



Removing Barriers to Care in Medicare Part D

Access to Epilepsy Medications in Medicare Part D

The Six Protected Classes policy was designed to ensure Medicare Part D beneficiaries living with chronic conditions like epilepsy have meaningful and timely access to lifesaving medications necessary for controlling their conditions and maintaining their quality of life. Epilepsy medications are not interchangeable and people living with epilepsy need access to the full range of therapies available so they can find the right medication or combination of medications that most effectively treats their condition.

Despite the intent of the Six Protected Classes policy, Medicare Part D beneficiaries living with epilepsy are increasingly confronting barriers to care due to utilization management activities, including high cost-sharing, that limit access to lifesaving epilepsy medications.

These barriers include:

- Utilization Management Practices that Limit Access to Anti-Epilepsy Drugs (AEDs)
- Utilization Management Hurdles that are Difficult for Beneficiaries and Providers
- High Cost-Sharing that Stands in the Way of Open Access to AEDs

Addressing these barriers and ensuring open access to lifesaving medications consistent with the purpose of the Six Protected Class policy will require restricting or limiting utilization management practices used by Medicare Part D insurers who are trying to save money at the expense of the most vulnerable Medicare beneficiaries.

About Epilepsy

Epilepsy is a medical condition that produces seizures affecting a variety of mental and physical functions and affects more than 2.8 million in the US. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime. For the majority of people living with epilepsy, AEDs are the most common and cost effective treatment for controlling and/or reducing seizures. Meaningful and timely access to physician directed care is critical to maintain seizure control.

There is no “one size fits all” treatment option for epilepsy and the response to AEDs can be different for each person. Medications in the Six Protected Classes are not interchangeable, and beneficiaries often react quite differently to the available treatments. Maintaining seizure control with minimal side effects requires careful evaluation and monitoring by the physician and patient. As a result, managing these serious, chronic, and life-threatening conditions requires access to the full range of therapies available. To change, limit, or deny access to medications as prescribed by the treating physician can be extremely dangerous and often leads to preventable seizures, increased hospitalizations, and associated complications, including death. These preventable complications result in increased medical costs for Medicare along with lost wages and productivity, not just for the individuals living with epilepsy but also their families and communities.

Utilization Management Practices are Limiting Access to AEDs

Contrary to the intent of the Six Protected Classes policy, Medicare Part D plans have created significant barriers for beneficiaries seeking timely access to the AEDs prescribed by their treating physician. **More than 68% of plans impose prior authorization requirements for AEDs, with 15.1% requiring beneficiaries to fail on a preferred drug, and about 5.6% of plans require beneficiaries to fail on two preferred drugs, before they can access the AED recommended by their treating physician.**¹

Prior Authorization and Step Therapy on Commonly Prescribed AEDsⁱⁱ

Edit	Aptiom	FYCOMPA	Lyrica	Vimpat	Vimpat Injection	Vimpat Solution	Total for Brands
Prior Authorization	45.1%	28.1%	80.1%	52.3%	23.0%	56.7%	47.6%
Single Step Edit	32.6%	26.0%	7.3%	1.9%	21.3%	1.9%	15.1%
Double Step Edit	0.9%	2.1%	1.2%	9.9%	9.9%	9.9%	5.6%
Total	78.6%	56.2%	88.6%	64.1%	45.2%	68.7%	68.3%

Navigating the Utilization Management Requirements is Difficult for Beneficiaries and Providers

The lack of transparency and uniformity associated with utilization management requirements make it particularly difficult and time consuming for beneficiaries and providers to secure prior authorization for a medication or a step therapy exemption. In many cases providers and beneficiaries are not aware of the prior authorization and step therapy requirements that must be met to gain access to the preferred medication. Beneficiaries often find out at the pharmacy counter that they need to go through the prior authorization process or fail on another medication before gaining access to the one prescribed by their provider. In many instances, all they are told is that their medication is not covered, and they must contact their provider or insurer to find out why.

Even when a provider is willing to navigate the complex process on behalf of the beneficiary, it can take a long time. The prior authorization process is not streamlined and it is easy for providers to submit wrong or incomplete forms and documentation, which leads to further delays and increases the risk of breakthrough seizure, which result in thousands of dollars – if not tens of thousands of dollars – in additional medical costs, most of which would be borne by Medicare.

Once a beneficiary gains access to medication, the success can be short-lived, as they may have to go through the prior authorization process for every refill. For example, health plans are increasingly imposing a Double Step Edit (DSE) on all brand name AEDs, thereby requiring beneficiaries living with epilepsy to have tried and failed on a thirty (30) day supply of at least two other medications before being able to access the medication that the treating physician deemed the preferred treatment option. Such an approach directly interferes with the physician-patient relationship.

Cost-Sharing Impedes Access to AEDs

High cost-sharing for epilepsy medications and the large disparity between the cost of generics and brands serve as significant barriers for patients seeking timely access to epilepsy medications, especially for individuals who rely on a branded medication for seizure control.

Out-of-pocket costs for different tiers of AEDsⁱⁱⁱ

Co-pays	Tier 1	Tier 2	Tier 3	Tier 4	Avg. Annual Co-Pay
Brand AED Commercial	N/A	\$420 (5%)	\$660 (90%)	\$1,100 (5%)	\$670
Brand AED Medicare Part D	N/A	N/A	\$515 (7%)	\$970 (93%)	\$950
Generic AED Medicare Part D	\$85 (4%)	\$144 (89%)	\$325 (7%)	N/A	\$150

Note: Medicare Part D plans may have AED generics on Tier 1 and Tier 2, while commercial plans generally have a single tier for AED generic medications.



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These high annual costs are an even greater barrier for beneficiaries and families with low and fixed incomes. According to the Kaiser Family Foundation, 30% of Medicare Part D beneficiaries have incomes that are at or less than 150% of the federal poverty level, which is \$17,655 for an individual in 2015. Most Part D beneficiaries pay at least \$20 in monthly out-of-pocket co-pays. For beneficiaries on fixed incomes \$1,000 in annual out-of-pocket costs would prevent them from accessing the medications they need, undermining the intent of the Six Protected Class policy.

Conclusion

Meaningful and timely access to AEDs for Medicare Part D patients is quickly eroding and steps must be taken to reverse that trend. The intent of the Six Protected Class policy is to ensure that the health and welfare of Medicare beneficiaries with certain chronic conditions like epilepsy. Over time, Medicare Part D plans have created barriers that are making it increasingly difficult for people living with epilepsy to have meaningful and timely access to the lifesaving medications prescribed by their physician. It is time to take steps to remove those barriers so Medicare Part D beneficiaries with chronic conditions like epilepsy can manage their conditions and maintain their quality of life.

About the Epilepsy Foundation

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of nearly three million Americans with epilepsy and seizures. The Foundation and nearly 50 affiliated organizations throughout the United States have led the fight against seizures since 1968. We are an unwavering ally for individuals and families impacted by epilepsy and seizures. The mission of the Epilepsy Foundation is to stop seizures and sudden unexpected death in epilepsy (SUDEP), find a cure, and overcome the challenges created by epilepsy through efforts including education, advocacy, and research to accelerate ideas into therapies. The Foundation works to ensure that people with seizures have the opportunity to live their lives to their fullest potential. For additional information, please visit www.epilepsy.com.

ⁱ Decision Resource Group (DRG) February 2015. DRG is the parent company of HealthLeaders Interstudy, Pinsonault, and Fingertip Formulary.

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