



## Step Therapy Reform: Gastroenterological Conditions

### ***Overview of gastroenterological conditions***

Gastroenterological conditions, including inflammatory bowel disease, Crohn's disease, diverticulitis, and ulcerative colitis, can cause significant inflammation, discomfort, and pain in the digestive tract.<sup>1</sup> Inflammatory bowel diseases, which are chronic, life-long conditions that can be treated but not cured, affect as many as 1.6 million Americans.<sup>2</sup> These conditions can significantly impact a patient's quality of life and may result in significant financial burdens on the patient.<sup>3</sup> The conditions can also weigh on patients' psychological health, as symptoms can be emotionally burdensome and socially limiting.<sup>4</sup>

### ***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.<sup>5</sup>

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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup>

### ***How does step therapy negatively impact patients with gastroenterological conditions?***

Step therapy can result in significant discomfort, hospitalization, and additional costs for patients with gastrointestinal diseases.<sup>9</sup> For example, two doctors described the "common experience" of patients with moderately active Crohn's disease or ulcerative colitis as having to delay preferred treatment for three to

---

<sup>1</sup> <https://www.uabmedicine.org/patient-care/conditions/common-gastroenterology-conditions>.

<sup>2</sup> <https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf>.

<sup>3</sup> <https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf>.

<sup>4</sup> <https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf>.

<sup>5</sup> <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey-Report.pdf>

<sup>6</sup> <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey-Report.pdf>

<sup>7</sup> <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf>

<sup>8</sup> <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf>

<sup>9</sup> <https://morningconsult.com/opinions/step-therapy-reform-will-help-physicians-put-patients-first/>.

six months.<sup>10</sup> Patients often remain ill and in great discomfort while waiting for the preferred treatment, sometimes to the point of being unable to work, which can lead to long-lasting damage to the patient.<sup>11</sup> Furthermore, the delays and costs in accessing physician-preferred treatment can lead to some patient abandoning treatment altogether.<sup>12</sup> Despite serious concerns with step therapy's effects on patients with gastrointestinal conditions, a recent survey found that over 40 percent of patients with Crohn's disease and ulcerative colitis have had to "try and fail" on one or more drugs before accessing the prescribed treatment.<sup>13</sup>

### ***Patient story***

Eitan, a New Yorker living with ulcerative colitis, spent over six months trying and failing on various medications required by his insurance company before the physician-prescribed treatment was covered.<sup>14</sup> The delay in receiving appropriate treatment resulted in significant social, medical, and financial cost to Eitan, and led to irreparable physical harm. During the delay, Eitan experienced extreme discomfort, bleeding, weight loss, inflammation, and eventually permanent damage to his colon. The discomfort was so significant that he missed his final semester of college and his graduation. By the time he was able to start the medication originally prescribed by his physician, his colon was beyond repair and he had to have his colon surgically removed. He now lives with an ostomy bag.

---

<sup>10</sup> <https://morningconsult.com/opinions/step-therapy-reform-will-help-physicians-put-patients-first/>.

<sup>11</sup> <https://morningconsult.com/opinions/step-therapy-reform-will-help-physicians-put-patients-first/>.

<sup>12</sup> <https://server1.gi.org/week/march-31-2018/>.

<sup>13</sup> <https://www.crohnscolitisfoundation.org/get-involved/be-an-advocate/steptherapy>

<sup>14</sup> <https://www.crohnscolitisfoundation.org/personal-stories/eitan>.