When Medication Coverage is Disrupted, People Pay the Price

The Economic Case for Preserving Medicare's Six Protected Classes Policy

What the Six Protected Classes Policy Does

Medicare's Six Protected Classes policy, covering immunosuppressants, antidepressants, antipsychotics, antiretrovirals, antineoplastics, and anti-seizure medications, requires Medicare Part D plans to cover all or substantially all FDA-approved drugs in these categories. This policy exists to ensure that people who rely on these medications are able to access the full range of therapies for their conditions, which are among the most serious and clinically complex. As abrupt medication changes can trigger cascading, life-threatening consequences, beneficiaries must have access to the full range of treatment options and be able to maintain their treatment once a successful therapy is found. If 6PC protection is weakened or repealed, individuals could be forced off proven, stabilizing therapies.

HIV is a special case within the 6 Protected Classes due to the importance of quick initiation onto therapy after diagnosis. This is called Rapid Start and helps insure proper clinical response *and* avoid the costs associated with delaying starting treatment. When patients are able to begin HIV treatment within a week of diagnosis, they are more likely to maintain care and achieve viral suppression, thereby increasing patient quality of life and reducing the risk of HIV transmission to others. This concept is also applicable to *re*starting HIV medications.

Living with HIV: Michael, Age 55

Michael has lived with HIV since 1998 and has been virally suppressed on antiretroviral therapy for the past five years, which means his disease is under control and he cannot transmit HIV to other people. He works part-time as a grocery store clerk, earning approximately $18,000 annually, and qualifies for both Medicare and Medicaid. Because of his limited income, he cannot afford to bridge unexpected gaps in medication coverage on his own.

Michael is one of a projected 336,000 Medicare beneficiaries living with HIV, a population expected to double by 2035.[1] When he unexpectedly experiences a four-week delay in access to his medication, Michael experiences viral rebound that goes undetected until he develops severe influenza and pneumonia requiring hospitalization and a short ICU stay. After restarting treatment under Rapid Restart protocols, resistance testing reveals that his virus is no longer responsive to his original medication regimen. During the period of unknown viral rebound, Michael unknowingly transmits HIV to a sexual partner, resulting in a new infection. While Michael's viral rebound was unfortunately not caught before HIV transmission to a partner, we also know that Rapid Restart prevents an estimated 88 HIV transmissions per 1,000 people, resulting in approximately $101 million in avoided lifetime health care costs.

When Michael's access to treatment is disrupted, he faces a cascade of medical and public health consequences that have a significant financial impact on his payers (Medicare and Medicaid), society, and himself:

Viral Rebound	Drug Resistance	HIV Transmission

[1] https://www.kff.org/hiv-aids/medicare-and-people-with-hiv/

Loss of viral suppression leaves Michael vulnerable to severe infections. Influenza progresses to pneumonia, requiring emergency care, hospitalization, and intensive care.	After treatment resumes, resistance testing shows that the virus is no longer responding to his original regimen. Managing drug resistance requires additional testing and a more complex and expensive treatment strategy.	During the period of undetected viral rebound, Michael unknowingly transmits HIV to a sexual partner. A temporary interruption in treatment thus creates lifelong medical consequences and costs extending beyond the person himself.

The Numbers: What Coverage Disruption Would Cost

If Michael experienced a treatment interruption that resulted in viral rebound, severe illness, drug resistance, and HIV transmission, the financial consequences would be substantial for both the public and the programs through which he receives insurance, as well as himself and his partner. The costs extend far beyond Michael himself, reflecting the broader public health impact of disruptions in antiretroviral therapy.

Table 1. Payer-Borne Costs if Michael Loses Access to His HIV Medications

Category	ED Visits (Incl. Transport)	Hospital Admission + Services	Viral Rebound Monitoring	Drug Resistance Management	Partner Transmission (Lifetime Cost of HIV Infection)	Total Cost to Payers
Estimated Cost	$28,480	$51,295	$1,510	$10,883	$240,449	**$332,617**

Table 2. Patient Out-of-Pocket Costs if Michael Loses Access to His HIV Medications

Category	OOP: Medical Cost	OOP: Transportation	OOP: Lost Wages	OOP: Partner Transmission	Total OOP Cost
Estimated Cost	$0*	$560	$6,228	$51,317	**$58,105**

**As a dually eligible beneficiary, Medicaid covers Medicare Part A deductibles, coinsurance, and Part B cost-sharing at no cost to the patient.*

The Bottom Line for Policy Makers

In this case, a four-week interruption in treatment would cost Medicare and Medicaid more than $330,000 while imposing nearly $58,000 in additional costs on Michael and those around him. Much of these costs are driven not by the temporary treatment gap itself, but by the downstream consequences of severe illness, drug resistance, and a preventable new HIV infection. Behind every one of these dollars is a person whose decades of successful viral suppression have been jeopardized and another individual whose life is permanently altered by a preventable HIV infection. Maintaining continuous access to effective antiretroviral therapy helps preserve health,

prevent transmission, and avoid costly complications that affect both individuals and the healthcare system.

Michael and his doctors together know the best course of action for his treatment, and continued, sustained access to his carefully prescribed medications is central to his health. The Six Protected Classes policy is not a regulatory technicality. It is the mechanism that allows physicians to prescribe the right medication for the right person without fear that unexpected changes could destabilize years of careful clinical management. Weakening this policy would shift costs, both financial and personal, onto the federal government and the people who can least afford to bear them.