

Centers for Medicare and Medicaid Services
Town Hall Meeting on Biktarvy Price Negotiations Comments
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Good morning. My name is Dr. Joseph Cherabie. I am an infectious diseases physician who provides HIV care in one of the largest HIV clinics in the Midwest, and I appreciate the opportunity to offer comments today about Medicare price negotiations for Biktarvy. I am participating in my capacity as a member of the HIV Medicine Association Board of Directors. HIVMA is a professional association that represents more than 6,000 HIV physicians, pharmacists and advanced practice providers working in communities across the United States.

Today's discussion is important as [more than a quarter of people with HIV](#) have Medicare coverage. In my remarks, I will discuss the role of Biktarvy in HIV clinical care, comparable alternative regimens, and considerations related to price and treatment access.

Biktarvy as a recommended first-line treatment option

Biktarvy combines bictegravir, emtricitabine and tenofovir alafenamide into a single-tablet regimen, or STR, that is highly effective at achieving and sustaining suppression of HIV, allowing people to benefit from extended, healthy lives. It has a high barrier to the development of drug resistance and very few side effects and, as an STR, is easier for many people to take reliably on a daily basis. The U.S. Department of Health and Human Services (DHHS) HIV treatment [guidelines recommend Biktarvy](#) as a first-line treatment option. The simplicity is particularly important for Medicare beneficiaries who are often taking upwards of six medications to treat co-occurring conditions, such as high blood pressure, diabetes, hyperlipidemia and mental health conditions.

Biktarvy is an [integrase strand transfer inhibitor \(INSTI\)](#)-based regimen. INSTIs are the U.S. DHHS preferred class of drugs for first-line therapy because of their effectiveness at suppressing HIV, barriers to drug resistance and tolerability.

Alternative recommended first-line HIV treatment regimens

Dolutegravir is an INSTI and also is a first-line therapy that is highly effective when taken with tenofovir alafenamide or tenofovir disoproxil fumarate plus emtricitabine. These regimens require more than one prescription, which creates treatment challenges if medications are filled or available at different times, leading to missed doses and the potential for resistance that limits further treatment options and makes it more difficult to achieve viral suppression. They also require multiple copayments that may end up being cumulatively higher than one single STR copayment.

Price and treatment access

While today's session is focused on clinical issues to consider in comparing therapeutic alternatives to Biktarvy, the role of price in determining access to a preferred treatment for Medicare beneficiaries is important. Medicare Part D drug plans typically place Biktarvy on a specialty or other high cost-sharing tier. For beneficiaries who are not eligible for extra financial assistance, cost-sharing for Biktarvy can range from between \$800 and \$900 per month until, thanks to the Inflation Reduction Act, the individual hits the \$2,100 out-of-pocket maximum. The cost-sharing that beneficiaries must pay when they have not yet met their deductible and when coinsurance is used is directly tied to the underlying price of Biktarvy.

In addition, the maximum fair price (MFP) negotiated for Biktarvy for Medicare beneficiaries may also set a new best price that could favorably impact Medicaid drug prices. [Forty percent of people with HIV are insured by Medicaid](#), and state Medicaid programs are increasingly responding to rising drug costs by considering prior authorization or other utilization strategies that restrict access to preferred HIV treatment regimens.

Biktarvy has been an important therapeutic advance for people who have access to it. Bringing down Medicare drug prices through the MFP process is important to the program's solvency and to ensuring that in the years to come Medicare beneficiaries will have access to the latest therapeutic breakthroughs — not only for HIV but across all disease states. The best way to ensure that scientific advances benefit people with HIV, especially communities facing persistent access barriers, is to ensure that drug prices are fair: fair to manufacturers, fair to federal payors and fair to the Medicare beneficiaries who depend on affordable access to lifesaving HIV treatment.

In negotiating a fair price for Biktarvy, we urge CMS to balance the high therapeutic value of the drug with the alternative regimens and the role of price in ensuring Medicare beneficiaries have affordable access to the most effective treatment option for them. The price point could impact the health and lifespan of Medicare beneficiaries with HIV and has public health and economic consequences for both Medicare and Medicaid programs and for efforts to end the HIV epidemic. Thank you.