

## Co-sponsor S 652/HR 2630, the Safe Step Act

Introduced by Senators Hassan (D-NH) and Murkowski (R-AK), and Representatives Wenstrup (R-OH-2) and Ruiz (D-CA-36), this bill would establish commonsense patient protections to insurer step therapy protocols. These protections would help patients access the right medication at the right time, and avoid unnecessary and potentially 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 fail on lower-cost medications before they will provide coverage for the medication originally prescribed by the patient's healthcare 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:** Physicians *report* that 92% of patients subjected to prior authorization experienced negative clinical outcomes.



**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