Access to medically necessary healthcare is critical for successful patient outcomes, yet access is often impeded or blocked entirely by cost sharing. Despite its value as a tool to limit discretionary healthcare spending, cost sharing can create insurmountable barriers between patients and medications, diagnostic tests, office visits, surgery and other needed services. There are significant concerns that cost sharing limits access to medically necessary treatment for economically vulnerable patients and families.

These barriers impact increasing numbers of chronically ill Medicare beneficiaries who are frequently exposed to very high out-of-pocket (OOP) costs for their prescription medications. This Issue Brief examines the impact of out-of-pocket costs on access to prescription medications under Medicare Part D.

PAN advocates for strategies that will increase access to medically necessary medications among Medicare beneficiaries by reducing out-of-pocket prescription drug costs. PAN believes:

» Out-of-pocket costs for prescription medications should be spread more evenly throughout the benefit year.

» Out-of-pocket costs for prescription medications should be capped through the use of monthly and/or annual OOP limits.

» All conditions should have at least one highly effective innovator drug on a fixed co-payment tier.

» Within today’s healthcare delivery system, charitable patient assistance programs provide a critical safety net for ensuring access to medically necessary treatment.
How do People Access Medications Under Medicare?

Established in 1965, Medicare is a federal health insurance program that covers people over the age of 65, as well as people under 65 with long-term disabilities and end-stage renal disease. In November of 2018, there were 60.1 million people enrolled in Medicare. This program covers a wide range of health services and supports, including prescription medications. Beneficiaries use prescription medications in a number of settings, and the setting in which prescription drugs are administered or acquired determines which part of the Medicare program covers their cost.1,2,3

» **PART A**: Covers drugs that are given during an inpatient hospital or skilled nursing facility stay.

» **PART B**: Covers drugs that are administered in a doctor's office or outpatient hospital setting.

» **PART C/MEDICARE ADVANTAGE**: Medicare Advantage (MA) plans cover Part A and Part B drugs, and may offer a benefit to cover Part D drugs. Beneficiaries enrolled in an MA plan can also purchase drug coverage separately under Part D.

» **PART D**: Covers drugs that are typically purchased at pharmacies.

Cost Sharing and Access to Prescription Medications

Cost sharing refers to healthcare expenses that insurers don't cover and must be paid OOP by the patient. These expenses include deductibles, co-pays, and coinsurance. In Medicare Part D drug plans, the deductible is the amount of money that beneficiaries pay upfront before the Part D plan starts to cover their drug costs, co-payments are fixed fees that beneficiaries pay each time they fill a prescription (e.g., a $15 co-pay for each prescription), and coinsurance is a fixed percentage of the cost of the medication (e.g., 30% of the cost of each prescription). Medicare Part D drug plans run on a January—December annual cycle. Although these plans can have different benefit structures, they are actuarially equivalent. The general structure of how Medicare Part D drug plans implements cost sharing during the 2019 calendar year is shown in the below figure.4
After paying their $415 Part D deductible, beneficiaries typically pay 25% percent of their drug costs during the “Initial Coverage Period.” After the patient and plan have spent $3,820 (including the initial deductible of $415), the initial coverage limit is met and the beneficiary enters the “Coverage Gap” phase, often termed “the donut hole.” In this phase, the beneficiary can incur considerable OOP drug costs; when total out-of-pocket drug costs reach $5,100, the beneficiary leaves the coverage gap and enters the “Catastrophic Coverage Threshold.” Here, they pay 5% of drug costs, with no cost-sharing limit until the end of the calendar year. The cycle resets on January 1.

Several important points concerning the relatively complex structure of Medicare Part D drug plans warrant emphasis:

» For some health conditions, a specialty medication, often placed on a plan’s highest formulary tier, is the most appropriate treatment. In these cases, there is no lower cost or generic alternative that offers the same benefit on a less expensive formulary tier.

» For Medicare beneficiaries who need specialty medications, cost sharing during the Initial Coverage Period can be as high as 33%, and cost sharing is even higher during the Coverage Gap phase.
» Although beneficiaries only pay 5% coinsurance during the Catastrophic Phase, there is no limit because there is no cap on OOP expenses. Patients can incur substantial OOP costs during this time, particularly if they need specialty medications.

» The structure of Medicare Part D drug plans results in an uneven distribution of OOP expenses during the calendar year, with beneficiaries paying very high OOP costs for their drugs in the early part of the year.7

» Unlike people with commercial insurance, it is unlawful for Medicare beneficiaries to use the coupons offered by pharmaceutical companies to help offset their OOP drug costs.

» To cover their OOP drug expenses, economically vulnerable older adults often turn to safety net organizations such as charitable foundations as payers of last resort.

**Case Study: Out-of-Pocket Costs for a Medicare Beneficiary with Chronic Myelogenous Leukemia**

Research on the patient-level impact of OOP drug costs among Medicare beneficiaries helps to highlight the challenges that are faced by many chronically ill older adults who seek to secure access to their medications. Recent work by Doshi and colleagues underscores these challenges as they relate to beneficiaries with conditions such as rheumatoid arthritis, multiple sclerosis, and chronic myelogenous leukemia (CML).6,7

Consider Ted, a Medicare beneficiary who has CML, a rare blood cancer, as well as diabetes and high blood pressure. Ted’s income is at 400% of the Federal Poverty Level, making him ineligible for Medicare’s low-income subsidy. CML guidelines call for treatment with drugs called tyrosine kinase inhibitors (TKIs), a relatively new class of chemotherapeutic medications. Medicare beneficiaries who do not receive low-income subsidies have high coinsurance requirements for TKIs because they are often designated as specialty medications. Coinsurance payments vary widely because they are based on the cost of the medication. Further, under Part D, the coinsurance percentage for specialty drugs fluctuates across the coverage year, with the highest costs at the beginning of the year. Doshi’s research demonstrates the following about a patient like Ted:

» **EVEN WITH PART D COVERAGE, TED WILL ACCUMULATE CONSIDERABLE OOP DRUG EXPENSES DURING THE YEAR.**

The average Medicare patient with CML accumulated $6,322 in OOP drug expenses for their health conditions. Of these OOP expenses, 95% were linked to their specialty medications.
MEDICARE BENEFICIARIES WHO NEED SPECIALTY MEDICATIONS ENTER THE CATASTROPHIC PHASE QUICKLY BECAUSE THEIR OOP COSTS PUSH THEM RAPIDLY THROUGH THE DEDUCTIBLE, INITIAL COVERAGE AND DONUT HOLE PHASES.

Although Ted pays only 5% coinsurance once he enters the Catastrophic Coverage Phase, the high cost of his medication results in the accumulation of 56% of his total OOP costs during this phase. This is due in part to the absence of a spending cap during the Catastrophic Phase.

BENEFICIARIES WHO NEED SPECIALTY MEDICATIONS OFTEN INCUR VERY HIGH OOP COSTS EARLY IN THE CALENDAR YEAR.

Of the $6,322 in OOP drug expenses that Ted incurs during the year, he was responsible for $2,456 in January alone. Of this amount, $2,374 was linked to his specialty medications. Ted must therefore pay 40% of all his OOP drug costs in the first month of the calendar year, with the vast majority of these unevenly-distributed expenses associated with his CML treatment.

Strategies to Increase Access to Medications Among Medicare Beneficiaries

A number of stakeholders have proposed strategies to help improve Medicare beneficiaries’ access to prescription medications. Some of these strategies include:

- Out-of-pocket costs for prescription medications should be capped through the use of monthly and/or annual limits.
- All conditions should have at least one highly-effective innovator drug on a fixed co-payment tier.
- Out-of-pocket costs for prescription medications should be spread more evenly throughout the benefit year.

Although it is unclear what strategies will ultimately provide a sustainable safety net for millions of Medicare beneficiaries who cannot afford their medications, researchers have proposed solutions involving annual and monthly caps on OOP drug costs. PAN agrees with the Institute of Medicine and the Congressional Budget Office which both advocate for limits on OOP drug spending for Medicare beneficiaries because a cap will facilitate access to needed treatments by lowering OOP costs and allowing beneficiaries to predict and plan for these costs throughout the year.
The PAN Foundation

The PAN Foundation is an independent, national 501 (c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic, and rare diseases with the out-of-pocket costs for their prescribed medications. PAN provides the underinsured population access to the healthcare treatments they need to best manage their conditions and focus on improving their quality of life. Since its founding in 2004, PAN has provided nearly one million underinsured patients with over $3 billion in financial assistance through nearly 70 disease-specific programs.

For more information about this Issue Brief, contact Amy Niles, Vice President of External Relations, at aniles@panfoundation.org.
Supporting Literature

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