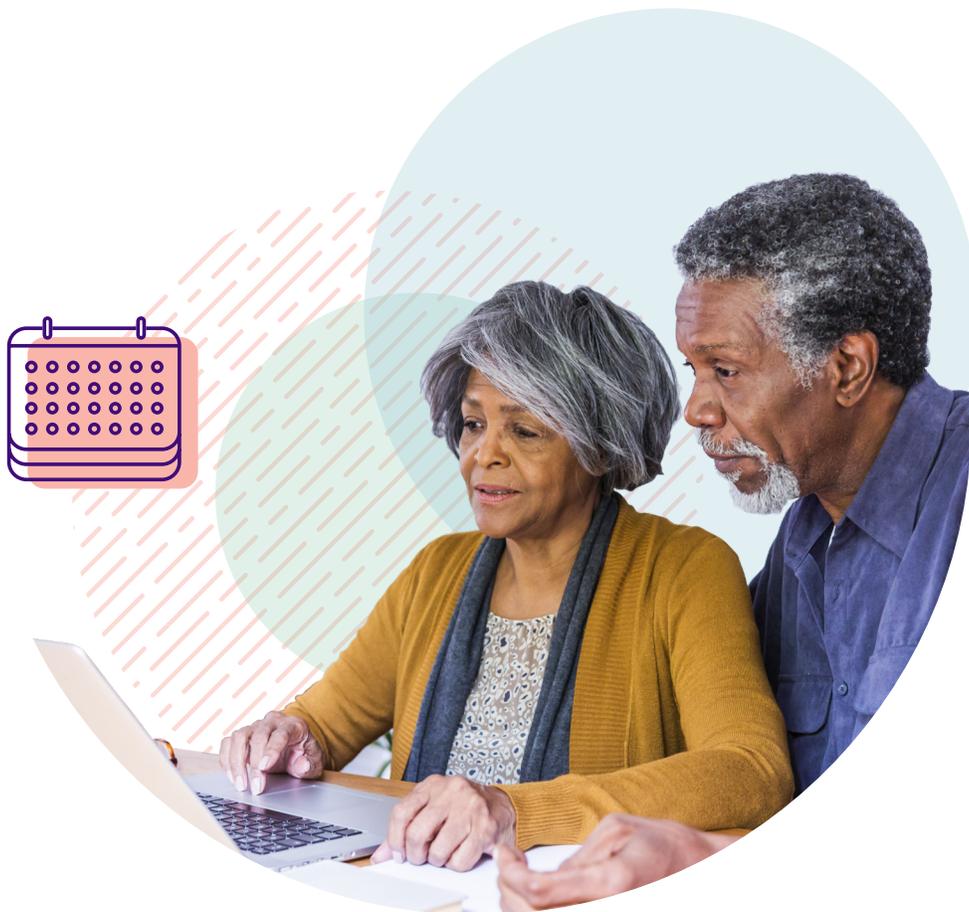




ISSUE BRIEF No. 6

“SEASONALITY” OF OUT-OF-POCKET DRUG COSTS FOR MEDICARE BENEFICIARIES

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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 out-of-pocket costs should not prevent individuals with life-threatening, chronic and rare diseases from obtaining their prescribed medications.

PAN advocates for strategies that will increase access to medically necessary medications among economically vulnerable Medicare beneficiaries by reducing their out-of-pocket (OOP) 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 health 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.

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.



The Basic Structure of Medicare Part D Drug Plans

A standard Medicare Part D drug plan includes the following elements:^{1,2}

MONTHLY BASIC PREMIUM

Average of \$42.05 in 2020

ANNUAL DEDUCTIBLE

\$435 in 2020

INITIAL COVERAGE PHASE

Enrollees pay 25% coinsurance for covered drugs

In 2020, Initial Coverage Period limit is \$4,020 in total drug costs

COVERAGE GAP PHASE

Enrollees pay 25% of covered drugs

In 2020, Coverage Gap limit is \$6,350 in “true out-of-pocket costs” (TrOOP; see below)

CATASTROPHIC COVERAGE PHASE

Enrollees pay 5% coinsurance for covered drugs

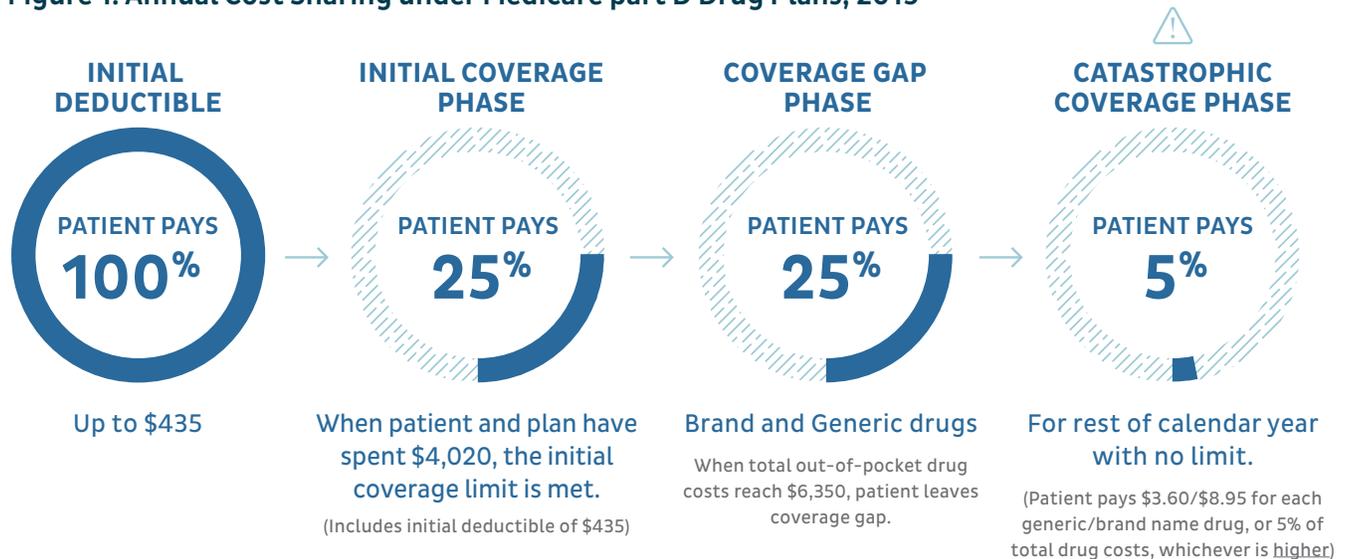
No cap on OOP costs for the remainder of the year

What payments towards TrOOP?

- **The annual deductible**, which is the amount patients pay for their Medicare Part D-covered prescriptions before their Medicare Part D drug plan coverage begins.
- **Out-of-pocket costs** and any additional cost sharing, which is what patients pay for each Medicare Part D plan-covered prescription drug after their drug plan begins to pay (i.e. co-pays 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.

Unintended Consequences of the Structure of Part D Drug Plans

Figure 1: Annual Cost Sharing under Medicare part D Drug Plans, 2019



Medicare Part D drug plans follow a January–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 frequently 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 percent of all OOP drug costs for the Initial Coverage Phase in the month of January.**

Part D enrollees enter the Coverage Gap Phase once they and their plan have spent \$4,020 in drug costs. Enrollees leave the Coverage Gap when total out-of-pocket drug costs reach \$6,350. **Compared to people who can be effectively treated with less expensive drugs, this \$6,350 threshold can be reached very quickly for patients who need specialty medications—sometimes entirely 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.

* 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.

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 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 1, when many patients are “hit” once again with high OOP medication costs.

What the Research Shows

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 the Low-Income Subsidy, 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 recent report³ 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 report showed that non-LIS beneficiaries were responsible for OOP of \geq \$2,800 for their initial prescription, compared to \leq \$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 report⁴ 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 study⁵ of specialty medications used for 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 in out-of-pocket costs for the same supply. Non-LIS patients were less likely to fill prescriptions for specialty medications for their RA, and those 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 study⁶ 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 and February and January through March.

Health Condition	Average Annual 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 percent 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 This Means for Medicare Beneficiaries

Medicare beneficiaries don't have enough cash to pay for their OOP medication costs

Many beneficiaries do not have enough cash on hand to pay for their OOP Medications 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 need to pay 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 is an independent, national 501 (c)(3) organization dedicated to helping underinsured people with life-threatening, chronic and rare diseases get the medications and treatments they need by assisting with their out-of-pocket costs and advocating for improved access and affordability.

For more information about this Issue Brief, contact Amy Niles, Executive Vice President, at: aniles@panfoundation.org.

Supporting Literature

¹ Cubanski J, Neman T. How Will The Medicare Part D Benefit Change Under Current Law and Leading Proposals? Available at: <https://www.kff.org/medicare/issue-brief/how-will-the-medicare-part-d-benefit-change-under-current-law-and-leading-proposals/>. (accessed February 29, 2020).

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³ 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.

⁴ 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.

⁵ 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.

⁶ 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.