



Step Therapy Reform: Rheumatological Conditions

Overview of rheumatological conditions

Rheumatological conditions, including rheumatoid arthritis, bursitis, gout, and lupus, affect nearly 50 million Americans and can cause significant joint and organ destruction, severe pain, and disability.¹ As a result, these conditions can prevent some individuals from completing otherwise simple tasks like bathing, getting dressed, or walking.² Timely and adequate treatment is for individuals with rheumatological conditions. For example, over 60 percent of people with rheumatoid arthritis are unable to work 10 years after the onset of their disease.³

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.⁴

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.⁵ 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.⁶ 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.⁷

How does step therapy negatively impact patients with rheumatological conditions?

Step therapy can be particularly harmful for people with rheumatological conditions. Step therapy interferes with the patient-provider relationship by preventing patients from accessing the intended and most appropriate treatments for their conditions.⁸ For example, a study published in 2020 found that patients with rheumatoid arthritis who were subject to step therapy faced 19 percent lower odds of

¹ https://www.bu.edu/enact/files/2012/10/ACR_Whitepaper_SinglePg.pdf.

² https://www.bu.edu/enact/files/2012/10/ACR_Whitepaper_SinglePg.pdf.

³ https://www.bu.edu/enact/files/2012/10/ACR_Whitepaper_SinglePg.pdf.

⁴ <https://aimedalliance.org/wp-content/uploads/2018/10/Aimed-Alliance-Primary-Care-Survey-Report.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-Step-Therapy-in-Medicare-Advantage-Plans-Fact-Sheet.pdf>

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

⁸ <http://blog.arthritis.org/advocacy/importance-step-therapy-reform/>

treatment effectiveness compared to patients whose plans did not require step therapy.⁹ These findings were driven by differences in medication adherence, with those forced to go through step therapy being less adherent to their treatment plans. The study's lead author noted that the study provides "compelling data that supports our hypothesis that step therapy, which delays people's access to the full range of available therapies, is associated with worse treatment outcomes."¹⁰ The study also found that twice as many individuals with rheumatoid arthritis who had treatment access restrictions (which included both step therapy and prior authorization) visited the emergency department at least once during follow-up compared to those without such access restrictions.¹¹ Therefore, cost-motivated access restrictions like step therapy may have actually resulted in higher healthcare utilization and costs compared to those whose plans did not have these restrictions.

Patient stories

Hunter, who was diagnosed with juvenile idiopathic arthritis at four and a half years old, faced significant barriers in accessing necessary treatment due to step therapy requirements.¹² Hunter's physician prescribed a biologic medication to ease his pain and joint destruction, but his family's insurance plan denied coverage, requiring Hunter to fail on other medications first. Hunter unsuccessfully tried the medication for 14 months, leaving him in immense pain and absent from school for many months. He also suffered permanent joint damage and required surgery on both knees to be able to walk again.

Karin, a New Yorker with rheumatoid arthritis, was prescribed a new generation biologic anti-inflammatory medication.¹³ Due to cost, Karin's insurer would not cover the prescribed medication until she tried a less expensive, older medication. The insurer-required treatment provided some relief but did not resolve Karin's pain and movement limitations. But, because she technically experienced some level of relief from the treatment, she was unable to receive the biologic prescribed by her physician. After switching to a new insurer, however, Karin finally received the medication originally prescribed by her physician and her pain and movement returned to a livable and comfortable level. Unfortunately, due to unforeseen circumstances, Karin once again had to switch insurers. Despite already failing on the older, less expensive medication *and* experiencing more success on the intended medication, Karin's newest insurer forced her to once again fail on the older medication.

⁹ <https://pubmed.ncbi.nlm.nih.gov/31177506/>

¹⁰ <https://www.centerforbiosimilars.com/view/step-therapy-in-ra-or-psa-leads-to-worse-treatment-outcomes-study-says>

¹¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7018889/>

¹² <http://blog.arthritis.org/advocacy/importance-step-therapy-reform/>

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