



# REFORM STEP THERAPY PROTOCOLS

## Recommendation

Pass the Safe Step Act (H.R. 2279/S. 2546), which would amend the Employee Retirement Income Security Act of 1974 (ERISA) to streamline step therapy protocols and require exceptions to step therapy requirements so that people with epilepsy can access the most effective medications in a timely manner.

## BACKGROUND

Step therapy, or fail first, is a process that requires individuals who have been prescribed a medication by their healthcare provider to try and fail one or more medication(s) preferred by the insurer before receiving the originally prescribed drug.

There is no “one size fits all” treatment option for epilepsy, and the response to epilepsy medications can be different for each person. People with epilepsy who are forced to fail on one or more medications other than those prescribed by their physician by step therapy requirements are at a higher risk for developing breakthrough seizures and related complications, including death.

The Safe Step Act does not ban the use of step therapy, but instead requires exemptions from step therapy protocols for people who are currently stable on their medication regime, who have already failed or had an adverse reaction to the treatment, or for whom the step is contraindicated. The legislation will also give healthcare providers and people with epilepsy a transparent and standardized process to appeal step therapy requirements when a particular treatment is needed.

## ABOUT EPILEPSY

Epilepsy is a disease or disorder of the brain which causes reoccurring seizures. Epilepsy is made up of many different types of seizures or syndromes, affects people throughout the lifespan, and can have many different causes and associated conditions.

3.4 million Americans live with active epilepsy. While some are able to gain seizure control, 30-40% of people with epilepsy live with uncontrolled seizures despite available treatments. Delayed recognition of seizures and inadequate treatment increase a person’s risk of subsequent seizures, brain damage, disability, and death. Epilepsy imposes an annual economic burden of \$19.4 billion on the country.

**25 states**

have passed step therapy protocol reform

**7 states**

have introduced step therapy reform legislation in 2020

**Up to 10x**

higher health care costs per year for people with uncontrolled epilepsy

FOR MORE INFORMATION, CONTACT:

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## PRISCILLA'S STORY

Priscilla (Maryland) was first diagnosed with epilepsy at the age of 11 after having a seizure in school. One of the most frustrating challenges Priscilla encounters is being able to access her anti-seizure medications in a timely manner. Once in college, Priscilla had an issue with prior authorization and her pharmacist informed her that her medication would be \$800 out-of-pocket for a 30-day supply. She couldn't possibly afford this as a college student—but knew that if she didn't have her anti-seizure medication, she could potentially have a seizure alone in her dorm room which is very dangerous. Fortunately, her mother was able to shoulder the financial cost in order to keep Priscilla safe.

Priscilla has tried and failed 10 anti-seizure medications. There is no “one-size-fits-all” anti-seizure medication, so some of these were simply because particular medications were ineffective for Priscilla's seizure type. Some of these failures, however, were because she was forced to go through step therapy. Often, Priscilla was made to try a generic form of an anti-seizure medication even though her healthcare provider had prescribed the brand name. Such changes can be dramatic and dangerous for people with epilepsy. Priscilla experienced breakthrough seizures and landed in the hospital. These medication changes which go against physician-directed care also make her quite anxious, as she is never sure how her body will react. In instances when she cannot access her prescribed anti-seizure medication, she has even skipped doses to stretch her prescribed medication.

Regardless of the obstacles that come her way, Priscilla makes it a point to keep pushing to achieve her life goals. She has obtained two Master's degrees—one



in cellular and molecular biology and a second in clinical research administration (she graduated with honors!). Priscilla is now leveraging her education and working as the Epilepsy Foundation's Clinical Research Coordinator. She shares her story more and more, but has also realized that she's been advocating for herself through her entire journey as an epilepsy patient.

Priscilla urges members of Congress to remember the struggles and dreams of people living with epilepsy like her as they legislate. Step therapy can be dangerous for people with epilepsy and passing the Safe Step Act will help ensure that people with epilepsy like Priscilla can access the most effective anti-seizure medication in a timely manner.