Cost Considerations and Antiretroviral Therapy

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Key Considerations
• The complexities of the U.S. health care system may require that the costs for antiretroviral therapy (ART), especially out-of-pocket costs for the person with HIV, be one of the considerations in regimen selection, because such expenditures can directly affect affordability and adherence. • Health insurance and prescription drug coverage can directly affect clinical outcomes for people with HIV; changes to coverage can result in lapses in viral suppression and should be anticipated as best possible. • The Ryan White HIV/AIDS Program offers opportunities to access essential HIV medical and support services, including medication assistance, to minimize cost as a barrier to care for people with HIV and lower incomes. • Both medical and nonmedical case management services can be used to identify and address cost-related barriers to ART by linking individuals to private and public funding sources. • Disengagement from care occurs more frequently during transitions in care and coverage (e.g., transitioning from pediatric to adult care; changing employment status; moving from one state to another; being released from incarceration; switching insurance, including to Medicare).

Introduction

The clinical benefits, public health impact, and cost-effectiveness of HIV treatment are well established,[1-6] and increased uptake and utilization of antiretroviral therapy (ART) is one of the four pillars of the *Ending the HIV Epidemic in the U.S.* initiative.[7,8] However, HIV treatment with ART is costly. A 2023 study estimated that the net Medicaid spending from 2007 through 2019 was $25 billion for 17 million 30-day supplies of antiretroviral (ARV) drugs.[9] Estimated annual spending—inclusive of statutorily required manufacturer rebates to offset federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries—increased 178%, from $1.1 billion to $3.0 billion during this 12-year period. According to a study of risk-adjusted 2016 Medicare claims, total spending for Medicare beneficiaries with HIV receiving ART was 221% greater than for beneficiaries without HIV, largely driven by ARV drug expenses.[10] Since the initial inclusion of an ARV cost table in these guidelines in 2012, the cost of brand-name, first-line ARV regimens has increased by more than 30% from 2012 to 2018,[11] which is 3.5 times the rate of inflation for that same time period.

This section provides guidance on cost considerations related to HIV clinical care. Ideally, ART costs do not influence regimen selection. However, the complexities of the U.S. health care system, including those related to out-of-pocket costs to people with HIV, may necessitate their consideration in regimen selection, because expenditures may directly or indirectly affect adherence and virologic outcomes. Additionally, health insurance and prescription drug coverage determinations, based in part on ART costs, can directly affect clinical outcomes for people with HIV; the clinical impact of changes to insurance coverage is also discussed in this section. Overall costs to the health care system, insurers, and society are also important, especially given the increasing number of people with HIV, rising drug costs, and increasing multimorbidity among people aging with HIV. Providers should make every effort to understand cost considerations that may limit HIV care and the support services available to mitigate cost as a barrier to effective HIV treatment.

Health Care Coverage to Maximize Access to ART

Health care access in the United States can vary, depending on factors such as location and income, among others. Although the Patient Protection and Affordable Care Act (ACA) has substantially improved access to HIV clinical services in many regions of the United States since 2010, an estimated 35% of people with HIV in the United States live in the 10 states—including Florida, Georgia, and Texas—that had not expanded Medicaid in accordance with the ACA as of November 2024.[12]

The ACA and its Medicaid expansion have greatly improved insurance coverage among people with HIV.[13] Before the ACA, many individuals with HIV were denied insurance due to pre-existing condition exclusions and high costs. Medicaid eligibility was also restricted to specific categories, such as disability, which excluded many low-income individuals from coverage.[14,15] Soon after implementation of the ACA and Medicaid expansion in a growing number of states, HIV testing and diagnoses increased, more individuals started ART and achieved viral suppression, uninsured hospitalizations among people with HIV decreased, and fewer people were unaware of their HIV status.[16-19]

A retrospective analysis of NA-ACCORD data examined the associations between state Medicaid expansion associated with the ACA and HIV outcomes in the United States.[20] The study found a beneficial effect of Medicaid expansion on higher CD4 T lymphocyte (CD4) cell counts at the point of enrollment in care. However, no evidence was observed indicating either a positive or negative impact on additional continuum of care outcomes. The authors suggest the null effect on downstream HIV measures for individuals with HIV may be due to the Ryan White HIV/AIDS Program (RWHAP), the highly cost-effective federal safety net program, potentially concealing HIV outcome deficits that might otherwise be apparent in states foregoing Medicaid expansion.[21] At the population level, Medicaid expansion could have a greater effect on reducing HIV incidence by increasing diagnoses and improving linkage to care.[22]

Changes or lapses in health insurance are common and can result in interruptions in clinical care and virologic suppression. Frequent recertification requirements for AIDS Drug Assistance Programs (ADAPs) or Medicaid can lead to lapses in ART use.[23,24] Providers should be aware of the certification needs for the states in which they provide care. Both ADAPs and Medicaid are administered at the state level; therefore, eligibility criteria and medication formularies differ from state to state. When people with HIV receiving Medicaid or ADAP ARV drug coverage move from one state to another, advanced planning is required to ensure uninterrupted access to ART. For example, specific antivirals covered by Medicaid may not be covered by the state ADAP (e.g., long-acting cabotegravir/rilpivirine [LA CAB/RPV]), potentially resulting in the need for regimen changes if a change from Medicaid to an ADAP is required.

Interruptions in health insurance and prescription drug coverage access are also common for people with HIV involved with the criminal justice system. While incarcerated, some people with HIV may be disenrolled from their healthcare insurance and prescription drug coverage. However, in 2023, the Centers for Medicare & Medicaid Services (CMS) released guidance for states when applying for a partial waiver of this policy, enabling coverage for services provided 30 to 90 days before release.[25] With approval of this waiver, states are expected to suspend (not terminate) Medicaid coverage during incarceration and must collaborate with correctional facilities to assist incarcerated individuals who are not currently enrolled in Medicaid with submitting applications during incarceration using presumptive eligibility. Minimum benefits expected by CMS in state waiver proposals include case management services for pre- and post-release (including linkage to outpatient HIV care), medication-assisted therapy for substance use disorders, and at least a 30-day supply of medications at release. Additionally, although federal RWHAP and ADAP funds cannot cover care

and treatment for individuals in state or federal prison systems, they can provide short-term, transitional support to people with HIV in local correctional facilities (e.g., city or county jails).[26]

Cost Sharing in the United States

Prescription drug pricing in the United States involves complex systems with varying requirements for mandatory and voluntary discounts, rebates, and reimbursement rates, and much of the pricing information is confidential. Prices can vary depending on the state, purchaser, type of public or private insurance coverage in use, and number of generic competitors to branded drugs (see Table 22 below). Therefore, providers may find it difficult to navigate payer cost-containment practices, including formulary restrictions, prior authorization requirements, and cost-sharing arrangements, such as copayments (a fixed dollar amount per prescription), coinsurance (a fixed percentage of the prescription cost), and insurance deductible payments.

Out-of-pocket costs for people with HIV can be prohibitive, creating a barrier to the initiation and continuation of ART. Cost sharing results in higher rates of people not initiating ART, prescription abandonment at the pharmacy, decreased adherence, and more frequent drug discontinuation. In turn, out-of-pocket costs may indirectly lead to worse health outcomes and an increased use of the medical system, especially among people with chronic diseases.[27-32] In 2022, the Centers for Disease Control and Prevention (CDC) Medication Monitoring Project (MMP) reported that less than 5% of people with HIV previously taking ART had stopped; however, among people in the MMP who were no longer taking ART, 34% reported that money or insurance problems were contributors to stopping ART.[33]

Conversely, reducing out-of-pocket costs (e.g., through RWHAP or ADAP cost-sharing assistance, manufacturer copayment-assistance programs, or by prescribing generic drugs instead of more costly brand-name products) has been associated with improved adherence.[34] Given the clear association between out-of-pocket costs and the ability to pay for and adhere to medications, clinicians should minimize out-of-pocket drug-related expenses for people with HIV whenever possible. However, many of the cost-sharing arrangements that determine out-of-pocket costs are not transparent to clinicians or people with HIV at the time decisions on ART are made. Asking people with HIV about their copays and working with case management specialists can help to identify and overcome this structural barrier to improving clinical care.

Maximum allowable copayments are statutorily capped at $4 for preferred drugs; in some states, maximum allowable copayments can increase to up to $8 for certain non-preferred drugs for beneficiaries with income <150% of the federal poverty level. For commercial insurers, cost sharing generally is subject to maximum payment rules under the ACA, which increase annually. Manufacturer cost-sharing assistance programs are available for most brand-name ARV products but may be restricted by pharmacy and by state. Manufacturer copay assistance also may be subject to copay accumulator programs implemented by insurers' pharmacy benefit managers, whereby manufacturer payments do not count toward a person's deductible or out-of-pocket maximum.

ADAPs make ARVs and other prescription drugs accessible to people with HIV who are underinsured and have limited financial resources, particularly during lapses in insurance coverage.[35,36] Furthermore, many ADAPs provide premium and/or cost-sharing assistance to eligible clients covered by Medicaid, commercial insurance plans, employer-sponsored insurance plans, or Medicare.[13]

Medicare Beneficiaries With HIV

ARV cost considerations associated with Medicare coverage are increasingly important as more people with HIV age into Medicare. According to CDC HIV prevalence data, 15% of all people with diagnosed HIV in the United States were aged 65 or older in 2022; an additional 27% were aged 55 to 64, with the vast majority expected to age into Medicare over the next 10 years.[37] Enrollment into Medicare can change out-of-pocket costs, which can cause unexpected changes to ART affordability and, ultimately, adherence.[38,39]

Medicare Part D prescription drug cost sharing includes deductibles and copayments or coinsurance, including out-of-pocket payments of up to 25%. However, beginning in 2025, as required under the Inflation Reduction Act, there will be a $2,000 out-of-pocket spending cap.[40]

Medicare Part B cost sharing is not subject to out-of-pocket caps. Where provider-administered drugs—such as long-acting injectable CAB/RPV, ibalizumab-uiyk (IBA) infusions, or subcutaneously (SQ) administered lenacapavir (LEN)—are covered under Medicare Part B, beneficiary cost sharing can be up to 20% of all medication costs.[41]

Low-income beneficiaries may qualify for subsidies to defray Part D cost-sharing payments or the Qualified Medicare Beneficiary program to defray Part B cost-sharing payments. Medicare Advantage and Part D plans are now required to offer beneficiaries an option to enroll in a Medicare Prescription Payment Plan[42] authorized under the Inflation Reduction Act, which will allow beneficiaries to pay cost sharing associated with high-cost prescription drugs in capped monthly payments instead of a single pharmacy payment. Manufacturer copay assistance programs may not be applied toward Medicare plan cost sharing, but assistance from state/territorial ADAPs, other State Pharmaceutical Assistance Programs, and independent foundations (e.g., Patient Access Network Foundation, Patient Advocate Foundation) may provide cost-sharing support if financial eligibility criteria are met.

In addition to its Medicare Part D cost-sharing provisions intended to lower out-of-pocket costs for beneficiaries, the Inflation Reduction Act also requires the Secretary of the U.S. Department of Health and Human Services to negotiate prices with manufacturers for certain drugs with the highest total Part D and Part B spending. Ten Part D drugs were selected for price negotiation in 2026 (2026 pricing was finalized in 2024), with another 15 Part D drugs selected for 2027, 15 Part D and Part B drugs for 2028, and 20 Part D and Part B drugs selected for 2029 and thereafter. The selected drugs will come from the 50 with the highest total Medicare Part D spending and the 50 with the highest total Medicare Part B spending. Although ARV drugs did not qualify for negotiated pricing during the 2026 and 2027 cycles, several ARV drugs are potentially subject to negotiated pricing going into effect in 2028.[43]

Generic Antiretrovirals and Multi-Tablet Regimens

In 2023, savings to the U.S. health care system generated from the use of generic drugs and biosimilar products totaled $445 billion, including $137 billion and $206 billion in savings to Medicare and commercial insurers, respectively.[42,44] Total generic and biosimilar savings for the past 10 years are estimated to be $3.1 trillion.

With substantial improvements in the long-term safety and effectiveness of contemporary ART, a number of regimens and regimen components in Tables 6a and 6b in the Initial Combination Antiretroviral Regimens for People With HIV section remain listed beyond their patent protection date and are or will be available as lower-cost generic options. Keen interest exists in assessing the economic value of using newer, more expensive drugs compared with older, less expensive generic drugs that have established clinical safety and efficacy, such as generic tenofovir disoproxil

fumarate (TDF), which has been available since 2018. A nationwide cross-sectional analysis of 2019 Medicare Part D formulary and pricing data investigated the cost-effectiveness of generic TDF-based regimens versus branded tenofovir alafenamide (TAF)–based regimens.[45] The study demonstrated that the similar efficacy—but slightly improved toxicity profile—of the TAF-based regimens would justify no more than a $1,000 higher annual premium for the TAF-based regimens than generically available TDF-based regimens. A cost-containment analysis evaluated the use of branded dolutegravir (DTG) plus generic lamivudine (3TC) as a two-pill regimen compared with a branded single-tablet regimen (STR).[46] Model findings supported that if 50% of people with newly diagnosed HIV initiated a two-pill regimen consisting of branded DTG plus generic 3TC, the cost savings would reach $550 million to $800 million over a 5-year period; similarly, if 25% of people with sustained viral suppression switched to branded DTG plus generic 3TC maintenance therapy, the cost savings would exceed $3 billion in 5 years.[46]

Because all commercially available STRs listed among the *Recommended Initial Regimens for Most People With HIV* (Table 6a) and *Other Initial Antiretroviral Regimens for Certain Clinical Scenarios* (Table 6b) are branded products, including STRs that contain ARV components that are no longer patent protected, use of generics in the United States may necessitate modest increases in pill burden, but without changes in drug frequency. One study of Medicare Part D spending, which included expenditures for one ARV fixed-dose combination tablet (abacavir [ABC]/3TC), demonstrated that splitting up brand-name coformulated products into their generic components could have saved Medicare an estimated $2.7 billion from 2011 through 2016, and it highlighted this approach as a critical cost-containment measure.[47]

However, to the extent that pill burden, rather than drug frequency, results in reduced adherence, generic ART could lead to decreased costs but at the potential expense of worsening virologic suppression rates and poorer clinical outcomes.[29,30] An additional benefit of STRs is that they eliminate the risk that one drug in the regimen will be temporarily or permanently discontinued because of prescribing error, unsynchronized refill schedules, or prohibitive out-of-pocket costs. Data to support or refute the superiority of once-daily STRs versus once-daily multi-tablet regimens, particularly based on virologic outcomes and especially following viral suppression, remain limited. One large observational cohort study demonstrated a small but statistically significant virologic efficacy benefit associated with STRs.[46] In this study, the time to treatment discontinuation was shorter for non-STRs than for once-daily STR regimens; however, this difference disappeared when modifications for regimen simplification were included in the analysis. On the other hand, observational data from Spain showed that coformulated DTG/ABC/3TC resulted in similar viral suppression compared with DTG plus ABC/3TC, both when used as an initial ARV regimen and when people with viral suppression on the STR were switched to the two-pill formulation as a cost-saving strategy.[48]

Importantly, when the costs of brand-name drug products and generic ARV drugs are compared, savings associated with generic ARV drugs may vary when branded drugs are subject to discounts or rebates across public and private payer systems. Although generic drug products may be associated with societal cost savings and, specifically, savings for public payers, commercial insurers, and people with HIV with significant out-of-pocket pharmacy expenses, manufacturer copay assistance is not generally available to commercially insured individuals. In cases where manufacturer copay assistance may be available for a brand-name ARV product but not for an equivalent generic ARV product, the generic drug prescription paradoxically may result in higher out-of-pocket costs.

Long-Acting Injectable ART

CAB/RPV, IBA, and LEN are ARVs with unique formulations and pharmacokinetic characteristics that allow for long-acting administration via intramuscular (IM) injection, intravenous (IV) infusion,

and SQ injection, respectively. IBA and LEN are approved for use among highly treatment-experienced people, typically in combination with an optimized background regimen consisting of at least one daily oral ARV drug product, and are associated with unique cost considerations. Conversely, monthly or bimonthly LA CAB/RPV injections can be prescribed and administered as a complete regimen replacement for daily oral ARV regimens.

Wholesale Acquisition Cost (WAC) prices for the LA CAB/RPV formulations are comparable to those of commonly prescribed oral regimens on an annual basis. However, long-acting HIV treatment options requiring administration by a licensed medical provider may be associated with costs not typically associated with oral ART, including clinic visit and administration fees, medical benefit determinations and prior authorization requirements, patient scheduling and follow-up to ensure adherence, upfront medication purchasing costs incurred by clinics, and inadequate "buy-and-bill" insurance reimbursements.

Cost-effectiveness modeling indicates that long-acting ART may be particularly advantageous for people struggling with adherence to daily oral regimens.[49-51] Studies have demonstrated that long-acting ART can achieve similar or better clinical outcomes than oral ART, particularly when adherence is factored into the equation. In cost terms, LA CAB/RPV may lead to lifetime savings, given lower health care expenditures associated with improved viral suppression and reduced risk of HIV transmission.

Costs and Cost-Effectiveness of ARV Regimens for Highly Treatment-Experienced People With Multidrug-Resistant HIV

For people with multidrug-resistant (MDR) HIV, an ARV regimen that includes IV IBA, SQ LEN, or oral fostemsavir can be effective in achieving viral suppression, though costly. Two cost-effectiveness analyses using independent simulation models have demonstrated that IBA-containing ARV regimens would substantially improve survival for people with MDR HIV, but at a high cost per quality-adjusted life years, given the high cost of IBA. However, the overall budget impact of such regimens would be relatively small, given the limited number of people for whom IBA would be necessary.[52,53]

340B Drug Pricing Program, Prescription Drug Affordability, and Program Savings for People With HIV

Created by Congress in 1992, the 340B Drug Discount Program requires pharmaceutical manufacturers to sell drugs at a discount to certain hospitals and federally funded clinics providing safety net care, including RWHAP providers and state/territorial ADAPs. 340B discounts help to ensure the affordability of outpatient prescription drugs for uninsured and underinsured people with HIV and to retain any revenue associated with discounted sales. This revenue, or program savings, is generated when 340B-covered entities are able to purchase discounted drugs but are reimbursed by third-party payers at usual and customary rates that do not account for discounted purchases. Although potentially incentivizing providers to prescribe higher-cost brand-name drugs that yield substantially greater revenue than generic alternatives, 340B savings can be used to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[54]

By purchasing ARV drugs and other essential medicines at significantly reduced prices, covered entities can reinvest savings into essential HIV care and support services, including case management, behavioral health care, offsetting uncompensated care, transportation, adherence support, and outreach efforts. These services can help improve HIV care retention, medication adherence, and viral suppression rates.[13]

Costs and Cost-Effectiveness of Routine Laboratory Services for People With HIV on ART

In the context of lifelong ART, the amount of money to be saved by reducing the frequency of expensive tests (e.g., genotypes, serologies) is modest. Even so, judicious use of laboratory testing, without compromising patient care, can still be an important way to reduce costs. For people with deductibles for laboratory tests, decreasing the use of tests with limited clinical value could reduce costs and improve adherence to a care plan. Several studies have examined the value of laboratory services in HIV care. One cost analysis study suggested that there may be no clinical benefit to continuing CD4 monitoring in people with suppressed viral loads and CD4 counts >200 cells/mm^3 after 48 weeks of therapy.[31] In the United States, reducing biannual CD4 monitoring to annual monitoring could save approximately $10 million per year.[55] Another study reviewed the records of 429 hospitalizations for 274 people with HIV during a 6-month period. The inpatient chart review demonstrated that 45% of ordered laboratory tests were not indicated, including hepatitis serologies, other serologies, and cytomegalovirus polymerase chain reaction. During this 6-month period at this single site, the estimated cost of excess and inappropriate laboratory testing totaled $14,000 to $92,000.[56]

Cost-effectiveness analyses from 2001 and 2005 demonstrated the value of genotypic resistance testing in people who are ART-experienced and ART-naive and supported the Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) recommendation to perform resistance testing before ART initiation and at the time of virologic failure.[57,58] More recent cost-effectiveness analyses have revisited the value of baseline, pre-treatment genotype testing in the setting of integrase strand transfer inhibitor (INSTI) plus two–nucleoside reverse transcriptase inhibitor (NRTI) regimens. One modeling study suggested that INSTI-specific genotype testing before initiation of a DTG plus two-NRTI regimen is not cost-effective and may lead to underutilization of INSTIs; the results highlighted that some people with minor INSTI resistance mutations would still become virologically suppressed on a DTG-based regimen.[59] A second modeling study found that standard (NRTI, non-nucleoside reverse transcriptase inhibitor, protease inhibitor) genotype testing before ART initiation also is not cost-effective because it may have little impact on outcomes, given the use of an INSTI plus two NRTIs in first-line treatment.[60] Both modeling studies assessed the use of genotype testing only for decision-making for initial ART and presumed that genotype testing would be available for use at the time of first-line failure. The results of these modeling studies suggest that additional clinical research is needed to define the role of genotypic resistance testing before initiation of an INSTI plus two-NRTI regimen. Importantly, these modeling data do not apply to the initiation of two-drug ARV regimens (e.g., DTG plus 3TC) or to people who have received oral (TDF or TAF) plus (3TC or FTC) or IM cabotegravir (CAB) as pre-exposure prophylaxis (PrEP), which are being prescribed increasingly in clinical practice. It should be noted that the Panel continues to recommend baseline testing for clinically relevant protease and reverse transcriptase mutations for most people, with additional genotypic resistance testing for integrase mutations for individuals with a history of CAB use for PrEP or an INSTI-based regimen for post-exposure prophylaxis (see Drug-Resistance Testing).

Costs and Cost-Effectiveness of Comprehensive HIV Care

Comprehensive person-centered HIV care offers substantial clinical benefits.[61] Such programs include the integration of social service needs and services for mental health, substance use disorders, sexual health, and age-associated multimorbidity (see Substance Use Disorders and HIV, Adherence to the Continuum of Care, and HIV and the Older Person). Integrated services can improve engagement in care and virologic suppression among people with HIV, but they require investment and resources. Several cost-effectiveness analyses have demonstrated that integrated

care programs can offer excellent value, especially if delivered to people at increased risk of disengagement in care.[62-64]

RWHAP provides a critical source of outpatient HIV clinical care for people with HIV who have low incomes and remain uninsured or underinsured under the ACA or who require wraparound support.[26] A recent cost-effectiveness analysis underscored the value of this safety net program and projected its clinical and cost impact over 50 years. Given higher rates of virologic suppression among people with HIV attending RWHAP clinics (compared with estimated virologic suppression in the absence of such supports), the analysis projects fewer HIV incident infections and longer life expectancy and demonstrates the cost-effectiveness of RWHAP.[21] RWHAP funds can be used to provide eligible individuals with services related to the delivery of HIV care, the treatment of related conditions, and support, as well as to address identified barriers to care. However, RWHAP funds cannot be used for inpatient care and services.[65]

Comprehensive HIV care and treatment often requires navigating a complex, dynamic patchwork of service delivery and both payer and financing mechanisms. Provider awareness of this patchwork, including the array of services available to people with HIV eligible for RWHAP, is therefore essential to maximizing clinical outcomes.

Conclusion

Ideally, costs should not drive clinical care, yet they are a factor in contemporary health care. Because regimen costs may affect people's ability to afford and adhere to therapy, understanding ART-related costs in the United States is increasingly important. Providers play a key role in ensuring optimal care while working to both (1) minimize costs for ARV drugs and avoid or minimize unnecessary laboratory monitoring and (2) retain excellent clinical outcomes in an environment of cost-containment strategies, including formulary restrictions, utilization management (e.g., prior authorization), and cost sharing. Providers should, therefore, remain informed of current insurance and payment structures, ART costs (see Table 22 below for estimates of average drug prices), out-of-pocket expenditure requirements, and available generic ARV options. Providers should work with people with HIV and pharmacists, social workers, case managers, financial service providers, and peer navigators to understand their clients' medication benefits and any potential financial hurdles to prescription fulfillment and full adherence. This information will help providers identify treatment options that are safe, effective, and affordable. Engaging people with HIV in discussions about cost constraints during regimen selection will likely facilitate adherence. Additionally, providers should familiarize themselves with ARV affordability resources (such as ADAPs and pharmaceutical company assistance programs for people who qualify) and refer them to such assistance if needed. Similarly, providers should help people with HIV to find comprehensive clinical care coverage when available and consider opportunities to integrate care when feasible.

Table 21. Insurance and Health Program Prescription Drug Pricing and Access

Insurance/Health Program	Prescription Drug Pricing and Access
Medicaid	Drug manufacturers must participate in the MDRP for their drugs to be covered by Medicaid and Medicare Part B. Manufacturers are required to pay Medicaid programs a rebate of at least 23.1% of the AMP for most brand-name drugs (13% for generics) sold to retail pharmacies or outpatient care providers (notably infused, injected, implanted, inhaled, or instilled drugs). Manufacturers pay additional rebates if this confidential AMP increases faster than the CPI-U rate of inflation. Additionally, many states negotiate with manufacturers for supplemental rebates. States are permitted to require "nominal" cost sharing for medical and pharmacy benefits for some beneficiaries, although many elect not to do so. States can obtain a waiver to allow them to apply higher cost sharing.
Medicare	ARVs are one of six "protected drug classes" under Medicare Part D. Part D plans must provide access to all, or substantially all, FDA-approved ARVs. Part D plan sponsors, or PBMs on their behalf, negotiate rebates on outpatient drugs with manufacturers; the extent of rebating is unclear. Most physician-administered drugs and biologics are covered under Medicare Part B at a set cost: ASP plus 6%. This pricing mechanism controls spending by narrowing the spread between what is actually paid for the drug and what is actually billed to Medicare. Premiums and cost-sharing payments may be significant for both services and prescription drugs, though caps on out-of-pocket spending for drugs covered by Medicare Part D went into effect in 2024; Part A (hospital care) and Part B place no cap on out-of-pocket spending. Some subsidies and supplemental coverage are offered for low-income beneficiaries. Manufacturer copay assistance programs cannot be applied to Part B or Part D cost sharing; cost-sharing support is available from ADAPs, foundations, and other sources and is based on financial eligibility criteria.
Commercial Insurance	Private insurance plans, or PBMs on their behalf, negotiate rebates on inpatient and outpatient drugs with manufacturers; the extent of rebating is unclear. Formulary restrictions and utilization management (prior authorization, step therapy, higher cost sharing) involving drugs and biologics covered under plans' pharmacy benefit or medical benefit (e.g., infused or injected ARVs) are possible cost-containment measures. Cost sharing can be highly variable. Manufacturer copay assistance programs can be applied in most cases but may not count toward annual ACA cost-sharing limits; cost-sharing support is also available from ADAPs, foundations, and other sources and is based on financial eligibility criteria.

Table 21. Insurance and Health Program Prescription Drug Pricing and Access

Insurance/Health Program	Prescription Drug Pricing and Access
ADAPs	Significant discounting on most ARVs negotiated by the ADAP Crisis Task Force is allowed under the 340B Drug Pricing Program. There is usually no cost sharing for ADAP clients who are uninsured. ADAP can assist with commercial or public insurance out-of-pocket costs.
Veterans Affairs	The FCP is the maximum price manufacturers may charge the four largest federal purchasers of pharmaceuticals (the "Big Four"): the U.S. Department of Veterans Affairs, U.S. Department of Defense, U.S. Public Health Service (including the Indian Health Service), and U.S. Coast Guard. The FCP of a drug includes a 24% discount on a drug's average price paid by nonfederal purchasers. Additional discounts may be applied if nonfederal purchase prices increase faster than the CPI-U inflation rate. Big Four prices may be 40% to 50% below list prices. Veterans Affairs may negotiate further price reductions. Prescription drug cost sharing is generally nominal; medications are not withheld from those who cannot afford cost-sharing expenses.
Community Health Centers	Many community health centers are enrolled in the 340B Drug Pricing Program, which allows discounted drug purchasing using the MDRP formula. Discounts start at 23.1% off AMP, with additional discounts if the AMP increases faster than the CPI-U rate of inflation. Cost sharing in community health centers is first driven by payer source. For clients who are uninsured, cost sharing, if required, is typically based on a sliding fee scale.
Jails and Prisons	Under the U.S. Constitution, correctional facilities have a legal obligation to provide necessary medical care, including prescription drugs, to incarcerated individuals.[a] Jails and prisons generally do not have access to discounted drugs available to government programs, such as Medicaid or "Big Four" purchasers (see Veterans Affairs above), but may benefit from centralized municipal or state purchasing mechanisms. Jails and prisons also may be able to purchase discounted ARV drugs and other medications under the 340B Drug Pricing Program, either as a recipient of certain federal funds associated with STI, HIV, and viral hepatitis prevention, or in partnership with other 340B-covered entities contracted to provide health care services to jailed or incarcerated individuals (e.g., disproportionate share hospital programs, community health centers). RWHAP programs and ADAPs also may provide time-limited HIV care and prescription drug access support for people with HIV in local prisons and jails.

Table 21. Insurance and Health Program Prescription Drug Pricing and Access

Insurance/Health Program	Prescription Drug Pricing and Access
Manufacturer and Charitable Prescription Drug Assistance Programs	Manufacturer PAPs are run by, or in association with, pharmaceutical companies to provide free or low-cost medications to people who meet certain eligibility requirements, including FPL-based income limits. A CAP is operated by manufacturers to provide assistance with cost-sharing requirements (including deductibles, copayments, and coinsurance) associated with prescription drug fills/refills for individuals with private health insurance. Pharmaceutical company CAPs cannot be used by individuals covered by Medicaid, Medicare, or other state and federal programs. Charitable third-party assistance programs, such as Patient Advocate Foundation Co-pay Relief, provide cost-sharing assistance to people who meet financial eligibility requirements. NASTAD maintains a number of PAP and CAP resources for use in clinical practice.

[a] *Estelle v. Gamble* [66]

Key: ACA = Affordable Care Act; ADAP = AIDS Drug Assistance Program; AMP = average manufacturer price; ARV = antiretroviral; ASP = average sales price; CAP = cost-sharing assistance program; CPI-U = consumer price index-urban; FCP = federal ceiling price; FDA = U.S. Food and Drug Administration; FPL = federal poverty level; NASTAD = National Alliance of State & Territorial AIDS Directors; MDRP= Medicaid Drug Rebate Program; PAP = patient assistance program; PBM = pharmacy benefits manager; RWHAP = Ryan White HIV/AIDS Program; STI = sexually transmitted infection

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

Table 22 includes three benchmark prices, rounded to the nearest dollar, for commonly used antiretroviral (ARV) drugs[a] as a general reference for health care providers when considering the cost of HIV treatment. Health care providers should contact pharmacies or payers regarding actual prices, comparative cost savings, formulary restrictions, and cost-sharing requirements. The **wholesale acquisition cost (WAC)** is the list price published by manufacturers for prescription drugs or biologics sold to wholesalers. The WAC price approximates what retail pharmacies pay wholesalers for single-source (e.g., brand-name) drugs. There is a range of WAC prices for generic ARV drugs, because these are multiple-source products with variable list prices. With increasing competition, actual transactional prices of generic drugs decrease substantially among wholesalers and pharmacies. **Average wholesale price (AWP)** has historically been used as the basis for setting public (e.g., Medicaid) and private (e.g., commercial insurer) reimbursement rates for pharmacies. Neither WAC nor AWP includes variable price concessions along supply and payment chains, including discounts and rebates to wholesalers, pharmacies, federal purchasers (e.g., the U.S. Department of Veterans Affairs), pharmacy benefit managers, commercial insurers, Medicaid, 340B pharmacies, and AIDS Drug Assistance Programs. The availability of these discounts and rebates depends on product demand, market competition, and WAC price increases set by manufacturers. Maximum Medicaid payment rates are assigned to generic products with three or more therapeutically and pharmaceutically equivalent products, as determined by the U.S. Food and Drug Administration. This federally established pharmacy reimbursement limit is the **federal upper limit (FUL).** Federal Medicaid will reimburse state Medicaid programs up to this limit for multiple-source drugs (plus the dispensing fee); states may set their own **state maximum allowable costs (SMACs)** and commercial insurers set their own reimbursement upper limits with pharmacies. Whereas WACs and AWPs are generally set annually, FULs are adjusted on a monthly basis, particularly for multiple-source drugs with fluctuating pharmacy acquisition costs. In this table, the FUL for a drug is described as "pending" if a generic drug currently lacks the competition required to trigger a FUL.

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
NRTIs					
Abacavir Generic	300-mg tablet	60 tablets	$100 to $150	$578 to $603	$22
Emtricitabine • Generic, *or* • Emtriva	200-mg capsule	30 capsules	*Generic* • $390 to $536 *Emtriva* • $537	*Generic* • $482 to $644 *Emtriva* • $644	Pending

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
Lamivudine • Generic, *or* • Epivir	300-mg tablet	30 tablets	*Generic* • $40 to $415 *Epivir* • $416	*Generic* • $429 *Epivir* • $499	*Generic* • $72 *Epivir* • N/A
Tenofovir Disoproxil Fumarate • Generic, *or* • Viread	300-mg tablet	30 tablets	*Generic* • $27 to $300 *Viread* • $1,254	*Generic* • $167 to $1,216 *Viread* • $1,504	*Generic* • $23 *Viread* • N/A
Zidovudine Generic	300-mg tablet	60 tablets	$36 to $54	$54 to $365	$13
NRTI Combination Products					
Abacavir + Lamivudine Generic	600-mg/300-mg tablet	30 tablets	$100 to $302	$1,393 to $1,395	$51
Tenofovir Alafenamide + Emtricitabine Descovy	25-mg/200-mg tablet	30 tablets	$2,202	$2,643	N/A
Tenofovir Disoproxil Fumarate + Emtricitabine • Generic, *or* • Truvada	300-mg/200-mg tablet	30 tablets	*Generic* • $25 to $853 *Truvada* • $1,842	*Generic* • $70 to $2,100 *Truvada* • $2,211	*Generic* • $67 *Truvada* • N/A
Tenofovir Disoproxil Fumarate + Lamivudine Cimduo	300-mg/300-mg tablet	30 tablets	$1,185	$1,422	N/A
Zidovudine + Lamivudine Generic	300-mg/150-mg tablet	60 tablets	$125 to $578	$265 to $932	$36

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
NNRTIs					
Efavirenz Generic	600-mg tablet	30 tablets	$80 to $894	$1,043 to $1,118	$40
Doravirine Pifeltro	100-mg tablet	30 tablets	$1,840	$2,208	N/A
Etravirine • Generic, *or* • Intelence	200-mg tablet	60 tablets	*Generic* • $1,287 *Intelence* • $1,498	*Generic* • $1,609 *Intelence* • $1,797	*Generic* • $842 *Intelence* • N/A
Nevirapine • Generic, *or* • Generic XR	*Generic* • 200-mg tablet *Generic XR* • 400-mg tablet	*Generic* • 60 tablets *Generic XR* • 30 tablets	*Generic* • $10 to $45 *Generic XR* • $135 to $565	*Generic* • $648 to $651 *Generic XR* • $595 to $706	*Generic* • $7 *Generic XR* • $149
Rilpivirine Edurant	25-mg tablet	30 tablets	$1,483	$1,780	N/A
PIs					
Atazanavir • Generic, *or* • Reyataz	200-mg capsule, *or* 300-mg capsule	*200-mg capsule* • 60 capsules *300-mg capsule* • 30 capsules	*Generic 200 mg* • $178 to $316 *Reyataz 200 mg* • $1,463 *Generic 300 mg* • $178 to $316 *Reyataz 300 mg* • $1,449	*Generic 200 mg* • $1,502 to $1,668 *Reyataz 200 mg* • $1,756 *Generic 300 mg* • $1,502 to $1,652 *Reyataz 300 mg* • $1,739	*Generic 200 mg* • $146 *Generic 300 mg* • $192 *Reyataz* • N/A

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
Atazanavir + Cobicistat Evotaz	300-mg/150-mg tablet	30 tablets	$1,605	$1,927	N/A
Darunavir • Generic, *or* • Prezista	*Generic* • 600-mg tablet • 800-mg tablet *Prezista* • 600-mg tablet • 800-mg tablet • 100-mg/mL suspension	*600-mg tablets* • 60 tablets *800-mg tablets* • 30 tablets *100-mg/mL suspension* • 200 mL	*Generic 600 mg* • $60 to $1,145 *Prezista 600 mg* • $2,158 *Generic 800 mg* • $60 to $1,153 *Prezista 800 mg* • $2,158 *Prezista suspension* • $1,199	*Generic 600 mg* • $1,373 to $2,388 *Prezista 600 mg* • $2,590 *Generic 800 mg* • $1,384 to $2,388 *Prezista 800 mg* • $2,590 *Prezista suspension* • $1,439	*Generic 600 mg* • Pending *Generic 800 mg* • Pending *Prezista* • N/A
Darunavir + Cobicistat Prezcobix	800-mg/150-mg tablet	30 tablets	$2,467	$2,960	N/A
Lopinavir + Ritonavir • Generic, *or* • Kaletra	200-mg/50-mg tablet	120 tablets	*Generic* • $885 *Kaletra* • $1,024	*Generic* • $1,106 *Kaletra* • $1,229	*Generic* • $747 *Kaletra* • N/A
Tipranavir Aptivus	250-mg capsule	120 capsules	$2,054	$2,466	N/A
INSTIs					
Dolutegravir Tivicay	50-mg tablet	30 tablets, *or* 60 tablets	*30 tablets* • $2,325 *60 tablets* • $4,650	*30 tablets* • $2,790 *60 tablets* • $5,580	N/A

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
Raltegravir • Isentress, *or* • Isentress HD	*Isentress* • 400-mg tablet *Isentress HD* • 600-mg tablet	60 tablets	*Isentress* • $2,083 *Isentress HD* • $2,083	*Isentress* • $2,500 *Isentress HD* • $2,500	N/A
Capsid Inhibitor					
Lenacapavir Sunlenca	300-mg tablet, *or* 927-mg injection kit	*300-mg tablet* • 4 tablets • 5 tablets *Injection kit* • 2 vials (1 kit every 6 months)	*Four 300-mg tablets* • $3,250 *Five 300-mg tablets* • $4,063 *Injection kit* • $19,500 (every 6 months)	*Four 300-mg tablets* • $3,900 *Five 300-mg tablets* • $4,875 *Injection kit* • $23,400 (every 6 months)	N/A
CCR5 Antagonist					
Maraviroc • Generic, *or* • Selzentry	150-mg tablet, *or* 300-mg tablet	*Generic* • 60 tablets *Selzentry* • 60 tablets • 120 tablets (300 mg)	*Generic 150 mg* • $700 *Selzentry 150 mg* • $1,730 *Generic 300 mg* • $700 *Selzentry 300 mg (60 tablets)* • $1,730 *Selzentry 300 mg (120 tablets)* • $3,460	*Generic 150 mg* • $1,764 *Selzentry 150 mg* • $2,076 *Generic 300 mg* • $1,764 *Selzentry 300 mg (60 tablets)* • $2,076 *Selzentry 300 mg (120 tablets)* • $4,152	*Generic 150 mg* • $1,382 *Generic 300 mg* • $1,148 *Selzentry* • N/A

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
CD4-Directed Post-Attachment Inhibitor					
Ibalizumab-uiyk Trogarzo	200-mg vial	8 vials	$12,196	$14,635	N/A
gp120-Directed Attachment Inhibitor					
Fostemsavir Rukobia	600-mg tablet	60 tablets	$9,280	$11,136	N/A
Coformulated Combination Products as Single-Tablet Regimens					
Bictegravir + Tenofovir Alafenamide + Emtricitabine Biktarvy	50-mg/25-mg/200-mg tablet	30 tablets	$4,216	$5,059	N/A
Darunavir + Cobicistat + Tenofovir Alafenamide + Emtricitabine Symtuza	800-mg/150-mg/10-mg/200-mg tablet	30 tablets	$4,717	$5,660	N/A
Dolutegravir + Abacavir + Lamivudine Triumeq	50-mg/600-mg/300-mg tablet	30 tablets	$3,897	$4,677	N/A
Dolutegravir + Lamivudine Dovato	50-mg/300-mg tablet	30 tablets	$3,096	$3,715	N/A
Dolutegravir + Rilpivirine Juluca	50-mg/25-mg tablet	30 tablets	$3,653	$4,383	N/A

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
Doravirine + Tenofovir Disoproxil Fumarate + Lamivudine Delstrigo	100-mg/300-mg/300-mg tablet	30 tablets	$2,800	$3,361	N/A
Efavirenz + Tenofovir Disoproxil Fumarate + Emtricitabine Generic	600-mg/300-mg/200-mg tablet	30 tablets	$82 to $252	$302 to $3,414	$51
Efavirenz + Tenofovir Disoproxil Fumarate + Lamivudine Symfi	*Symfi* • 600-mg/300-mg/150-mg tablet	30 tablets	$1,926	$2,312	N/A
Elvitegravir + Cobicistat + Tenofovir Alafenamide + Emtricitabine Genvoya	150-mg/150-mg/10-mg/200-mg tablet	30 tablets	$4,216	$5,059	N/A
Elvitegravir + Cobicistat + Tenofovir Disoproxil Fumarate + Emtricitabine Stribild	150-mg/150-mg/300-mg/200-mg tablet	30 tablets	$4,423	$5,307	N/A
Rilpivirine + Tenofovir Alafenamide + Emtricitabine Odefsey	25-mg/25-mg/200-mg tablet	30 tablets	$3,840	$4,604	N/A
Rilpivirine + Tenofovir Disoproxil Fumarate + Emtricitabine Complera	25-mg/300-mg/200-mg tablet	30 tablets	$3,837	$4,604	N/A

Table 22. Monthly Average Prices of Commonly Used Antiretroviral Drugs

ARV Drug (Generic and Brand Names)	**Strength, Formulation**	**Tablets, Capsules, Vials, or mLs** (Monthly, Unless Otherwise Noted)	**WAC** (Monthly, Unless Otherwise Noted)[b]	**AWP** (Monthly, Unless Otherwise Noted)[b]	**FUL** (As of April 30, 2025)[c]
Copackaged Combination Products as Injectable Regimens					
Cabotegravir + Rilpivirine Cabenuva	*3 mL* • 600 mg • 900 mg *2 mL* • 400 mg • 600 mg	*3 mL* • 2 vials (every other month) *2 mL* • 2 vials	*3 mL* • $6,789 (every other month) *2 mL* • $4,526	*3 mL* • $8,147 (every other month) *2 mL* • $5,431	N/A
PK Enhancers (Boosters)					
Cobicistat Tybost	150-mg tablet	30 tablets	$315	$378	N/A
Ritonavir • Generic, *or* • Norvir	100-mg tablet	30 tablets	*Generic* • $80 to $160 *Norvir* • $257	*Generic* • $278 *Norvir* • $309	*Generic* • $51 *Norvir* • N/A

[a] The following less commonly used ARV drugs are not included in this table: fosamprenavir and nelfinavir.
[b] **Source:** Micromedex Red Book [database]. Merative. 2025. Available at: https://www.micromedexsolutions.com.
[c] **Source:** Federal Upper Limits–May 2025 [database]. Centers for Medicare & Medicaid Services. 2025. Available at: https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html.

Key: ARV = antiretroviral; AWP = average wholesale price; CD4 = CD4 T lymphocyte; FUL = federal upper limit; HD = high dose; INSTI = integrase strand transfer inhibitor; N/A = not applicable; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; PI = protease inhibitor; PK = pharmacokinetic; WAC = wholesale acquisition cost; XR = extended release

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