American College of Rheumatology
Empowering Rheumatology Professionals

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Step Therapy: Instead of "Fail First," Put Patients First

Support the Safe Step Act of 2021 (S. 464/H.R. 2163)

- **Creates a clear and transparent process for patients** with employer-sponsored insurance to seek exceptions to step therapy.
- **Establishes a reasonable and clear timeframe** for override decisions and requires insurers to consider the patient's medical history and the provider's expertise before denying a patient medically necessary treatment.
- **The bipartisan legislation is sponsored** by Reps. Raul Ruiz, MD (D-CA) and Brad Wenstrup, DPM (R-OH)–medical providers who have encountered step therapy in their own practices.

Ask: Co-Sponsor the Safe Step Act of 2021 (S. 464/ H.R. 2163)

Step therapy–also known as "fail first"–is a troubling practice employed by most insurers that forces patients to try therapies preferred by the insurance company before the therapy their doctor prescribed will be approved–even when doctors are certain the initial therapy is not best for the patient. Step therapy ranks the financial benefit of insurers and pharmacy benefit managers above the judgment of healthcare providers and poses unnecessary risk to patients' health by delaying effective treatment. Step therapy is tantamount to practicing medicine without a license; we advocate that physicians be empowered to treat their patients appropriately and in accordance with accepted guidelines. Though many states have acted on this topic, federal legislation is necessary to address this threat to the health of patients covered by ERISA plans.

Step Therapy Hurts Patients

A 2016 Arthritis Foundation survey found that most respondents experienced negative health effects from delays in getting on the right treatment. According to the survey:

- **Over 50% of all patients reported having to try two or more different drugs** prior to getting the one their doctor had originally ordered.
- **Step therapy-required medications were stopped in 39% of cases** because the drugs were ineffective, and 20% of the time due to worsening conditions.
- **Nearly 25% of patients who switched insurance providers were required to repeat** step therapy with their new carrier.

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Treatments for rheumatic conditions are not one-size-fits-all and must be carefully tailored to a patient's individualized needs. Step therapy unnecessarily prolongs this process by requiring patients to try and fail drugs their doctors know will not be effective. This delay of care is a de facto denial of care. Further, patients may be subjected retroactively to step therapy when they change insurers, forcing them to step back and receive ineffective measures to document failure, even when they were already on effective therapy. For example, a patient currently on biologic therapy that kept their disease controlled may be forced to switch from that agent when changing insurers, to prove failure of a different "preferred" medication. This break in the continuity of care risks altering the impact of the drug that was working for the patient as well as the return of often debilitating symptoms as well as risking permanent disability. Patients often must try multiple drugs before finding one that works for them, so the ability to remain on a drug that works–without having to go through step therapy–is critical.

What Does the Safe Step Act DO Exactly?

The legislation amends the Employee Retirement Income Security Act (ERISA) to require that group health plans provide an exception process for any medication step therapy protocol by:

1. **Establishing a clear exemption process.** It requires insurers to implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.
2. **Outlining 5 exceptions to step therapy/fail first protocols.** Requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:
    a. Patient has tried the plan-required drug and the treatment failed to be effective.
    b. The plan-required drug is reasonably expected to be ineffective for the patient, and a delay of effective treatment would lead to severe or irreversible consequences.
    c. The plan-required drug is contraindicated or has caused/is likely to cause an adverse reaction to the patient.
    d. The plan-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), meaning basic personal everyday activities such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).
    e. The patient is already stable on the prescription drug treatment selected by their provider, and that drug has been covered by their previous or current insurance plan.
3. **Requires a group health plan to respond to an exemption request** with a determination of whether the conditions for the exception are met within 72 hours of receiving the request or within 72 hours of receiving additional requested information if deemed necessary to make the determination.
4. **Where the step therapy protocol may seriously jeopardize** the life or health of the patient the plan must respond with a determination within 24 hours.

On behalf of our patients, the American College of Rheumatology supports the bipartisan Safe Step Act of 2021 (S. 464/H.R. 2163), which puts patients first by establishing reasonable parameters for the use of step therapy.