FACT SHEET

Access Considerations for People Aging with HIV: IRA Negotiations and BIKTARVY®

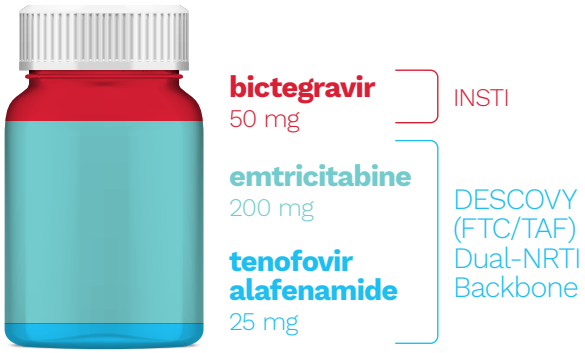
WHAT'S HAPPENING

The Centers for Medicare & Medicaid Services (CMS) recently selected 15 Medicare-covered drugs for the third cycle of Medicare drug price negotiation, known as IPAY 2028, under the Inflation Reduction Act (IRA).

BIKTARVY (bictegravir, emtricitabine, and tenofovir alafenamide), a widely used single-tablet HIV treatment regimen, is one of the selected drugs.

CMS is negotiating with manufacturers over what Medicare will pay for these drugs. This mainly affects Medicare Part D prescription drug coverage, including stand-alone Part D plans and Medicare Advantage plans that include drug coverage.

CMS has held IPAY 2028 public engagement activities, including opportunities for patients, advocates, and providers to share input on how the selected drugs affect people covered by Medicare.



Any new negotiated Medicare price for BIKTARVY would take effect January 1, 2028.

HOW COVERAGE DECISIONS CAN AFFECT TREATMENT STABILITY

ADDITIONAL RESOURCES FROM HealthHIV

- HealthHIV IPAY 2028 comments
- HealthHIV IPAY 2027 comments
- HealthHIV Utilization Management (UM) Toolkit

Medicare negotiation doesn't automatically change a person's HIV treatment.
In 2028, the negotiated price for BIKTARVY will take effect in Medicare Part D. The key access question is how CMS, Part D plans, manufacturers, and pharmacies will apply it—and what that will mean for People aging with HIV.

Providers should also watch how the negotiated price works at the pharmacy.
Pharmacies may sometimes fill a prescription before they receive the payment adjustment tied to the negotiated Medicare price, which can create short-term payment or processing issues. Clinics and pharmacies participating in the 340B program may also need to determine which discounted price applies. The key question is whether these behind-the-scenes issues lead to stocking, dispensing, or refill delays for patients.

HOW COVERAGE DECISIONS CAN AFFECT TREATMENT STABILITY

Treatment choice has clinical context. Coverage rules can disrupt that context.
Coverage doesn't guarantee access when payer requirements interfere with prescribed treatment.

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IMPLEMENTATION IS WHERE ACCESS TAKES SHAPE

QUESTIONS PATIENTS AND NAVIGATORS SHOULD BE ASKING:

- Is my HIV medication still covered?
- Has my cost-sharing changed?
- Are there new coverage or pharmacy requirements I should know about?
- Can I keep using my current pharmacy?
- Has anything changed that could affect staying on my current regimen?
- What should I do if there is a delay, denial, or refill problem?

ACCESS CHANGES TO WATCH:

- **Cost-sharing changes**
- **Formulary tier placement**
- **Pharmacy network or dispensing requirements**
- **Refill, stocking, or dispensing issues**

ACCESS AND CLINICAL CONTEXT FOR PEOPLE AGING WITH HIV

COVERAGE/MEDICATION SUPPORT PATHWAYS*

PEOPLE WITH HIV NATIONAL DATA

- **47**% Ryan White HIV/AIDS Program support
- **45**% Medicaid
- **43**% Private insurance
- **30**% Medicare
- **9**% Uninsured

DUAL ELIGIBLE

- **61**% Medicare
- **25–31**% Medicaid

* Coverage/Medication Support Pathways data from CDC Medical Monitoring Project (www.cdc.gov/hiv-data/mmp) and KFF (www.kff.org/state-category/hivaids)

COST AND AFFORDABILITY†

- **24**% found HIV out-of-pocket costs difficult to afford
- **20**% delayed care over insurance/out-of-pocket concerns

PRIOR AUTHORIZATION/ APPEALS†

- **11**% switched meds after non-coverage or PA
- **12**% appealed HIV medication decision

PHARMACY ACCESS†

- **25**% switched pharmacies after plan/formulary changes
- **35**% use two or more pharmacies

REFILL/DELIVERY DISRUPTION†

- **13**% had pharmacy or mail service/ delivery challenges
- **10**% had transportation barriers obtaining HIV medications
- **1 in 9** people aging with HIV had to switch HIV medications because their plan would not cover one or denied prior authorization

CLINICAL CONTEXT†

- **81**% take medication for another chronic condition
- **22**% adjusted HIV treatment because of drug interactions
- **52**% of Medicare enrollees relied on Ryan White/ADAP for HIV medications

† Data from HealthHIV State of Aging with HIV™ Fifth Annual National Survey (HealthHIV.org/stateof)

WHY KEEPING TREATMENT STABLE MATTERS

After negotiation, coverage or pharmacy requirements could change. If that happens, people aging with HIV may have to navigate extra rules and refill timing just to stay on the treatment that works.

When plans or payers second-guess a stable regimen, they can disrupt patient-provider decisions made over time. A provider may choose a regimen because of a person's treatment history or resistance history. They may be trying to avoid side effects, prevent drug interactions, manage hepatitis B, or reduce the risk of treatment gaps.

A coverage change can turn that balance into missed doses, refill delays, pharmacy confusion, a harder switch, or a more difficult treatment restart after a gap in care.

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