



Step Therapy Reform: Neurological Conditions

Overview of neurological conditions

Neurological conditions affect more than 100 million Americans. Examples include Alzheimer's disease, migraine disease, Parkinson's disease, stroke, traumatic brain injury, and multiple sclerosis (MS). Symptoms vary widely based on the specific disease or disorder, and some can be debilitating. Patients may experience severe headaches, memory loss, impaired mental ability, or weakness or loss of muscle strength.¹ The cost of treating neurological conditions is estimated to be more \$500 billion annually.²

What is step therapy?

Step therapy policies, also referred to as "fail first," require insured individuals to try and fail on alternative treatments, sometimes with adverse effects, before the insurer or pharmacy benefit manager will cover the prescribed treatment.

Problems with step therapy

Step therapy policies can be unethical and inconsistent with standards of care, resulting in interference with the practitioner-patient relationship and significant delays in access to prescribed treatments.³

Step therapy requirements can be especially burdensome for patients who need highly individualized care. For them, trying and failing on alternative treatments may not be in their best interest.⁴ This could be due to lack of efficacy, lack of therapeutic equivalence, the patient's preference regarding the medication and its associated side effects, or clinical characteristics unique to the patient that necessitate one treatment over another.⁵ Yet, the time that the patient spends trying and failing on the alternative treatment could cause the patient's condition to progress or relapse due to the treatment's ineffectiveness.⁶

How does step therapy negatively impact patients with neurological conditions?

Step therapy can have significant negative impacts on patients and prescribers alike. When choosing an individualized treatment for a neurological condition, prescribers must consider several factors, including potential side effects, route of administration, disease progression, comorbidities, lifestyle, and the patient's

¹ <https://www.hopkinsmedicine.org/health/conditions-and-diseases/overview-of-nervous-system-disorders>.

² <https://ihpi.umich.edu/news/out-pocket-costs-neurologic-medications-rise-sharply-over-12-years#:~:text=The%20research%20was%20funded%20by,is%20more%20than%20%24500%20billion>.

³ <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey-Report.pdf>

⁴ <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey-Report.pdf>

⁵ <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf>

⁶ <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf>

ability to manage the medication and access care for appropriate monitoring.^{7,8} Yet, by implementing step therapy requirements, the insurer undercuts the prescriber's careful consideration of these factors. As a result, these cost-driven, non-individualized policies can negatively impact outcomes. "Try and fail" is particularly concerning in the context of disease modifying therapies (DMTs)⁹ for degenerative neurological conditions such as MS or Alzheimer's disease, as step therapy-related delays can result in damage to the central nervous system that otherwise could be slowed down with timely, effective treatment.¹⁰

Patient story

Sheldon, a patient living with MS, has faced significant difficulties accessing his physician-prescribed treatment due to step therapy.¹¹ Following his diagnosis, his neurologist prescribed an oral DMT that had recently received FDA approval. Despite his provider's careful decision to prescribe the DMT, Sheldon's insurance company instead required him to step through an older, injectable medication. The medication required by his insurer caused significant side effects, including 10 weeks of flu-like symptoms that resulted in Sheldon missing work. The insurance company allowed Sheldon to switch medications, but only to another injectable, not the oral medication originally prescribed by his neurologist. This medication prevented a major relapse, but has not prevented Sheldon's disease progression. For over five years, Sheldon has been unable to access his neurologist's preferred treatment.

⁷ <https://www.cjonline.com/opinion/columns/2017-02-16/amber-wagnon-kansas-needs-protect-patients-step-therapy>.

⁸ <https://www.aan.com/policy-and-guidelines/policy/position-statements/availability-of-disease-modifying-therapies-dmt-for-treatment-of-relapsing-forms-of-multiple-sclerosis/>

⁹ DMTs are treatments that reduce the activity and progression of diseases like MS.

¹⁰ <https://www.aan.com/policy-and-guidelines/policy/position-statements/availability-of-disease-modifying-therapies-dmt-for-treatment-of-relapsing-forms-of-multiple-sclerosis/>

¹¹ <https://www.nationalmssociety.org/About-the-Society/News/Progress-on-Bills-to-Address-Step-Therapy>