

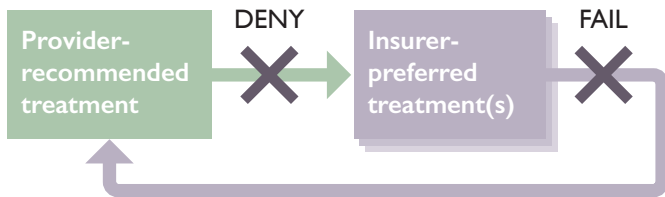


CO-SPONSOR the SAFE STEP ACT

(H.R. 5509/S.2903)

WHAT IS STEP THERAPY (FAIL-FIRST REQUIREMENT)?

Step therapy, sometimes called a “fail-first requirement,” is a protocol in which a health insurer will deny coverage for a prescribed prescription or treatment until an alternative insurer-preferred treatment is first attempted.



The goal of step therapy is to cut treatment costs, but for many patients, fail-first protocols delay needed treatment sometimes for months at a time while patients work their way through multiple insurer required steps. Furthermore, step therapy protocols may ignore a patient’s unique circumstances and medical history. That means patients may have to use medications that previously failed to address their medical issue, or – due to their unique medical conditions – could have dangerous side effects.

AHDA ASK:
Co-Sponsor the Safe Step Act

The “Safe Step Act” is a bi-partisan bill which seeks to address the medical concerns associated with step therapy. The bill would amend the Employee Retirement Income Security Act (ERISA) to require health insurers and group health plans to grant exceptions for step therapy protocols in medically appropriate cases.

IMPACT ON HEADACHE DISORDERS PATIENTS:

Patients with headache disorders are some of the most impacted by step therapy protocols. In a recent study of such impacted individuals:¹

93% were required to follow step therapy protocols before receiving their provider’s originally recommended care

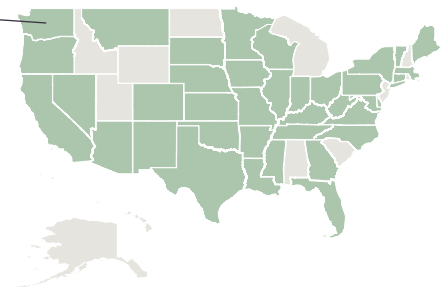
Over 50% were required to try at least **3 medications** before getting the treatment their provider originally recommended

89% reported an adverse impact to their quality of life **72%** reported negative effects on their work life

When migraine patients experience delays in care, their conditions can progress **from episodic to chronic**.

People who experience such conditions may opt to abandon specialized migraine care, **turning to opioids or other treatments** which do not address the root cause of symptoms and can carry risks and side effects.

At least **38 states** have already enacted similar step therapy legislation, but federal action is needed.



1. Survey Report: Step Therapy for Migraine and Other Headache Disorders, Headache & Migraine Policy Forum & Migraine Meandering

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The Safe Step Act amends the Employee Retirement Income Security Act (ERISA) to require a group health plan provide an exception process for any medication step therapy protocol.



THE BILL ESTABLISHES A CLEAR EXEMPTION PROCESS:

The Safe Step Act requires insurers implement a clear and transparent process for a patient or clinician to request an exception to a step therapy protocol.

OUTLINES 5 EXCEPTIONS FOR FAIL-FIRST PROTOCOLS:

Requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations, and requires a group health plan respond to an exemption request within 72 hours in all circumstances, and 24 hours if the patient's life is at risk.

1
Patient already tried and failed on the required drug.

A patient has already tried the medicine and failed before.

2
Delayed treatment will cause irreversible consequences.

The drug is reasonably expected to be ineffective, and delay of effective treatment would leave to severe or irreversible consequences.

3
Required drug will cause harm to the patient.

The treatment is contraindicated or has caused/is likely to cause an adverse reaction.

4
Required drug will prevent a patient from working or fulfilling Activities of Daily Living.

The treatment has or will prevent a participant from fulfilling their occupational responsibilities at work or performing Activities of Daily Living (ADLs), such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).

5
Patient is stable on their current medication.

The patient is already stable on the prescription drug selected by his or her clinician, and that drug has been covered by their previous or current insurance plan.

References:: Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A; American Headache Society. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. *Headache*. 2024 Apr;64(4):333-341. doi: 10.1111/head.14692. Epub 2024 Mar 11. PMID: 38466028.

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