ISSUE BRIEF 6
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PAN Foundation

"Seasonality" of Out-of-Pocket Drug Costs for Medicare Beneficiaries

Access to medically necessary healthcare is critical for successful patient outcomes, yet access is often impeded or blocked entirely by cost sharing in the form of high deductibles, co-pays and coinsurance. Despite its value as a tool to limit discretionary healthcare spending, excessive cost sharing often creates insurmountable barriers between patients and medications, diagnostic tests, office visits, surgery and other needed services. There is significant concern that cost sharing limits access to medically necessary and appropriate treatment for seriously ill and economically vulnerable patients.

The Patient Access Network Foundation believes that cost sharing should not prevent anyone from obtaining medically necessary treatment.

PAN advocates for strategies that will increase access to necessary medications among economically vulnerable Medicare beneficiaries by reducing their out-of-pocket (OOP) drug costs. PAN urges consideration of the following changes to the benefit structure of Medicare Part D prescription drug plans:

- Put a "hard cap" on OOP costs once beneficiaries reach Part D's catastrophic threshold.
- Ensure that health conditions have at least one effective drug that is not on a specialty tier.
- Spread OOP costs more evenly throughout the calendar year.

This *Issue Brief* explores how Medicare Part D drug plans can concentrate OOP costs at the beginning of the calendar year, and the resulting impact on Medicare beneficiaries—especially those with health conditions that require high-cost, "specialty medications."

What is the Basic Structure of Medicare Part D Drug Plans?

A standard Medicare Part D drug plan includes the following elements:[1]

» MONTHLY PREMIUM

- Average of $33.50 in 2018

» ANNUAL DEDUCTIBLE

- $405 in 2018

» INITIAL COVERAGE PHASE

- Enrollees pay 25% coinsurance for covered drugs
- In 2018, Initial Coverage Period limit is $3,750 in total drug costs

» COVERAGE GAP PHASE

- Also known as the "donut hole"
- Enrollees pay for a percentage of covered drugs
    i. In 2018, 35% for brand-name drugs, 44% for generic drugs
    ii. Percentages change each year as part of the closing of the Coverage Gap
- In 2018, Coverage Gap limit is $5,000 in "True Out-of-Pocket" costs (TrOOP; see sidebar)

» CATASTROPHIC COVERAGE PHASE

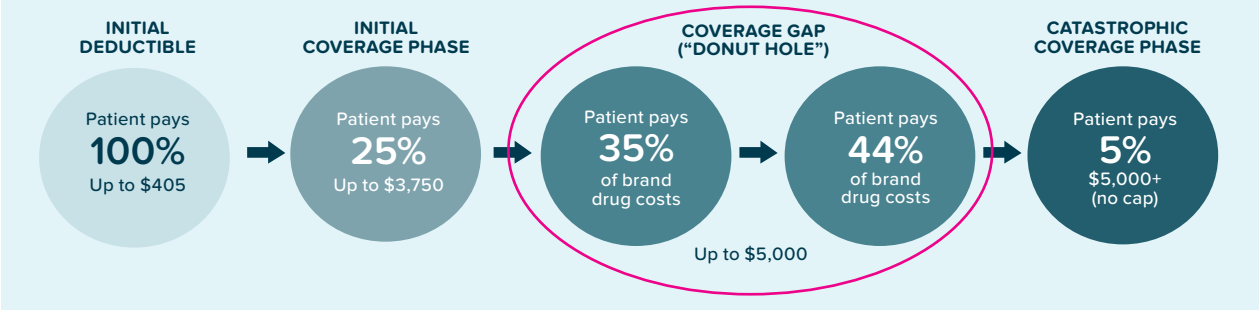
- Enrollees pay 5% coinsurance for covered drugs
- No cap on OOP costs for the remainder of the year

WHAT PAYMENTS COUNT TOWARD TROOP?

- » The annual deductible, which is the amount patients pay for their Medicare Part D covered prescriptions before their Medicare Part D drug plan begins to pay.
- » Out-of-pocket/cost-sharing costs, which is what patients pay for each Medicare Part D plan covered prescription drug after their drug plan begins to pay (i.e., co-payments or coinsurance).
- » Any payments the patient makes during their plan's Coverage Gap Phase.
- » Any payments for drugs made on the patient's behalf by sources such as charities, State Pharmaceutical Assistance Programs, Medicare's Low Income Subsidy, and money a patient uses from their Medicare Savings Account, Health Savings Account, or Flexible Spending Account.

These features are summarized in the figure below.

FIGURE 1.
Annual Cost Sharing Under Medicare Part D Drug Plans, 2018



Unintended Consequences of the Structure of Part D Drug Plans

Medicare Part D drug plans follow a January through December cycle. Compared to patients who take less expensive medications and whose OOP costs are spread out more evenly over the course of the year, patients who take specialty medications* often pay considerable OOP drug costs immediately after the start of each calendar year. This is because specialty medications are often very costly, and they can "burn through" the enrollee's deductible as well as the Initial Coverage Phase very quickly. ***In many cases, enrollees who take specialty medications pay their deductible and a large percentage of all OOP drug costs for the Initial Coverage Phase in the month of January.***

When Part D enrollees enter the Coverage Gap Phase, they are faced with reduced drug coverage until they incur $5,000 in TrOOP. ***Compared to people who can be effectively treated with less expensive drugs, patients who need specialty medications often reach the $5,000 threshold very quickly—sometimes in the month of January.*** The rapid accumulation of OOP drug costs often propels seriously ill patients into the Catastrophic Coverage Phase early in the calendar year.

When enrollees reach the Catastrophic Coverage Phase, they are typically responsible for 5% of the cost of their drugs for the rest of the calendar year. ***Despite being responsible for only 5% of the cost of their drugs during the Catastrophic Phase, people who need specialty medications***

* There is no standard definition for a specialty medication, but drugs in this category typically share one or more of the following characteristics: They are expensive, they can be difficult to administer, they may require special handling such as temperature control, and patients who take these medications may need ongoing clinical assessment to manage side effects. In Medicare Part D drug plans, specialty medications are defined as drugs that cost $670 per month or more.

continue to incur very high OOP spending because of the high cost of these drugs. These expenses are overwhelming for many patients because there is no cap on OOP spending during the Catastrophic Coverage Phase, which continues until the end of the calendar year. The cycle resets on January 1st, when many patients are "hit" once again with high OOP medication costs.

What Does the Research Show?

There is considerable research demonstrating how the structure of Part D plans impacts the timing and distribution of OOP drug costs on Medicare enrollees, and the impact that this has on patients' adherence to their prescribed medications. This body of research focuses on Part D enrollees whose incomes are greater than 150% of the Federal Poverty Level (FPL) and who do not qualify for the Low Income Subsidy (LIS) program. Medicare beneficiaries below 150% of FPL who are enrolled in LIS have limited OOP drug costs. However, there are millions of beneficiaries who are ineligible for LIS, but whose low incomes and limited assets inhibit their access to needed treatments. These beneficiaries are especially vulnerable to high OOP costs for prescription medications because they do not have sufficient savings to cover these costs.

The impact of OOP drug costs among low income Medicare beneficiaries who are not eligible for LIS is well documented. A new report[2] on initiation of targeted therapies—a type of specialty medication—for kidney cancer among Medicare beneficiaries with and without LIS reinforced that non-LIS beneficiaries have extremely high OOP costs for these medications, and that these costs inhibited patients from accessing life-saving treatment. The new report showed that non-LIS beneficiaries were responsible for OOP of ≥$2,800 for their *initial* prescription, compared to ≤$6.60 for patients with LIS. A considerably lower percentage of non-LIS patients initiated treatment for their kidney cancer, and those who did were slower to begin treatment. Failure to access prescribed treatment, as well as delaying initiation of treatment have obvious implications for the health and well-being of these patients.

Another report[3] on Medicare beneficiaries with plaque psoriasis—a chronic, multisystem inflammatory disease—showed that among people who started specialty medications for their psoriasis, those without LIS were more likely to stop treatment. A similar study[4] of specialty medications used in rheumatoid arthritis (RA) showed that compared to RA patients with LIS who paid $5 for a 30-day supply of their specialty medications, non-LIS Part D enrollees paid $484 OOP for the same supply. Non-LIS patients were less likely to fill prescriptions for specialty medications for their RA, and non-LIS patients who did fill them had approximately twice the odds of an interruption in their treatment.

Some researchers and stakeholders believe that the main reason non-LIS Medicare beneficiaries do not initiate and continue to take their specialty medications as prescribed is because of how the OOP costs for their drugs are distributed throughout the year.

One study[5] examined non-LIS Part D enrollees who needed specialty medications for RA, multiple sclerosis (MS) and chronic myeloid leukemia (CML). The table below shows the total OOP costs for the year, as well as how much, and what percent of these costs were incurred in the month of January, January+February, and January+February+March.

TABLE 1.

HEALTH CONDITION	AVERAGE ANNNUAL OOP COSTS FOR SPECIALTY MEDICATIONS	OOP COSTS: JANUARY	OOP COSTS: JANUARY + FEBRUARY	PERCENT OOP: JANUARY + FEBRUARY + MARCH
Rheumatoid Arthritis	$3,949	$977 (24.7%)	$1,835 (46.5%)	$2,610 (66.1%)
Multiple Sclerosis	$5,238	$1,613 (30.8%)	$2,840 (54.2%)	$3,107 (59.3%)
Chronic Myeloid Leukemia	$6,322	$2,452 (38.8%)	$3,052 (48.3%)	$3,405 (53.9%)

These data show that in terms of absolute dollars as well as the percentage of total OOP costs, Part D enrollees who use specialty medications for RA, MS and CML incur significant costs very early in the calendar year. In all cases, patients incurred one-quarter or more of all their annual OOP drug costs in January alone, and more than half—and in one case, two-thirds—of their OOP costs by the end of March.

What Does this Mean for Medicare Beneficiaries?

Medicare Part D drug plans create unintended consequences for many older and disabled Americans who rely on prescription medications.

- **MEDICARE BENEFICIARIES DON'T HAVE ENOUGH CASH TO PAY FOR THEIR OOP MEDICATION COSTS.** Many beneficiaries do not have sufficient cash on hand to pay for their OOP medication expenses, especially in the first few months of the year when they can incur as much as two-thirds of all OOP drug costs they will shoulder during the year.
- **THE EXISTING PART D PLAN STRUCTURE INHIBITS BOTH ACCESS AND LONG-TERM ADHERENCE TO TREATMENT.** The need to pay large OOP sums for drugs during the first few months of the year prevents beneficiaries from filling expensive prescriptions, and among people

who can initially fill their prescriptions, OOP costs contribute to interruptions in, and cessation of treatment.

» **SMOOTHING OOP COSTS THROUGHOUT THE YEAR WILL INCREASE ACCESS TO NEEDED TREATMENTS.** Strategies that help Medicare beneficiaries distribute their OOP costs more evenly throughout the year will help alleviate the burdens associated with large upfront medication costs, thereby enhancing access and long-term adherence to treatment.

» **SUPPORT FROM CHARITABLE FOUNDATIONS AND OTHER SAFETY NET RESOURCES WILL STILL BE NECESSARY.** Growing numbers of economically-vulnerable older adults who need specialty medications and other prescription drugs that result in high OOP costs will result in the continued need for support from safety net organizations. The need for support from charitable organizations are projected to increase in the future in response to these trends.

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 OOP 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 over $3 billion in financial assistance through over 60 disease-specific programs.

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

Supporting Literature

[1]https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/ (accessed January 31, 2018).

[2]Li P, Wong YN, Jahnke J, Pettit AR, Doshi JA. Association of high cost sharing and targeted therapy initiation among elderly Medicare patients with metastatic renal cell carcinoma. Cancer Med. 2018 Jan; 7(1): 75–86.

[3]Doshi JA, Takeshita J, Pinto L, et al. Biologic therapy adherence, discontinuation, switching, and restarting among patients with psoriasis in the US Medicare population. Journal of the American Academy of Dermatology. 2016;74(6):1057-1065.e4.

[4]Jalpa A. Doshi Tianyan Hu Pengxiang Li Amy R. Pettit Xinyan Yu Marissa Blum. Specialty Tier-Level Cost Sharing and Biologic Agent Use in the Medicare Part D Initial Coverage Period Among Beneficiaries With Rheumatoid Arthritis. Arthritis Care & Research, 68: 1624-1630.

[5]Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP. Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon". Am J Manag Care. 2017;23(3 Suppl):S39-S45.