

ACCESS TO PRESCRIPTION MEDICATIONS

BACKGROUND

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of the 3.4 million Americans with epilepsy and seizures. Epilepsy is a disease or disorder of the brain which causes reoccurring seizures affecting a variety of mental and physical functions. Epilepsy affects people across the lifespan and can have many different causes and associated conditions. Approximately 1 in 26 Americans will develop epilepsy at some point in their lifetime.

For the majority of people living with epilepsy, epilepsy medications are the most common and most cost-effective treatment for controlling and/or reducing seizures. There is no “one size fits all” anti-seizure medication, and the response to anti-seizure medications can differ between seizure type and be different from person to person. Because it is such an individualized and complex condition, it is vital that people with epilepsy have access to the full range of approved treatment options. Maintaining seizure control with minimal side effects on the correct anti-seizure medication(s) requires careful evaluation and monitoring by healthcare providers and person with epilepsy.

Delays and barriers to accessing needed medications stem from many factors, including insurance practices and high drug costs, and have serious consequences. For instance, a thorough literature search focusing on step therapy across conditions found little evidence that formulary controls and restrictive benefit designs achieve the intended goal of reducing total costs while maintaining quality care. Patients subjected to step therapy are less inclined to fill prescriptions, they underutilize medications, and have lower therapy adherence.¹ Twenty-one percent of adults with epilepsy have reported not being able to afford prescription medications within the last year.² Delaying access to the anti-seizure medication(s) that work(s) for a particular person puts him/her at risk for breakthrough seizures and related complications including injury, disability, loss of mobility or employment, and even death. Mortality rates among people with epilepsy are three times higher and sudden death rates are twenty times higher than rates for the general population. Each year, about 1 out of 1,000 adults and 1 out of 4,500 children with epilepsy die from Sudden Unexpected Death in Epilepsy (SUDEP). In addition to these serious and potentially life-ending consequences, when people with epilepsy are not on the anti-seizure medication that works for them, it causes higher costs for the healthcare system. A review of studies has shown that direct, epilepsy-related medical costs associated with uncontrolled epilepsy are 2 to 10 times higher than costs associated with controlled epilepsy.³

FOR MORE INFORMATION CONTACT:

RACHEL PATTERSON *Senior Director, Government Relations & Advocacy, Epilepsy Foundation* | 301.918.3791
rpatterson@efa.org

PRINCIPLES

The Epilepsy Foundation leads the fight to overcome the challenges of living with epilepsy and to accelerate therapies to stop seizures, find cures and save lives. Because prescription medications are the most common and effective treatment, the Foundation advocates for access to the full range of anti-seizure medications so that each person living with epilepsy and seizures—with his/her healthcare provider’s guidance—can have timely, affordable and consistent access to the anti-seizure medication(s) that works for him/her. Policy proposals should improve prescription medication access and treatment plans and the Epilepsy Foundation examines policy proposals related to prescription medications against the following principles:

- **Safe & Effective:** Will the policy proposal improve, or at least not diminish, the safety and efficacy of prescription drugs on the market?
- **Affordable:** Will the policy proposal improve the affordability of prescription drugs to consumers?
- **Accessible & Continuous:** Will the policy proposal ensure that people with epilepsy can access medications in a timely manner without unreasonable barriers and delays?
- **Physician-Directed & Person-Centered:** Will the policy proposal promote the treatment plans that are developed by a healthcare provider in partnership with the person with epilepsy and not dictated by factors and pressures within the drug supply chain?

For too long, there has been an opaqueness of the drug supply chain which leaves many unanswered questions and confusion as to where the primary problems lie. Battles and finger pointing persist—leaving people with complex, expensive health conditions like epilepsy caught in the crossfire with unaffordable bills and impossible-to-navigate health coverage. Instead of this system where patients often lose, the Epilepsy Foundation calls on elected officials to stand up for people with chronic conditions and diseases like epilepsy to declare that enough is enough and advance solutions. All relevant entities including pharmaceutical manufacturers, pharmacy benefit managers, and health insurance issuers must be a part of the systemic reforms that must happen to improve access to medications for people with epilepsy.

INSURANCE REFORMS

Frontline access to medications for people with epilepsy and seizures is driven by health insurance design. Insurance barriers, like step therapy/fail first, prior authorization, cost sharing, and other utilization management practices keep people with epilepsy from accessing the medical treatment(s) that they need in a timely manner which can lead to breakthrough seizures and related complications like injury, disability or even death. The Epilepsy Foundation:

- Supports reforms to eliminate utilization management or put practical limitations in place. We particularly oppose imposing step therapy or prior authorization on people who are currently stable on their anti-seizure medication(s). Studies have demonstrated that people with epilepsy are at greater risk of seizure after a switch. In one study, seizure-free individuals who switched their medication had a 16.7% rate of seizure recurrence at 6 months, compared to 2.8% among people remaining on the same medication.⁴
- Supports passing all rebates and discounts to the consumer at the pharmacy counter through lower cost sharing.

- Supports smoothing out-of-pocket costs across the plan year.
- Supports maintaining current protections for people with pre-existing conditions including prohibition of annual and lifetime limits, out-of-pocket limits and subsidies for lower income individuals and families
- Opposes discriminatory formulary designs and other practices that use patient access as leverage to extract greater price concessions from drug manufacturers.
- Opposes mid-year formulary changes that remove drugs from formularies (while supporting changes that add drugs, such as newly approved generics).
- Supports requirements for all copays – including copays provided through assistance programs, or for brand name drugs when generics are available – to count toward out-of-pocket limits and deductibles.

MEDICARE AND MEDICAID

Medicare Part D

Medicare Part D provides essential access to medications for the 1.1 million Medicare beneficiaries living with epilepsy. In recent years, premiums, deductibles, and overall cost-sharing have increased, placing more of a burden on beneficiaries. The increasing use of specialty tiers, which are subject to significant coinsurance and excluded from cost-sharing exceptions, forces beneficiaries to pay a significant percentage of their medication cost. The Epilepsy Foundation supports:



- Capping out-of-pocket costs in Medicare Part D, including simplifying the benefit structure and increasing the affordability and ease of navigation of Part D;
- Eliminating or putting practical limitations in place on utilization management practices like step therapy and prior authorization and not allowing utilization management for people who are currently stable on their medication(s);
- Ensuring that rebates and discounts negotiated by Part D plans are fully passed through to consumers resulting in lower cost sharing;
- Maintaining and not weakening Medicare's Six Protected Classes policy; and
- Expanding the low-income subsidy (LIS) program by eliminating the asset test and raising the income threshold.

Medicare Negotiation

Currently, Part D plans negotiate for rebates and discounts with pharmaceutical manufacturers, in exchange for formulary placement. The idea of increasing the negotiation that occurs in Medicare, including negotiating on a Medicare-wide basis, has gained popularity. While the Epilepsy Foundation appreciates the goal of bringing down prices, the Foundation is concerned that such negotiations would harm beneficiaries in other respects such as increased restriction of formularies (including nation-wide noncoverage of a medication), increased cost sharing, and increased utilization management. The Epilepsy Foundation opposes the creation of a national formulary.

Medicaid

The Medicaid Drug Rebate Program (MDRP) achieves substantial rebates for states, significantly reducing their prescription drug costs and allowing them to continue to provide all needed prescription drugs to Medicaid beneficiaries. The Epilepsy Foundation:

- Opposes any change that could undermine the MDRP;
- Supports ensuring that medications are correctly classified in the MDRP;
- Supports changes that could strengthen the programs, such as lifting the cap on Medicaid rebates to states; and
- Supports Medicaid reforms that eliminate or limit prior authorization or other barriers to access.

QUALITY ADJUSTED LIFE YEARS AND MEASURES OF HEALTH CARE VALUE

The use of the Quality Adjusted Life Years (QALY) undervalues people with disabilities by claiming to be able to measure, in numbers and dollars, how much less valuable a year of life lived with disability is compared to a year of life lived without disability. We adamantly disagree that life with disability is less valuable than life without disability. Such claims and measurements are not only discriminatory and offensive, they can keep lifechanging and lifesaving treatments from reaching people if those people have disabilities and chronic conditions. The Epilepsy Foundation opposes the use of QALYs.

SPEEDING GENERICS TO MARKET

The Epilepsy Foundation supports efforts to bring more treatments including generic medications to market. While we encourage the development of more generics, we wish to emphasize that generics are not a panacea to the unaffordability of prescription medications. Bringing generics to market doesn't always result in more affordable medications or improved access. Generic medications can have higher cost sharing due to formulary placement. The introduction of a generic can increase cost sharing and prior authorization requirements for both the brand and the generic. Furthermore, generic medications frequently have different side effect profiles, different drug interactions, or different levels of effectiveness than the brand equivalent. The Epilepsy Foundation therefore believes that people with epilepsy should have access to the full range of medications (brand and generic) and should be free to work with their doctors to develop a medication regime that works best for each individual. The Epilepsy Foundation:

- Supports efforts to address and stop practices that slow the development or marketing of generics;
- Supports specific reforms to address practices such as: agreements to delay generic entry into the market (pay for delay), limiting generic manufacturers' access to samples, manipulation of the citizen petition process, and abuse of a generic's 180 days of exclusivity; and
- Opposes any policy proposal which punishes individual people who must continue to take a brand name medication through higher cost sharing, nonapplication of cost sharing to out-of-pocket limits, or other penalties.



INTERNATIONAL PRICE COMPARISON

While we understand that many medications are available at a lower price in other countries, the Epilepsy Foundation's focus is to address price and other access barriers within the United States. However, we are also aware that many other countries use discriminatory pricing controls and medication value measures such as QALY that undervalue the lives of people with disabilities. The Epilepsy Foundation opposes any pricing structure that uses a QALY measure or imports a QALY measure from another pricing system.

TRANSPARENCY OF THE DRUG SUPPLY CHAIN

The opacity of the drug supply chain makes it difficult for people to navigate their benefits, anticipate their costs, and make health care choices. It also makes it difficult for patient advocacy organizations to anticipate, understand and support when the people we represent face a shortage, price increase, or institution of prior authorization, step therapy, or other utilization management. For these reasons, the Epilepsy Foundation:

- Supports efforts to increase transparency of the drug supply chain, including manufacturers, pharmacy benefit managers, and health insurance companies;
- Supports requiring drug manufacturers to provide public notice of price increases, acquisitions, or other changes to business practices that will impact patient access without penalties for failure to comply;
- Supports requiring pharmacy benefit manufacturers to pass through all rebates and discounts to patients through lower cost sharing, and issuers having oversight of PBMs' use of spread pricing, steering to PBM-owned or other pharmacies, and other business practices not in the patient interest;
- Supports prohibiting health insurance companies from making adverse formulary changes during the plan year that the consumer has purchased, and requiring insurers to provide adequate notice of these changes for future plan years during open enrollment periods; and
- Supports requiring all of these entities to furnish data to MacPAC and MEDPAC for their government funding lines to facilitate research on drug pricing and the drug supply chain.



Endnotes

1 Carlton, R.I., Bramley, T.J., Nightengale, B., Conner, T.M., & Zacker, C. (2010). Review of outcomes associated with formulary restrictions: focus on step therapy. *American Journal of Pharmacy Benefits*, 2(1), 50-58. Retrieved from https://www.ajpb.com/journals/ajpb/2010/vol2_no1/review-of-outcomes-associated-with-formulary-restrictions-focus-on-step-therapy.

2 Thurman, D.J., Kobau, R., Luo, Y., Helmers, S.L., & Zack, M.M. (2016). Health-care access among adults with epilepsy: The U.S. National Health Interview Survey, 2010 and 2013. *Epilepsy & Behavior*, 55, 184-88. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/>.

3 Begley, C.E. & Durgin, T.L. (2015). The direct cost of epilepsy to the United States: A systematic review of the estimates. *Epilepsia*, 56(9), 1376-87. Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084>.

4 Finamore, J.M., Sperling, M.R., Zhan, T., Nei, M., Skidmore, C.T., & Mintzer, S. (2016). Seizure outcome after switching anti-epileptic drugs: A matched, prospective study. *Epilepsia* 57(8), 1294-300. Retrieved from <https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13435>.