



Step Therapy Reform: Oncological Conditions

Overview of oncological conditions

Oncological conditions, primarily various kinds of cancers and tumors, have a wide variety of symptoms and affect an array of organs and systems.¹ No two patients are alike; each requires highly individualized care to best address their specific conditions while accounting for age, medical history, disease progression, expected outcome, and treatment risks and alternatives, among other things.² Cancer treatment can involve a whole team of providers across various disciplines or specialties.³ Cancer has a significant societal impact, with roughly 1.7 million new cases in the United States each year and patient out-of-pocket costs reaching \$4 billion annually.⁴

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.⁵

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.⁶ 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.⁷ 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.⁸

How does step therapy negatively impact patients with oncological conditions?

Step therapy poses major health risks to individuals with cancer. An oncologist’s choice of initial treatment may be based on a variety of factors including the patient’s comorbidities, and potential medication interactions or intolerances. If an insurer takes a one-size-fits all approach and requires a patient to first

¹ <https://hospitals.jefferson.edu/departments-and-services/medical-oncology/diseases-and-conditions.html>

² <https://www.uclahealth.org/mattel/pediatric-hematology-oncology/oncology-disorders>

³ <https://healthinfo.uclahealth.org/Library/DiseasesConditions/Pediatric/Oncology/90,P02718>

⁴ <https://www.fightcancer.org/sites/default/files/Costs%20of%20Cancer%20-%20Final%20Web.pdf>

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

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

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

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

step through a medication that is less effective than the medication carefully selected by the health care provider, then the patient's condition could progress. Such ineffective treatment could result in serious consequences including premature death.⁹ Step therapy sometimes also limits the use of ancillary or supportive care medications to treat side effects, leaving patients uncomfortable during their treatment.¹⁰ Furthermore, some step therapy protocols require treatments for which no financial assistance is available. As a result, patients can incur significant out-of-pocket costs during treatment.¹¹

In sum, while step therapy policies are put in place to reduce the insurer's costs, step therapy can actually increase the overall cost of care where the insurer's required treatment proves ineffective, leading to more tests, procedures, or other treatments than would have resulted had the patient started with the provider's preferred medication.¹²

Patient story

A patient being treated for lung cancer was responding well to the chemotherapy medications prescribed by her oncologist.¹³ The oncologist allowed the patient a "temporary break" from chemotherapy to get some relief from the side effects before attempting to restart treatment. The patient's insurance company refused, finding that the temporary break was evidence that the treatment failed, and required the patient to move to another treatment, despite the patient having only a five percent chance of responding to the insurer-required treatment. When the treatment failed to work, as the oncologist expected, the insurer required another treatment that was not prescribed by her oncologist, rather than a return to the first treatment recommended by her doctor that was proven to be effective for her. The patient was only allowed to return to the first treatment after switching insurers in the midst of cancer treatment.

⁹ <https://www.asrs.org/advocacy/step-therapy>

¹⁰ <https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2019/11/18/step-therapy-in-oncology-it-s-complicated>

¹¹ <https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2019/11/18/step-therapy-in-oncology-it-s-complicated>

¹² <https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2019/11/18/step-therapy-in-oncology-it-s-complicated>

¹³ <https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/>