new role would entail.

### Access to Long-Acting HIV Prevention

Federal programs that provide financial and other assistance to facilitate access to PrEP and related services, either through the CDC or the Ryan White HIV/AIDS Program, do not currently exist. Some program administrators and community advocates have sought to use 340B revenues in support of PrEP access. To date, administrative interpretations requiring Ryan White HIV/AIDS Program recipients to adhere to the scope of their grant have limited their ability to play a role in providing access to PrEP. This type of issue may become more prominent as additional PrEP agents are approved, especially if long-acting PrEP products become available. Therefore, further consideration may be needed to understand whether these restrictions are easily remedied, or whether statutory or regulatory changes are needed.

The existence of new long-acting products for HIV prevention will not create a new problem as much as highlight the fact that the absence of a financial assistance program already is a serious barrier to the scale-up of PrEP services. Assistance is needed not only to cover medication costs, but also laboratory and provider monitoring services. As policy makers contend with adapting their programs to accommodate highly effective long-acting products, greater attention may need to be paid to devising new ways to help individuals and health departments provide supplemental assistance for accessing HIV prevention services.

## Conclusion

The treatment and prevention of HIV infection have come a long way. Long-acting HIV treatment and prevention options offer the potential to build on existing progress. FDA approval of a new drug product is only the first step in a long chain of policy decisions that will be needed to offer people with HIV and people at high risk of HIV infection new options. The diversity of products under development likely will offer individuals and providers a range of new choices. Yet the potential for products to be administered in different ways raises new challenges that must be considered alongside the complexities of promoting access to innovation while effectively safeguarding limited resources in ways that reduce health inequities. Now, even before new products are available, is the time to begin multiple dialogues with people living with and at risk for HIV, payers, and the researchers and clinicians who provide care.

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39. In a separate document, we explore some of the complicated questions about who is the target population for new long-acting therapies for HIV treatment and prevention.

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