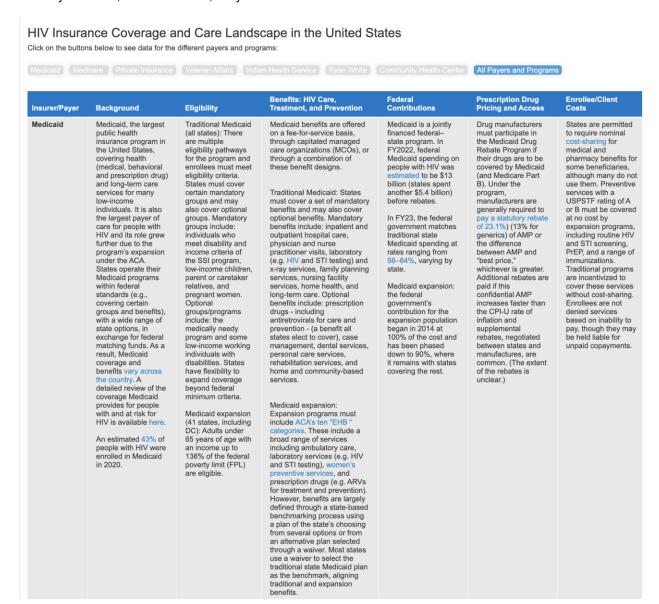


May 2023 | Issue Brief

The Health Insurance and Financing Landscape for People with and at Risk for HIV

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Medicare

Medicare, the federal health insurance program for people age 65 and older and for younger adults with long-term disabilities, plays an important role in delivering health coverage to people with HIV. A detailed review of Medicare's coverage for people with HIV is available here.

An estimated 28% of people with HIV were enrolled in Medicare in 2020. Some people dually covered by both Medicare and Medicaid.

There are three eligibility pathways: Individuals aged 65 and older with sufficient work history; individuals younger than 65 years with permanent disability and sufficient work history; and individuals with endstage renal disease or ALS of any age

Medicare covers a range of services that are important to people with and at risk for HIV, including prescription drugs, inpatient and outpatient care, and preventive services. Medicare benefits are organized and paid for in different ways, separated into four parts:

- Part A: Covers inpatient hospital stays, SNF stays, some home health visits, and hospice care.
- Part B: Covers physician visits, outpatient services, preventive services, and some home health visit, prevention services, and most physician-administered drugs.
 Preventive services include, annual HIV testing for people aged 15–65 (regardless of risk), annual screening for those younger than 15 or older than 65 who are at increased risk, and up to three tests during pregnancy. It also covers STI screening for people at risk and pregnant people and covers injectable PrEP (see section on prescription drugs).
- Part C: Medicare advantage or private plans, which are primarily HMOs and PPOS through which enrollees receive Part A and B benefits, and typically Part D.
- Part D: Part D is the outpatient prescription drug benefit which is delivered through private plans that contract with Medicare as stand-alone plans or through Medicare Advantage plans with drug coverage. Part D plans cover most ARVs used for care and prevention (see section on prescription drugs).

Medicare is a federal program and in fiscal year 2022, Medicare spending on people with HIV was estimated to be \$11.28 billion (including both traditional Medicare and Medicare Advantage) for all care and treatment costs prior to any manufacturer rebates.

Prescription drugs are covered under both Parts B and D. ARVs are one of six protected classes under Part D. As a result, Part D plans must provide access to all, or substantially all, FDA-approved ARVs (excluding those covered under Part B). Part D plans (or pharmacy benefits managers on their behalf) negotiate rebates on outpatient drug costs with manufacturers (the extent of the rebates is unclear). Most physician-administered drugs and biologics are covered under Part B (including some ARVs). HHS does not negotiate prices for most drugs covered under Medicare Part B. However, under the Inflation Reduction Act, the federal government is required to negotiate prices for some highspending drugs covered under Medicare Parts B and D and drug manufacturers are required to pay rebates to Medicare if prices increase faster than inflation, which has the potential to impact ARV drugs.

In addition, for drugs covered under Part D utilization management (prior authorization, step therapy, higher cost-sharing) is possible as cost-containment measures, including for drugs in the protected classes.

Premiums and costsharing might be substantial for both services and prescription drugs. There is no cap on out-of-pocket spending under Part A and Part B. However, subsidies and supplemental coverage are offered to low-income beneficiaries, including for the 61% are dually eligible for Medicaid. Part D (outpatient prescription drug) costs can be high, especially given the cost of ARVs, though there are protections through the LIS, for which 74% of beneficiaries with HIV are eligible. Additionally, a cap on Part D out-of-pocket costs will be introduced in 2025 Part B preventive services with a USPSTF A or B grade that have been approved under a Medicare NCD are covered without cost-sharing, including routine HIV and STI screening, and a range of immunizations.
Medicare is currently conducting an NCD for injectable PrEP covered under Part B. Cost-sharing support is available in some cases from the Ryan White Program, and other sources, on the basis of financial eligibility criteria but manufacturer co-pay assistance programs cannot be applied to Medicare costs.

Private Insurance population overall, most people with HIV who are privately insured obtain coverage through an employer. However, a smaller share obtain coverage in the individual market, especially through ACA health insurance marketplaces. An estimated 40% of people with HIV were covered with private insurance in 2020.

Medicaid expansion (41 states, including DC): Adults under 65 years of age with an income up to 138% of the federal poverty limit (FPL) are eligible.

ACA-compliant individual and employer-based plans generally cover a broad range of benefits. Most individual and small group plans are required to cover ten EHB categories , one of which is prescription drugs. Additionally, these plans cover HIV and STI testing, PrEP, women's health services (e.g. contraceptives), immunizations, and other prevention services. Non-ACA compliant plans, such as short-term limited duration or grandfathered plans, may have more restricted benefits (e.g., no drug or behavioral health coverage) and may not even cover people with HIV.

The federal government contributes to premium assistance support for people purchasing coverage in the health insurance marketplaces with incomes between 100–400% of the FPL (spending estimate not available for people with HIV).

Private insurance plans (or pharmacy benefits managers on their behalf) negotiate rebates on inpatient and outpatient drug costs with manufacturers but the extent of rebating is unclear. Formulary restrictions and utilization management (prior authorization, step therapy, higher costsharing) are commonly used as cost-containment measures. The ACA envisioned that several sets of preventive services be covered without cost-sharing by most private plans. În April 2023, a district court judge ruled that one such set of services (those services with A or B USPSTF grades since March 2010) are no lor required to be covered without costsharing. This could impact PrEP costs and coverage, among other services. An

appeal is pending

HIV care and treatment costs in the private market (e.g., premiums and costsharing) can be highly variable, depending on plan generosity and subsidy eligibility. Pharmaceutical manufacturers assistance programs/coupons may be available to offset drug costs for those with low to moderate incomes but these might not count towards annual cost-sharing limits or deductibles. Cost-sharing support is available through Ryan White (though with some limitations and differences by location), and other sources based on financial eligibility criteria.

In general, HIV and STI screenings are covered without cost-sharing. PrEP is generally covered but the no cost-sharing element environed by the ACA has recently been called into question (see section on prescription drug pricing and access for more information). Women's Preventive Service, including contraceptives, are covered without cost-sharing as are most major immunizations.

Veteran Affairs (VA)

The Department of Veteran Affairs offers medical coverage for people who served in the active military, naval, or air service.

An estimated 3% of people with HIV received health benefits through the VA in 2020.

Those who enlisted or entered active duty in the military, naval, or air service may be eligible for VA health care benefits, if they met minimum service and discharge requirements. Current and former members of the National Guard or Reservist members who had active duty by federal order and completed the full period of active duty are also eligible

The VA provides primary and specialty care, prescription drug coverage (includes all top recommend HIV initial treatment regimens, among other ARVs) mental health care, home health care, geriatrics and extended care, among other services. Some benefits under the VA vary, such as dental care, based on need and priority group. HIV testing, PrEP (with a facility level prior-authorization restriction), STI screening, immunizations and other prevention services are covered.

In FY 2022, federal VA spending on HIV care and prevention services was estimated to be \$1.6 billion. Prescription drug coverage includes all top recommend HIV initial treatment regimens, among other ARVs.

The FCP, the maximum price manufacturers may charge the "Big Four" federal purchasers, including the VA, includes a 24% discount off of a drug's AMP paid by non-FAMP. Additional discounts occur if non-FAMP prices increase faster than CPI-U. Big Four drug prices may be 40% to 50% below list prices VA may negotiate further price reductions using its preferred formulary

Many veterans qualify for health care without cost-sharing. For those that do face cost-sharing, it is nominal compared to the private market and Medicare but slightly higher than Medicaid. Treatment and medications are not withheld from those who cannot afford copayment.

Indian Health Service (IHS)

The Indian Health Service is an agency, within the Department of Health and Human Services, responsible for providing federal health services to American Indians and Alaska Natives. Its mission is to raise the physical, mental, social and spiritual health of these communities.

An estimate for the number of people with HIV served through IHS is not available. The most common eligibility pathway is membership in a federally recognized tribe (as well as non-Indian children, spouses, and some other family members) and, in some cases, is limited to those who live on or near federal reservations.

The IHS primarily provides primary care and prevention services, but also some ancillary and specialty services. Prevention services include: HIV surveillance, risk assessment, education, HIV testing and counseling, provider HIV training and technical assistance, as well as PrEP.

In FY2022 the IHS is estimated to have spent \$6.3 million on HIV (details on estimate available upon request). IHS is a "Big Four" federal purchaser subject to FCP protections. (Additional information about the "Big Four" pricing under the VA). There are three IHS formulary types:

- Agency level, NCF.
- Some Areas (e.g. Oklahoma City) have regional formularies.
- Additionally, each local site has a local formulary and exceptions process for non-formulary drugs.

Traditional IHS services are provided without cost-sharing. Services provided through the Urban Indian Program are offered on a sliding scale. The Urban Indian Program contracts with the IHS to provide services to American Indians and Alaskan Natives living in urban areas.

Ryan White HIV/AIDS Program (Ryan White) The Ryan White HIV/AIDS Program is the largest federal program designed specifically for people with HIV in the United States. Functioning as the "payer of last resort," Ryan White helps fill the gaps for those who have no other source of coverage or face coverage imits or cost barriers. A detailed overview of the services Ryan White provides for people with HIV is here.

An estimated 54% of people with HIV received support from Ryan White in 2020.

Rvan White serves uninsured and underinsured individuals with HIV. Income and other eligibility criteria are set by grantees (e.g. state, county, CBO, etc.) but the program is typically limited to those with low and moderate incomes. The program is divided into five major parts which operate and are funded independently

•Part A: Funds counties/cities most severely affected by HIV.

*Part B: Funds all states, territories, Puerto Rico, Washington D.C. and includes ADAP - the prescription drug and insurance program.

Part C and Part D: Fund public and private communitybased organizations providing medical care and support service with Part D focused on serving women and children.

-Part F: Has multiple funding components for 1) dental schools and community programs, 2) technical assistance and training (AETCs) and development of innovative models of care (SPNS), and 3) the MAI.

Ryan White provides a range of outpatient HIV "core medical" and "support" services, which vary by Part and grantee. Parts A-C must spend at least 75% of funds on core services, unless they receive a waiver.

 Core medical services may include: ADAPs (insurance assistance, ARVs, and many other HIV-related medications are covered), pharmaceutical assistance, early intervention services, health insurance premium and cost sharing assistance, home and community-based services, home health care, hospice, medical case management, medical nutrition therapy, and mental health, oral health, outpatient and ambulatory medical, and substance use outpatient care.

 Support services may include: Child care services, emergency financial assistance, food services, health education, housing, legal and linguistic services, medical transportation, nonmedical case management, other professional and outreach services, permanency planning and psychosocial support, referral services, reabilitation services, respite care and residential substance use services.

Primary prevention services are generally not provided as the program is intended to serve people with HIV but the program does support risk reduction counseling and targeted testing and some partner services. Existing program infrastructure can be used to support PrEP programming, but Ryan White funds cannot be used directly for PrEP. Many CHCs receive both federal CHC and Ryan White funding and provide both prevention and treatment services using the two streams.

In FY2023, federal funding for Ryan White was \$2.6 billion. This includes federal contributions from the EHE initiative. Many Ryan White clinics are enrolled in the 340B Drug Pricing Program which allows for discounted drug purchasing using a formula, 340B discounts start at 23.1% of AMP, with additional discounts if AMP increases higher than CPI-U Additionally, ADAPs receive significant voluntary discounts (>50% off list prices) on most ARVs. as negotiated by the ADAP Crisis Task Force. Program grantees can generate 340B revenue when a drug is purchased at a discounted 340B rate and grantee is reimbursed by insurance at a higher rate. The revenue (i.e. the spread) is then used to support provision of services, including funding HIV care and support

Cost-sharing in Ryan White programs is typically low and often on a sliding scale basis. Ryan White grantees, including state ADAP programs, can also assist with offsetting private or public insurance costs (e.g premiums, and costsharing). Community Health Centers (CHCs) Community health centers are a national network of safety-net primary care providers serving low-income and medically underserved communities, including people with and at risk for HIV.

In 2021, CHCs treated more than 200,000 people with HIV (who may also have a primary payer and/or be receiving Ryan White support), over 3 million visits included a test for HIV reaching 2.8 million patients, and provided PrEP to 79,163 patients.

There is no eligibility requirement. Health centers primarily serve low-income individuals, including uninsured or underinsured individuals and families, as well as those with Medicaid and private insurance.

CHCs provide primary care, prescription drugs, dental, mental health, substance use services, and support services. Offerings may vary by site. Prevention services may vary depending on the site, but generally, HIV testing and screening, STI screening, PrEP, and other services are offered.

Total CHC spending on HIV is not available. However, in FY23, CHCs directly received \$157 million as part of funding for the federal EHE initiative. Dually funded CHCs also receive funding from the Ryan White program (see section on Ryan White), totaling \$87 million from Part C in FY2021.

CHCs are eligible for the 340B Drug Pricing Program, allowing discounted drug purchasing using formula similar to Medicaid Drug Rebate Program. Discounts start at 23.1% off AMP, with additional discounts if AMP increases higher than CPI-U. Many health centers received both CHC and Ryan White funding. (See further discussion of 340B under the Ryan White section).

Cost-sharing in CHCs is first determined by payer source. Insurance is billed for patients with coverage and, depending on coverage and services, individuals may face cost-sharing. For the uninsured, cost-sharing is typically based on a sliding scale, if required.

NOTE: ABP=alternative benefit plan. ACA = Affordable Care Act. ADAP = AIDS Drug Assistance Program. AETC = AIDS Education and Technical Assistance Centers. ALS = amyotrophic lateral sclerosis, AMP = average manufacturer price. ARVs = antiretrovirals. CHC = community health centers. CPI-U = consumer price index for all urban consumers. EHB = Essential Health Benefits. EHE = Ending the HIV Epidemic. FCP = federal powerly limit. HMO = health maintenance organization. HS = Indian Health Service. LIS = low-income subsidy. MAI = Minority AIDS initiative. NCD = national coverage determination. NCF = National Core Formulary, Non-FAMP = average manufacturer price paid by non-federal purchasers. PPOS = preferred provider organization. FIPE = pre-exposure prophylaxiss. Ryan White = Ryan White HIV/AIDS Program. SPNS = Special Programs of National Signific. SSI = Supplemental security income. STI = sexually transmitted infection. USPSTF = United States Preventive Services Task Force. VA = Veteran Affairs.