Cost Considerations and Antiretroviral Therapy

Updated: September 21, 2022
Reviewed: September 21, 2022

The clinical benefits, public health impact, and cost-effectiveness of HIV treatment have been well established since the advent of combination antiretroviral therapy (ART),[1-6] and the expanded use of 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 2015 study using 2012 health care expenditure data estimated that the discounted lifetime medical costs for an individual who acquires HIV at 35 years of age is $326,500 ($597,300 undiscounted), with 60% of the costs attributable to ART.[9] The estimated total direct expenditure for HIV/AIDS care and treatment between 2002 and 2011 was $10.7 billion annually, which is 800% to 900% higher than similar expenditures for other chronic conditions.[10] These guidelines first included an antiretroviral (ARV) cost table in 2012,[11] and since then, the overall cost of brand-name, first-line ARV regimens has increased by more than 30% from 2012 to 2018,[12] which is 3.5 times the rate of inflation for that same time period. Total annual undiscounted spending on ARV drugs has more than doubled since 2010, reaching $22.5 billion in 2018.[13,14] Consequently, ART was among the top five therapeutic classes in nondiscounted spending on medications in 2018, after medications for diabetes, autoimmune diseases, cancer, and respiratory disorders.[14]

This section provides guidance on cost considerations related to HIV clinical care. The cost of ART, especially out-of-pocket costs to the patient, should be one of the many considerations in regimen selection, because such expenditures may directly affect adherence. Overall costs to the health care system, to insurers, and to 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 prevent cost from limiting HIV care.

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 22b below). Additionally, provider-administered drugs and biologics, including those used in the management of HIV (e.g., intramuscular injections of long-acting cabotegravir [CAB] and rilpirivine [RPV]), are typically associated with product, administration, and/or office visit costs. Providers may, therefore, find it difficult to navigate payer cost-containment practices, including formulary restrictions, prior authorization requirements, and patient 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 patients can be prohibitive, creating a barrier to the initiation and continuation of ART. Cost sharing results in higher rates of patients not initiating ART, prescription abandonment at the pharmacy, decreased adherence, and more frequent drug discontinuation. In turn, these may lead to worse health outcomes and an increased use of the medical system, especially among patients with chronic diseases.[15-20] Conversely, reducing patient out-of-pocket costs (e.g., through manufacturer copayment-assistance programs or by prescribing generic drugs instead of more costly brand-name products) has been associated with improved adherence.[21] Given the clear

association between out-of-pocket costs and the ability to pay for and adhere to medications, clinicians should minimize patients' out-of-pocket drug-related expenses whenever possible. However, many of the cost-sharing arrangements that determine out-of-pocket costs are not transparent to clinicians or patients at the time decisions on ART are made.

Maximum allowable copayments on prescription drugs covered by Medicaid can vary by family income, but they are usually nominal. For commercial insurers, cost sharing generally is subject to maximum payment rules under the Affordable Care Act (ACA). 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 patient's deductible or out-of-pocket maximum.

Medicare Part D plan cost sharing can include deductibles and copayments or coinsurance, including out-of-pocket payments of up to 25% on prescription drugs, until total out-of-pocket spending reaches $6,550.[22-24] Medicare Part B cost sharing on provider-administered drugs, such as long-acting injectable CAB and RPV or ibalizumab-uiyk (IBA) infusions, can be up to 20% of all medication costs.[25] 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. Manufacturer copay assistance programs may not be applied toward Medicare plan cost sharing, but assistance from independent foundations (e.g., Patient Access Network Foundation, Patient Advocate Foundation) may provide cost-sharing support if financial eligibility criteria are met.

AIDS Drug Assistance Programs (ADAPs), through the Ryan White HIV/AIDS Program (RWHAP), make ARVs and other prescription drugs accessible to people with HIV who are underinsured and have limited financial resources. Furthermore, many ADAPs provide premium and cost-sharing assistance to eligible clients covered by Medicaid, commercial insurance plans, or Medicare.[26]

Generic Antiretrovirals and Multi-Tablet Regimens

In 2017, savings to the U.S. health care system generated from the use of generic drugs and biosimilar products totaled $265 billion, including $40.6 billion and $82.7 billion in savings to Medicaid and Medicare, respectively.[27]

With substantial improvements in the long-term safety and effectiveness of contemporary ART, a number of regimens and regimen components in Table 6 remain listed beyond their patent protection date and are or will be available as lower-cost generic options. In one study, the savings associated with a transition to a hypothetical lower-cost generic ART could potentially help cover the 20-year, $480 billion projected costs to reach national treatment targets.[5]

Some research informs the cost impact of using specific generic ARV regimens or regimen components. In a cost-effectiveness analysis conducted before the availability of integrase strand transfer inhibitors (INSTIs), the use of generic efavirenz (EFV) had an estimated saving of nearly $1 billion, and a regimen with generic EFV was very cost-effective.[2] A more recent study describes a 25% reduction in both the wholesale acquisition cost (WAC) and federal supply schedule cost associated with switching from branded coformulated dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) to branded DTG plus generic ABC and generic 3TC.[2,28]

A number of generic options of ARV regimen components included in Table 6 are commercially available. Generic tenofovir disoproxil fumarate (TDF), generic 3TC, or a lower-cost, brand-name coformulation of TDF and 3TC may be combined with DTG, darunavir, or other ARVs. Generic versions of ABC, 3TC, and ABC/3TC also can be used. Generic versions of EFV, atazanavir, and ritonavir are available for use, along with lower-cost, brand-name coformulations of EFV (either 600 mg or 400 mg) with TDF and 3TC. TDF and 3TC also have been coformulated with doravirine, with a list price that is moderately lower than other single-tablet regimens (STRs) containing only proprietary ARVs (see Table 22b below).

There is keen interest in assessing the economic value of using newer, more expensive drugs compared with older, less expensive drugs that have established clinical safety and efficacy. One study investigated the cost-effectiveness of TDF-based versus tenofovir alafenamide (TAF)-based regimens.[22] The study demonstrated that the similar efficacy—but slightly improved toxicity profile—of the TAF-based regimens would justify a $1,000 higher annual premium for the TAF-based regimens. The study further highlighted that once generic TDF becomes available at much lower costs, TAF-based regimens will remain cost-effective only if their annual cost is no more than $1,000 above that of generically available TDF-based regimens. (Generic TDF was approved in 2018.)

The use of DTG plus generic 3TC for initial therapy has been evaluated in a cost-containment analysis. One study projected that if just 50% of patients 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.[29] If 25% of patients with sustained viral suppression switched to branded DTG plus generic 3TC maintenance therapy, cost savings were projected to exceed $3 billion in just 5 years.[29]

Because all commercially available STRs, including those containing ARV components that are no longer patent protected, are branded products, 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 (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.[30] 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.[17,18] 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.[31] In this study, the time to treatment discontinuation was shorter for non-STRs than for STR once-daily 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 to DTG plus ABC/3TC, both when used as an initial ARV regimen and when persons with viral suppression on STR were switched to the two-pill formulation as a cost-saving strategy.[32]

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.

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 intravenous IBA 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-year, 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.[33,34]

Laboratory Services

In the context of lifelong ART, the amount of money to be saved by performing infrequent or one-time tests (e.g., genotypes, serologies) is modest, even for expensive tests. Even so, judicious use of laboratory testing, without compromising patient care, can still be an important way to reduce costs. For patients with deductibles for laboratory tests, decreasing the use of tests with limited clinical value could reduce patient 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 T lymphocyte (CD4) monitoring in patients with suppressed viral loads and CD4 counts >200 cells/mm^3 after 48 weeks of therapy.[19] In the United States, reducing biannual CD4 monitoring to annual monitoring could save approximately $10 million per year.[35] Another study reviewed the records of 429 hospitalizations for 274 patients 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.[36]

Cost-effectiveness analyses from 2001 and 2005 demonstrated the value of genotypic resistance testing in ART-experienced and ART-naive patients and supported the Panel on Antiretroviral Guidelines for Adults and Adolescents (the Panel) recommendation to perform resistance testing before ART initiation and at time of virologic failure.[37,38] More recent cost-effectiveness analyses have revisited the value of baseline, pre-treatment genotype testing in the setting of 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 was not cost-effective and may lead to underutilization of INSTIs; the results highlighted that some patients with minor INSTI resistance mutations would still become virologically suppressed on a DTG-based regimen.[39] A second modeling study found that standard (NRTI, non-nucleoside reverse transcriptase inhibitor, protease inhibitor) genotype testing before ART initiation also was not cost-effective, because it may have little impact on outcomes given the use of an INSTI plus two NRTIs in first-line

treatment.[40] Both these modeling studies assessed the use of genotype testing only for decision-making for initial ART and presumed that such 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 2-NRTI regimen. Importantly, these modeling data do not apply to the initiation of two-drug ARV regimens (i.e., DTG plus 3TC) or to people who have received 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 patients, with additional genotypic resistance testing for integrase mutations for individuals with a history of CAB use for PrEP (see Drug-Resistance Testing).

Costs and Cost-effectiveness of Comprehensive HIV Care

Comprehensive patient-centered HIV care offers substantial clinical benefits.[41] Such programs include 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, Transgender People with 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.[42-44]

Health care access in the United States can be inequitable and limited, depending on location and income. Although the ACA has substantially improved access to HIV clinical services in many regions of the United States since 2010, an estimated 36% of people with HIV in the United States live in the 11 states that had not expanded Medicaid in accordance with the ACA as of August 2020.[26]

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.[45] However, because RWHAP is focused on HIV care and support services, people with HIV who have other important outpatient and inpatient health needs may experience underdiagnosis and undertreatment if patients cannot pay the out-of-pocket costs of clinical care.

Comprehensive HIV care and treatment often requires navigating a complex, dynamic patchwork of service delivery and 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 patient outcomes.

Conclusion

Ideally, costs should not drive clinical care, yet they are a factor in contemporary health care. Because regimen costs may affect patients' 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 22b below for estimates of average drug prices), out-of-pocket expenditure requirements, and available generic ARV options. Providers should work with patients and their pharmacists, social workers, case managers, and peer navigators to understand their patients' medication benefits and any potential financial barriers to prescription fulfillment and full adherence. This information will help providers identify treatment options that are safe, effective, and affordable. Engaging with patients about cost constraints during the process of regimen selection will likely facilitate adherence. Additionally, providers should familiarize themselves with ARV affordability resources (such as ADAP and pharmaceutical company assistance programs for patients who qualify) and refer patients to such assistance if needed. Similarly, providers should help patients find comprehensive clinical care coverage when available and consider opportunities to integrate care when feasible.

Table 22a. 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 under 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; 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.

Table 22a. Insurance and Health Program Prescription Drug Pricing and Access

	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.
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 Department of Veterans Affairs (VA), Department of Defense, Public Health Service (including the Indian Health Service), and the Coast Guard. The FCP of a drug includes a 24% discount on a drug's average price paid by non-federal purchasers. Additional discounts may be applied if non-federal purchase prices increase faster than the CPI-U inflation rate. Big Four prices may be 40% to 50% below list prices. The VA 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.

Key: ACA = Affordable Care Act; ADAP = AIDS Drug Assistance Program; AMP = average manufacturer price; ARV = antiretroviral; ASP = average sales price; CPI-U = consumer price index-urban; FCP = federal ceiling price; FDA = U.S. Food and Drug Administration; MDRP = Medicaid Drug Rebate Program; PBM = pharmacy benefits manager

Table 22b. Monthly Average Prices of Commonly Used Antiretroviral Drugs

Table 22b includes three benchmark prices, rounded to the nearest dollar, for commonly used ARV drugs[a] as a general reference for health care providers when considering the cost of HIV treatment. Health care providers should contact patients' pharmacies or payers regarding actual prices, comparative cost savings, formulary restrictions, and patient cost-sharing requirements. **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. **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 Department of Veterans Affairs), pharmacy benefit managers, commercial insurers, Medicaid, 340B pharmacies, and ADAPs. 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 **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 **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, or mLs per Month	WAC (Monthly)[b]	AWP (Monthly)[b]	FUL (As of Apr. 1, 2022)[c]
NRTIs					
Abacavir					
• Generic	300-mg tablet	60 tablets	$100 to $150	$578 to $603	$52
• Ziagen	300-mg tablet	60 tablets	$559	$670	
Emtricitabine					
• Generic	200-mg capsule	30 capsules	$464	$579	Pending
• Emtriva	200-mg capsule	30 capsules	$537	$644	

Table 22b. Monthly Average Prices of Commonly Used Antiretroviral Drugs

Lamivudine					
• Generic	300-mg tablet	30 tablets	$75 to $343	$324 to $430	$39
• Epivir	300-mg tablet	30 tablets	$416	$499	
Tenofovir Disoproxil Fumarate					
• Generic	300-mg tablet	30 tablets	$27 to $142	$167 to $1,216	$53
• Viread	300-mg tablet	30 tablets	$1,254	$1,504	
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	$185 to $1,116	$1,393 to $1,395	$138
• Epzicom	600-mg/300-mg tablet	30 tablets	$1,292	$1,550	
Tenofovir Alafenamide/Emtricitabine					
• Descovy	25-mg/200-mg tablet	30 tablets	$2,039	$2,447	N/A
Tenofovir Disoproxil Fumarate/Emtricitabine					
• Generic	300-mg/200-mg tablet	30 tablets	$25 to $853	$70 to $2,100	$28
• Truvada	300-mg/200-mg tablet	30 tablets	$1,842	$2,211	
Tenofovir Disoproxil Fumarate/Lamivudine					
• Cimduo	300-mg/300-mg tablet	30 tablets	$1,055	$1,266	N/A
Zidovudine/Lamivudine					
• Generic	300-mg/150-mg tablet	60 tablets	$125 to $578	$265 to $932	$40
• Combivir	300-mg/150-mg tablet	60 tablets	$901	$1,082	
Abacavir Sulfate/Zidovudine/Lamivudine					
• Trizivir	300-mg/300-mg/150-mg tablet	60 tablets	$1,610	$1,932	N/A
NNRTIs					
Efavirenz					

Table 22b. Monthly Average Prices of Commonly Used Antiretroviral Drugs

• Generic	600-mg tablet	30 tablets	$80 to $980	$1,073 to $1,117	$193
• Sustiva	600-mg tablet	30 tablets	$981	$1,177	
Doravirine					
• Pifeltro	100-mg tablet	30 tablets	$1,597	$1,917	N/A
Etravirine					
• Generic	200-mg tablet	60 tablets	$1,287	$1,609	Pending
• Intelence	200-mg tablet	60 tablets	$1,439	$1,728	
Nevirapine					
• Generic	200-mg tablet	60 tablets	$10 to $45	$648 to $651	$47
• Generic XR	400-mg tablet	30 tablets	$135 to $565	$595 to $706	$149
• Viramune XR	400-mg tablet	30 tablets	$840	$1,008	
Rilpivirine					
• Edurant	25-mg tablet	30 tablets	$1,286	$1,543	N/A
PIs					
Atazanavir					
• Generic	200-mg capsule	60 capsules	$178 to $800	$1,517 to $1,668	$711
• Reyataz	200-mg capsule	60 capsules	$1,463	$1,756	
• Generic	300-mg capsule	30 capsules	$178 to $1,018	$1,502 to $1,652	$270
• Reyataz	300-mg capsule	30 capsules	$1,449	$1,739	
Atazanavir/Cobicistat					
• Evotaz	300-mg/150-mg tablet	30 tablets	$1,605	$1,927	N/A
Darunavir					
• Prezista	600-mg tablet	60 tablets	$1,948	$2,338	N/A
• Prezista	800-mg tablet	30 tablets	$1,948	$2,338	N/A
• Prezista	100-mg/mL suspension	200 mL	$1,948	$2,338	N/A
Darunavir/Cobicistat					
• Prezcobix	800-mg/150-mg tablet	30 tablets	$2,227	$2,673	N/A

Table 22b. Monthly Average Prices of Commonly Used Antiretroviral Drugs

Lopinavir/Ritonavir					
• Generic	200-mg/50-mg tablet	120 tablets	$885	$1,106	Pending
• Kaletra	200-mg/50-mg tablet	120 tablets	$1,024	$1,229	
Tipranavir					
• Aptivus	250-mg capsule	120 capsules	$1,918	$2,302	N/A
INSTIs					
Dolutegravir					
• Tivicay	50-mg tablet	30 tablets	$2,011	$2,414	N/A
• Tivicay	50-mg tablet	60 tablets	$4,022	$4,828	N/A
Raltegravir					
• Isentress	400-mg tablet	60 tablets	$1,821	$2,186	N/A
• Isentress HD	600-mg tablet	60 tablets	$1,821	$2,186	N/A
Fusion Inhibitor					
Enfuvirtide					
• Fuzeon	90-mg injection kit	60 doses (1 kit)	$3,586	$4,303	N/A
CCR5 Antagonist					
Maraviroc					
• Selzentry	150-mg tablet	60 tablets	$1,633	$1,960	N/A
• Selzentry	300-mg tablet	60 tablets	$1,633	$1,960	N/A
• Selzentry	300-mg tablet	120 tablets	$3,366	$3,920	N/A
CD4-Directed Post-Attachment Inhibitor					
Ibalizumab-uiyk					
• Trogarzo	200-mg vial	8 vials	$10,704	$12,845	N/A
gp120-Directed Attachment Inhibitor					
Fostemsavir					
• Rukobia	600-mg tablet	60 tablets	$8,027	$9,633	N/A

Table 22b. Monthly Average Prices of Commonly Used Antiretroviral Drugs

Coformulated Combination Products as Single-Tablet Regimens					
Bictegravir/Tenofovir Alafenamide/Emtricitabine					
• Biktarvy	50-mg/25-mg/200-mg tablet	30 tablets	$3,584	$4,301	N/A
Darunavir/Cobicistat/Tenofovir Alafenamide/Emtricitabine					
• Symtuza	800-mg/150-mg/10-mg/200-mg tablet	30 tablets	$4,292	$5,151	N/A
Dolutegravir/Abacavir/Lamivudine					
• Triumeq	50-mg/600-mg/300-mg tablet	30 tablets	$3,339	$4,007	N/A
Dolutegravir/Lamivudine					
• Dovato	50-mg/300-mg tablet	30 tablets	$2,652	$3,183	N/A
Dolutegravir/Rilpivirine					
• Juluca	50-mg/25-mg tablet	30 tablets	$3,129	$3,755	N/A
Doravirine/Tenofovir Disoproxil Fumarate/Lamivudine					
• Delstrigo	100-mg/300-mg/300-mg tablet	30 tablets	$2,431	$2,917	N/A
Efavirenz/Tenofovir Disoproxil Fumarate/Emtricitabine					
• Generic	600-mg/300-mg/200-mg tablet	30 tablets	$120 to $252	$302 to $3,414	$144
• Atripla	600-mg/300-mg/200-mg tablet	30 tablets	$2,995	$3,594	
Efavirenz/Tenofovir Disoproxil Fumarate/Lamivudine					
• Symfi	600-mg/300-mg/150-mg tablet	30 tablets	$1,715	$2,057	N/A
• Symfi Lo	400-mg/300-mg/150-mg tablet	30 tablets	$1,715	$2,057	N/A
Elvitegravir/Cobicistat/Tenofovir Alafenamide/Emtricitabine					
• Genvoya	150-mg/150-mg/10-mg/200-mg tablet	30 tablets	$3,584	$4,301	N/A
Elvitegravir/Cobicistat/Tenofovir Disoproxil Fumarate/Emtricitabine					
• Stribild	150-mg/150-mg/300-mg/ 200-mg tablet	30 tablets	$3,759	$4,511	N/A
Rilpivirine/Tenofovir Alafenamide/Emtricitabine					
• Odefsey	25-mg/25-mg/200-mg tablet	30 tablets	$3,262	$3,914	N/A
Rilpivirine/Tenofovir Disoproxil Fumarate/Emtricitabine					
• Complera	25-mg/300-mg/200-mg tablet	30 tablets	$3,362	$3,914	N/A

Table 22b. Monthly Average Prices of Commonly Used Antiretroviral Drugs

Copackaged Combination Products as Injectable Regimens					
Cabotegravir + Rilpivirine					
• Cabenuva	600 mg (3 mL) 900 mg (3 mL)	2 vials	$6,088	$7,306	NA
• Cabenuva	400 mg (2 mL) 600 mg (2 mL)	2 vials	$4,059	$4,871	NA
PK Enhancers (Boosters)					
Cobicistat					
• Tybost	150-mg tablet	30 tablets	$268	$321	N/A
Ritonavir					
• Generic	100-mg tablet	30 tablets	$80 to $160	$278	$67
• Norvir	100-mg tablet	30 tablets	$257	$309	

[a] The following less commonly used ARV drugs are not included in this table: fosamprenavir and nelfinavir.

[b] Source: Micromedex Red Book [database]. IBM Watson Health. 2022. Available at: https://www.micromedexsolutions.com

[c] Source: Federal Upper Limits–March 2022 [database]. Medicare & Medicaid Services. 2022. Available at: https://www.medicaid.gov/medicaid/prescription-drugs/pharmacy-pricing/index.html

Key: ADAP = AIDS Drug Assistance Program; 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; SMAC = state maximum allowable cost; WAC = wholesale acquisition cost; XR = extended release

References

1. Freedberg KA, Losina E, Weinstein MC, et al. The cost effectiveness of combination antiretroviral therapy for HIV disease. *N Engl J Med*. 2001;344(11):824-831. Available at: https://www.ncbi.nlm.nih.gov/pubmed/11248160.

2. Walensky RP, Sax PE, Nakamura YM, et al. Economic savings versus health losses: the cost-effectiveness of generic antiretroviral therapy in the United States. *Ann Intern Med*. 2013;158(2):84-92. Available at: http://www.ncbi.nlm.nih.gov/pubmed/23318310.

3. Bayoumi AM, Barnett PG, Joyce VR, et al. Cost-effectiveness of newer antiretroviral drugs in treatment-experienced patients with multidrug-resistant HIV disease. *J Acquir Immune Defic Syndr*. 2013;64(4):382-391. Available at: http://www.ncbi.nlm.nih.gov/pubmed/24129369.

4. Holmes C, Hallett T, Walensky R, Bärnighausen T, Pillay Y, Cohen M. Effectiveness and cost-effectiveness of treatment as prevention for HIV. Vol. 3 ed. Washington (DC): The World Bank; 2017.

5. Borre ED, Hyle EP, Paltiel AD, et al. The clinical and economic impact of attaining National HIV/AIDS Strategy treatment targets in the United States. *J Infect Dis*. 2017;216(7):798-807. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29029344.

6. Walensky RP, Ross EL, Kumarasamy N, et al. Cost-effectiveness of HIV treatment as prevention in serodiscordant couples. *N Engl J Med*. 2013;369(18):1715-1725. Available at: https://www.ncbi.nlm.nih.gov/pubmed/24171517.

7. Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV Epidemic: A Plan for the United States. *JAMA*. 2019;321(9):844-845. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30730529.

8. U.S. Department of Health and Human Services. What is *Ending the HIV Epidemic in the U.S.*? 2021. Available at: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview.

9. Schackman BR, Fleishman JA, Su AE, et al. The lifetime medical cost savings from preventing HIV in the United States. *Med Care*. 2015;53(4):293-301. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25710311.

10. Ritchwood TD, Bishu KG, Egede LE. Trends in healthcare expenditure among people living with HIV/AIDS in the United States: evidence from 10 years of nationally representative data. *Int J Equity Health*. 2017;16(1):188. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29078785.

11. U.S. Department of Health and Human Services. Adult and adolescent ARV archived guidelines. Available at: https://clinicalinfo.hiv.gov/en/guidelines/archived-guidelines/adult-and-adolescent-guidelines.

12. McCann NC, Horn TH, Hyle EP, Walensky RP. HIV antiretroviral therapy costs in the United States, 2012–2018. *JAMA Intern Med*. 2020;180(4):601-603. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32011622.

13. Aitken M, Kleinrock M, Lyle J, Nass D, Caskey L. Medicines use and spending shifts: a review of the use of medicines in the U.S. in 2014. IMS Institute for Healthcare Informatics; 2015. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicines-use-and-spending-shifts-in-the-us-in-2014.pdf?la=en&hash=34E4E2AD15D82812DD3FAA229854A0E9. Accessed: July 7, 2022.

14. IQVIA. Medicine use and spending in the U.S.: a review of 2018 and outlook to 2023. IQVIA Institute for Human Data Science; 2019. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023. Accessed: July 7, 2022.

15. Zamani-Hank Y. The Affordable Care Act and the burden of high cost sharing and utilization management restrictions on access to HIV medications for people living with HIV/AIDS. *Popul Health Manag*. 2016;19(4):272-278. Available at: https://www.ncbi.nlm.nih.gov/pubmed/26565514.

16. Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA*. 2007;298(1):61-69. Available at: http://www.ncbi.nlm.nih.gov/pubmed/17609491.

17. Doshi JA, Li P, Ladage VP, Pettit AR, Taylor EA. Impact of cost sharing on specialty drug utilization and outcomes: a review of the evidence and future directions. *Am J Manag Care*. 2016;22(3):188-197. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27023024.

18. Kolasa K, Kowalczyk M. Does cost sharing do more harm or more good? A systematic literature review. *BMC Public Health*. 2016;16:992. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27633253.

19. Campbell DJ, Soril LJ, Clement F. Impact of cost-sharing mechanisms on patient-borne medication costs. *JAMA Intern Med*. 2016;176(11):1703-1704. Available at: https://www.ncbi.nlm.nih.gov/pubmed/27618359.

20. Remler DK, Greene J. Cost-sharing: a blunt instrument. *Annu Rev Public Health*. 2009;30:293-311. Available at: https://www.ncbi.nlm.nih.gov/pubmed/18976141.

21. Maciejewski ML, Farley JF, Parker J, Wansink D. Copayment reductions generate greater medication adherence in targeted patients. *Health Aff*. 2010;29(11):2002-2008. Available at: https://pubmed.ncbi.nlm.nih.gov/21041739.

22. Tseng CW, Dudley RA, Chen R, Walensky RP. Medicare Part D and cost-sharing for antiretroviral therapy and preexposure prophylaxis. *JAMA Netw Open*. 2020;3(4):e202739. Available at: https://www.ncbi.nlm.nih.gov/pubmed/32286656.

23. Kasier Family Foundation. An overview of Medicare. 2019. Available at: https://www.kff.org/medicare/issue-brief/an-overview-of-medicare. Accessed: July 7, 2022.

24. U.S. Centers for Medicare & Medicaid Services. Costs for Medicare drug coverage. Available at: https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage.

25. U.S. Centers for Medicare & Medicaid Services. Part B costs. 2021. Available at: https://www.medicare.gov/your-medicare-costs/part-b-costs.

26. Kates J, Dawson L, Horn TH, et al. Insurance coverage and financing landscape for HIV treatment and prevention in the USA. *Lancet*. 2021;397(10279):1127-1138. Available at: https://www.ncbi.nlm.nih.gov/pubmed/33617778.

27. Association for Accessible Medicines. The case for competition: 2019 generic drug & biosimilars access & savings in the U.S. report. 2019. AAM-2019SR-0919-BODP. Available at: https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf. Accessed: July 7, 2022.

28. Martin EG, Schackman BR. Treating and preventing HIV with generic drugs—barriers in the United States. *N Engl J Med*. 2018;378(4):316-319. Available at: https://www.ncbi.nlm.nih.gov/pubmed/29365306.

29. Girouard MP, Sax PE, Parker RA, et al. The cost-effectiveness and budget impact of 2-drug dolutegravir-lamivudine regimens for the treatment of HIV infection in the United States. *Clin Infect Dis*. 2016;62(6):784-791. Available at: https://www.ncbi.nlm.nih.gov/pubmed/26658053.

30. Sacks CA, Lee CC, Kesselheim AS, Avorn J. Medicare spending on brand-name combination medications vs their generic constituents. *JAMA*. 2018;320(7):650-656. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30140875.

31. Cotte L, Ferry T, Pugliese P, et al. Effectiveness and tolerance of single tablet versus once daily multiple tablet regimens as first-line antiretroviral therapy—results from a large French multicenter cohort study. *PLoS One*. 2017;12(2):e0170661. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28152047.

32. Suárez-García I, Alejos B, Ruiz-Algueró M, et al. Effectiveness and tolerability of dolutegravir and abacavir/lamivudine administered as two separate pills compared to their equivalent single-tablet regimen in a multicentre cohort in Spain. *J Int AIDS Soc*. 2021;24(7):e25758. Available at: https://pubmed.ncbi.nlm.nih.gov/34291580/.

33. Millham LRI, Scott JA, Sax PE, et al. Clinical and economic impact of ibalizumab for people with multidrug-resistant HIV in the United States. *J Acquir Immune Defic Syndr*. 2020;83(2):148-156. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31929403.

34. Brogan AJ, Talbird SE, Davis AE, La EM, Kumar PN. The cost-effectiveness and budget impact of ibalizumab-uiyk for adults with multidrug-resistant HIV-1 infection in the United States. *Pharmacoeconomics*. 2021;39(4):421-432. Available at: https://www.ncbi.nlm.nih.gov/pubmed/33532919.

35. Hyle EP, Sax PE, Walensky RP. Potential savings by reduced CD4 monitoring in stable patients with HIV receiving antiretroviral therapy. *JAMA Intern Med*. 2013;173(18):1746-1748. Available at: http://www.ncbi.nlm.nih.gov/pubmed/23978894.

36. Bolles K, Woc-Colburn L, Hamill RJ, Hemmige V. Ordering patterns and costs of specialized laboratory testing by hospitalists and house staff in hospitalized patients with HIV at a county hospital: an opportunity for diagnostic stewardship. *Open Forum Infect Dis*. 2019;6(6):ofz158. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31205970.

37. Weinstein MC, Goldie SJ, Losina E, et al. Use of genotypic resistance testing to guide HIV therapy: clinical impact and cost-effectiveness. *Ann Intern Med*. 2001;134(6):440-450. Available at: https://www.ncbi.nlm.nih.gov/pubmed/11255519.

38. Sax PE, Islam R, Walensky RP, et al. Should resistance testing be performed for treatment-naive HIV-infected patients? A cost-effectiveness analysis. *Clin Infect Dis*. 2005;41(9):1316-1323. Available at: https://www.ncbi.nlm.nih.gov/pubmed/16206108.

39. Koullias Y, Sax PE, Fields NF, Walensky RP, Hyle EP. Should we be testing for baseline integrase resistance in patients newly diagnosed with human immunodeficiency virus? *Clin Infect Dis*. 2017;65(8):1274-1281. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28605418.

40. Hyle EP, Scott JA, Sax PE, et al. Clinical impact and cost-effectiveness of genotype testing at HIV diagnosis in the United States. *Clin Infect Dis*. 2019. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31055599.

41. Thompson MA, Horberg MA, Agwu AL, et al. Primary care guidance for persons with human immunodeficiency virus: 2020 update by the HIV Medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis*. 2020. Available at: https://www.ncbi.nlm.nih.gov/pubmed/33225349.

42. Stevens ER, Nucifora KA, Irvine MK, et al. Cost-effectiveness of HIV care coordination scale-up among persons at high risk for sub-optimal HIV care outcomes. *PLoS One*. 2019;14(4):e0215965. Available at: https://pubmed.ncbi.nlm.nih.gov/31022280/.

43. Flash MJE, Garland WH, Martey EB, et al. Cost-effectiveness of a medical care coordination program for people with HIV in Los Angeles County. *Open Forum Infect Dis*. 2019;6(12):ofz537. Available at: https://www.ncbi.nlm.nih.gov/pubmed/31909083.

44. Barocas JA, Morgan JR, Fiellin DA, et al. Cost-effectiveness of integrating buprenorphine-naloxone treatment for opioid use disorder into clinical care for persons with HIV/hepatitis C co-infection who inject opioids. *Int J Drug Policy*. 2019;72:160-168. Available at: https://pubmed.ncbi.nlm.nih.gov/31085063/.

45. Goyal R, Luca D, Klein PW, et al. Cost-effectiveness of HRSA's Ryan White HIV/AIDS Program? *J Acquir Immune Defic Syndr*. 2021;86(2):174-181. Available at: https://www.ncbi.nlm.nih.gov/pubmed/33093330.