**Medicare Drug Price Negotiation Town Hall: Biktarvy Testimony**
**Kevin Herwig**
**HIV+Hepatitis Policy Institute**
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Good morning. I'm Kevin Herwig, Health Policy Manager with the HIV+Hepatitis Policy Institute. We advocate for quality, affordable healthcare for people affected by HIV, viral hepatitis, and other conditions.

HIV's transformation from a death sentence to a manageable chronic condition is one of modern medicine's greatest triumphs. Treatment has evolved from complex, toxic multi-pill regimens with debilitating side effects to simpler, more tolerable regimens that are easier to adhere to and offer a much higher barrier to viral resistance.

Regimen selection in HIV treatment is highly personalized, especially for treatment-experienced patients who are switching regimens. Clinicians must account for resistance history, comorbidities, drug-drug interactions, side effects, and individual patient circumstances. There is no one-size-fits-all regimen.

That said, Biktarvy is a key regimen for HIV treatment today, one of just three regimens recommended as "preferred" regimens for first-line treatment. More than half of all people receiving HIV treatment in the US take Biktarvy. It is the most prescribed regimen for both starts and switches.

Real-world evidence shows Biktarvy has higher persistence and lower switch rates than dolutegravir-based alternatives.

Biktarvy's very high barrier to resistance is an important advantage. Resistance mutations are irreversible and transmissible, limiting future treatment options both at the individual and at the population level.

Clinical trial data for Biktarvy showed zero cases of treatment-emergent resistance through five years, confirmed through an additional five years of follow-up. Real-world studies show that recommended alternatives for first-line therapy all have higher resistance rates.

This matters especially for patients with imperfect adherence. Pooled data show Biktarvy delivers lower virologic failure rates than dolutegravir-based regimens when adherence falls below 85 percent. For people facing housing instability, mental health challenges, or the daily burden of lifelong treatment, a forgiving regimen makes a real difference.

HIV treatment access in Medicare is fairly good, and this framework should be preserved.

Antiretrovirals are one of Six Protected Classes in Medicare Part D, meaning plans must cover all drugs in the class. Antiretrovirals are the only protected class where prior authorization is prohibited. Combined with the new $2,100 annual out-of-pocket cap, Medicare beneficiaries living with HIV have meaningful, timely access to their medications. This contrasts with commercial insurance, where patients may face restricted formularies and out-of-pocket maximums exceeding $10,000. AIDS Drug Assistance Programs also cover Biktarvy for people with lower incomes.

In 2025, CDC added Biktarvy to its post-exposure prophylaxis, or PEP, guidelines, the first and only single-tablet regimen recommended. Medicare's Part D protections mean beneficiaries can access PEP within the critical 72-hour window after a potential exposure to HIV without prior authorization—an advantage many commercially insured patients lack.

Despite remarkable progress, significant unmet needs remain, starting with a cure or long-term viral suppression that does not require lifelong treatment. Those goals remain beyond current science.

But the drug development pipeline is full of promise. Long-acting formulations make adherence easier; new drug classes may produce options for those with a high resistance burden or those who still struggle with side effects. Continued drug development will yield new options for an aging population with HIV and multiple comorbidities, who face high levels of stigma and discrimination and structural and social barriers to uninterrupted care.

As Medicare's HIV population is expected to double by 2035, we need continued innovation alongside continued access to current and new treatments.

Thank you for the opportunity to share these perspectives.