

The Safe Step Act (S 2905 / HR 5509)

Introduced by Senator Lisa Murkowski (R-AK) and Maggie Hassan (D-NH) in the Senate and Congressman Rick W. Allen (R-GA-12) and Lucy McBath (D-GA-6) in the house, this bill would establish common-sense patient protections within insurance-mandated step therapy protocols. These protections would help patients access the right medication at the right time, thereby avoiding unnecessary and expensive adverse health outcomes that result from delayed or ineffective treatment.

What is step therapy/fail first?

Step therapy (also known as fail-first) is the most common prior authorization protocol imposed by insurance companies and pharmacy benefit managers. It requires patients to try and demonstrate clinical failure on medications preferred by the insurance company before they provide coverage for the medication originally prescribed by the patient's health care provider.

How does step therapy/fail first impact patients with inflammatory bowel disease (IBD)?

When implemented inappropriately, step therapy causes delays in needed treatment, leads to worsened health outcomes, and contributes to increased healthcare costs.



Step Therapy Delays Needed Care: [97% of IBD patients](#) subjected to prior authorization were ultimately granted access to their physician prescribed medications, but delays lasted anywhere from multiple days to months.



Delays Harm Patients: [85% of patients](#) who have been subjected to step therapy report that they suffered adverse health outcomes as a result of delayed access to medically needed care.



Step Therapy Increases Healthcare Costs: Medication utilization management protocols such as step therapy are estimated to cost the U.S. health care system [\\$93.3 billion](#) annually.

What would the Safe Step Act do?

- Requires group health plans to implement a clear appeals process for step therapy/fail first
- Establishes a 24–72-hour time frame in which insurers must respond to appeals
- Establishes circumstances in which a patient may be excepted from step therapy when:
 - The required treatment is contraindicated or has been ineffective in the treatment of the patient
 - The required treatment is reasonably expected to be ineffective
 - The required treatment will cause or is likely to cause an adverse reaction or physical harm to the patient
 - The required treatment is expected to decrease the patient's ability to perform daily activities or work, or to adhere to the treatment plan