



Step Therapy Reform: Ophthalmological Conditions

Overview of ophthalmological conditions

Ophthalmological conditions, which include cornea and external eye diseases, glaucoma, cataracts, and retina diseases, have a significant effect on patients' quality of life due to their impact on vision.¹ More than 4.2 million Americans over the age of 40 are legally blind or have low vision, and treatments that prevent eye degradation can help reduce the prevalence and cost of vision decline.² For example, timely treatment for degenerative eye conditions like macular degeneration can be particularly impactful by slowing disease progression and preventing serious damage like permanent vision loss. Age-related macular degeneration is the leading cause of permanent impairment of close-up vision in adults aged 65 years and older.³ It is estimated that 22 million people will have the disease by the year 2050.⁴

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 individuals 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

¹ <https://utswmed.org/conditions-treatments/ophthalmology/>

² <https://www.cdc.gov/visionhealth/basics/ced/index.html>

³ <https://www.cdc.gov/visionhealth/basics/ced/index.html>

⁴ <https://www.brightfocus.org/macular/article/age-related-macular-facts-figures#:~:text=degeneration%20is%20widespread,->

[,As%20many%20as%2011%20million%20people%20in%20the%20United%20States,to%20288%20million%20by%202040](https://www.brightfocus.org/macular/article/age-related-macular-facts-figures#:~:text=degeneration%20is%20widespread,-,As%20many%20as%2011%20million%20people%20in%20the%20United%20States,to%20288%20million%20by%202040)

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>

How does step therapy negatively impact patients with ophthalmological conditions?

Step therapy for individuals with ophthalmological conditions can result in delaying or foregoing necessary treatments, disease progression requiring more extensive and expensive care, and higher out-of-pocket costs for the patient.⁹ Step therapy barriers also can effectively be indefinite in duration, preventing access to a treatment without any chance of approval.¹⁰ This greatly limits the ophthalmologist's ability to select and adjust treatment to an individual's specific circumstances.¹¹

Delays in effective ophthalmology treatment can have serious long-term consequences.¹² Unfortunately, some plans have implemented rather extreme step therapy protocols related to vision care. For instance, a plan required patients to lose more than "15 letters of visual acuity" or fail on three treatments before authorizing a medication switch.¹³ While certain treatments generally might be considered safe for patients with a specific ophthalmological condition, the health care provider ultimately must decide what is right for the patient's unique circumstances based on comorbidities, potential medication interactions, and other patient-specific factors. Otherwise, if access to provider's selected treatment is hindered by step therapy in favor of a less effective treatment, some patients could experience devastating consequences like irreversible vision loss.¹⁴

Patient story

Kathleen, a New Yorker with complicated autoimmune conditions, developed glaucoma and received a sample medication that quickly lowered the pressure in her eye. However, she was unable to fill her prescription because her insurance determined that she would have to try and fail on two other less costly medications before the prescribed medication would be covered. Due to allergies to the preservatives used in these alternative treatments, the medications she was forced to try caused damaging inflammation to the surface of her cornea. Kathleen is ineligible for a corneal transplantation and blind in one eye: a result that could have been avoided if her physician's orders were followed and step therapy was not required.

⁹ <https://retinatoday.com/articles/2013-oct/step-therapy-undermines-physician-choice-of-amd-treatment>

¹⁰ <https://retinatoday.com/articles/2013-oct/step-therapy-undermines-physician-choice-of-amd-treatment>

¹¹ <https://retinatoday.com/articles/2013-oct/step-therapy-undermines-physician-choice-of-amd-treatment>

¹² <https://eyewire.news/articles/aao-calls-on-health-plans-to-suspend-prior-authorization-and-step-therapy/>

¹³ <https://www.retinalphysician.com/issues/2020/jan-feb-2020/coding-q-amp;a-cms-brings-step-therapy-to-medicare>

¹⁴ <https://www.asrs.org/advocacy/step-therapy>