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PAN Foundation

Out-of-Pocket Costs and Specialty Medications

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 seriously ill and economically vulnerable patients and families.

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

This *Issue Brief* describes formulary tiers, explores the rationale for specialty drug tiers, and how OOP costs for specialty medications can reduce access to these drugs. The brief also examines the financial hardship that results from high OOP costs for specialty medications.

What are Specialty Tiers and What is Their Purpose?

Most commercial health insurance plans include at least some coverage for prescription medications. For Medicare beneficiaries, prescription drug coverage is obtained through a Medicare Part D drug plan or through a Medicare Advantage plan. The list of drugs that is covered under a commercial or federal health insurance drug plan is known as the plan's "formulary." Formularies can contain hundreds of medications, including relatively inexpensive generic drugs, as well as extremely costly brand-name medications.

The formularies of most prescription drug plans categorize covered medications into groups called "cost-sharing tiers," or "tiers," and most plans have three to five tiers. In general, the lower formulary tiers contain less expensive, preferred generic drugs, and higher tiers contain more expensive medications. The highest tier on a drug plan's formulary is often called the "specialty tier."

Cost sharing—the amount of the cost of a prescription medication that is paid by the patient—is greater for drugs that are on higher formulary tiers. For example, a patient may have a $10 co-pay for a preferred generic drug on tier 1, but the coinsurance may be 33% or more for a drug on a specialty tier.

A typical 5-tier formulary is generally organized as follows:

TABLE 1.
Structure of a Standard Formulary

TIER	INCLUDED DRUGS	PATIENT OUT-OF-POCKET COSTS
1	Low-cost, preferred generic drugs	$
2	Preferred generic drugs	$$
3	Preferred brand name drugs, and non-preferred generic drugs	$$$
4	Non-preferred brand drugs, and non-preferred generic drugs	$$$$
5	Specialty medications, and high cost, brand name and generic drugs	$$$$$

The main purpose for categorizing prescription medications into formulary tiers is to encourage patients and providers to use the least expensive medications that are clinically appropriate and medically necessary. However, when patients need medications that are on the highest tier, and these medicines do not have generic equivalents, they are faced with high OOP costs.

How Do Drugs Get Placed on Specialty Tiers?

In recent years, there have been remarkable advances in drug development, including new treatments for certain cancers, autoimmune conditions, rare diseases and other life-threatening conditions. New medications for these conditions are often very expensive, and because of their high cost, these drugs are frequently placed on the specialty tier. These drugs are called “specialty medications.”

There is no standard definition for a specialty medication, but these drugs typically have 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.

Why Do Patients and Their Providers Choose Specialty Medications?

Although many patients can be effectively treated with low-cost generic medications, in some cases, the only drug that is effective is a specialty medication, or a high cost generic drug that is on the specialty

tier. In these cases, patients have no choice but to incur high OOP drug costs because there is no lower-cost alternative. The table below illustrates how the need for a specialty medication impacts a patient's annual OOP medication costs. A Medicare beneficiary with rheumatoid arthritis (RA) who can be effectively treated with a common generic drug could incur as little as $171 in OOP costs for her RA medication. However, if she did not respond to the lower cost drug and required a specialty medication, her annual OOP costs could be as high as $29,390.

In contrast to RA, where clinicians often try to manage patients with low-cost drugs before moving to a specialty medication, in other conditions such as chronic myelogenous leukemia (CML), effective treatment can only be achieved with a specialty medication. For a Medicare beneficiary with CML, annual OOP drug costs can be as high as $49,969.

Given the choice, most Medicare beneficiaries would choose to incur low OOP costs for their medications if they provided effective treatment. However, for many patients who need specialty medications, there is no lower cost equivalent medication available.

TABLE 2.

HEALTH CONDITION	DRUG	ESTIMATED ANNUAL OOP COST FOR THIS MEDICATION
Rheumatoid arthritis	Drug A - generic	$171–$2,269
Rheumatoid arthritis	Drug B - specialty	$3,760–$29,390
Chronic myelogenous leukemia	Drug C - specialty	$4,978–$49,969

Note: Estimated annual OOP costs for a Medicare beneficiary living in Maryland who uses a retail pharmacy and does not receive a Low Income Subsidy to help with prescription medications.[1]

How Do Patients Respond to the OOP Cost Burdens for Their Specialty Medications?

- **PATIENTS ARE WORRIED ABOUT THE COST OF THEIR MEDICATIONS.** Concern about how to pay for expensive medications is a top priority for many Americans. When asked about many different aspects of healthcare delivery and the healthcare system, a Kaiser Family Foundation survey showed that the issue that comes out on top is making sure that high-cost drugs for chronic conditions, such as HIV, hepatitis, mental illness and cancer, are affordable to those who need them. Seventy-six percent of the public said this is a top priority.[2]
- **HIGH OOP COSTS REDUCE ACCESS TO SPECIALTY MEDICATIONS.** A growing body of research shows that as OOP medication costs go up, patients' access to needed medications diminishes. Not only do high OOP costs reduce the likelihood that patients will initiate treatment, but among patients who do fill an initial prescription for specialty medications, high OOP costs increase the likelihood that

they will delay refilling their prescription, that they will stop treatment early, skip doses or cut pills to make their prescriptions last longer.[3,4,5,6]

» **HIGH OOP COSTS FOR SPECIALTY MEDICATIONS CAUSE FINANCIAL HARDSHIP.** In addition to the impact of high drug OOP costs on access to specialty medications, people with medical conditions for whom these medications are frequently prescribed often experience severe financial hardship that is linked to these costs.[7,8] This hardship is caused by "financial toxicity" that disproportionately impacts economically vulnerable, sick patients, further hindering their ability to cope with, and recover from their health conditions and remain economically viable.[9,10,11,12]

The Bottom Line on Specialty Medications

PAN advocates for strategies that increase access to medically necessary medications among economically vulnerable patients by reducing their out-of-pocket drug costs. PAN believes that **all health conditions have at least one highly effective innovator drug that is not on a specialty tier.**

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 close to 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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