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Utilizing State Prior Authorization Policies to Secure Treatment of Choice



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SAFE STEP ACT OVERVIEW

The Safe Step Act is a bipartisan bill designed to protect step therapy exceptions for patients in group health plans nationwide.¹⁻³

Purpose: Improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them.⁴

While this federal bill is still pending, many states have enacted legislation to assist in overcoming step therapy requirements.⁵



Consider using state-specific step therapy exception requests to help eligible patients access their prescribed medications.*

Reference(s): 1. McBath, colleagues reintroduce bipartisan Safe Step Act to improve patient access to treatments. Lucy McBath (D-GA). April 13, 2023. Accessed August 2025. <https://mcbath.house.gov/2023/4/mcbath-colleagues-reintroduce-bipartisan-safe-step-act-to-improve-patient-access-to-treatments> 2. H. R. 2630. Congress.gov. April 13, 2023. Accessed August 2025. <https://www.congress.gov/118/bills/hr2630/BILLS-118hr2630ih.pdf> 3. S. 464. Congress.gov. February 25, 2021. Accessed August 2025. <https://www.congress.gov/117/bills/s464/BILLS-117s464is.pdf> 4. Safe Step Act, S 652/H.R. 2630. Flyer. StepTherapy.com; July 2023. Accessed August 2025. <https://steptherapy.com/wp-content/uploads/2023/07/Flyer-Safe-Step-Act.pdf> 5. Step therapy legislation by state. Step Therapy. September 2024. Accessed August 2025. <https://steptherapy.com/step-therapy-legislation-by-state>

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STATE-SPECIFIC STEP THERAPY EXCEPTION REQUESTS

- Many US states have enacted step therapy laws, and other states and territories may have introduced step therapy legislation.¹ State-specific step therapy laws vary in scope.¹
- **These legislative efforts are brand-agnostic and apply broadly across therapeutic classes.**
- To help your patients with step therapy restrictions receive their prescribed medications, consider reviewing step therapy protections in their area.[‡]
- Patients may potentially qualify for step therapy protection if a first-step medication was contraindicated, expected to be ineffective, known or likely to cause an adverse reaction, or not in the best interest of the individual.²

You may review the state-specific legislation to see which step therapy protections are available in your or your patient's state of residence.

State-specific step therapy exception request forms may be available.

Reference(s): 1. McBath, colleagues reintroduce bipartisan Safe Step Act to improve patient access to treatments. Lucy McBath (D-GA). April 13, 2023. Accessed August 2025.

<https://mcbath.house.gov/2023/4/mcbath-colleagues-reintroduce-bipartisan-safe-step-act-to-improve-patient-access-to-treatments> 2. Tharp L, Rothblatt Z. Do patients benefit from legislation regulating step therapy? Health Econ Policy Law. 2022;17(3):282-297.

[‡] For patients insured through national carriers, such as Aetna, Cigna, UnitedHealthcare, or Humana, consider using a step therapy exception request for the state in which treatment is rendered. For patients insured through regional associations, such as Blue Cross Blue Shield (BCBS), consider using a step therapy exception request for the home state of the network affiliate, as indicated on the patient's insurance card. For more information, contact the state's insurance regulator.

WHERE STEP THERAPY EXCEPTIONS APPLY

Step therapy exception legislative efforts are **brand-agnostic** and **apply broadly across therapeutic classes** and therefore are appropriate for use in **any** therapeutic area requiring a step¹

Common therapeutic areas within specialty impacted by step therapy²⁻⁴

- Targeted Therapies/Precision Medicine
- Immuno-therapy
- Hematologic Malignancies
- Supportive Care, such as IV iron

Reference(s): 1. Safe Step Act, S 652/H.R. 2630. Flyer. StepTherapy.com; July 2023. Accessed August 2025. <https://steptherapy.com/wp-content/uploads/2023/07/Flyer-Safe-Step-Act.pdf>
2. McBride A. Step therapy in oncology: It's complicated. *ACCC Buzz*. November 18, 2019. Accessed October 2025. <https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2019/11/18/step-therapy-in-oncology-it-s-complicated/> 3. Rddad Yossef. "It's Anxiety-Provoking": Step Edits Drive Complexity, Costs, and Physician Burnout in Oncology. *Oncology News Central*. Published October 8, 2024. Accessed October 2025. <https://www.oncologynewscentral.com/article/its-anxiety-provoking-step-edits-drive-complexity-costs-and-physician-burnout-in-oncology/> 4. Poole S, Blakely LJ, Schleicher SM, Dickson NR. Increased biosimilar options in oncology and impact on administrative burden caused by drug switches: implications of step therapy. Presented at: ASCO Annual Meeting; 2024; Chicago, IL. Poster Session 18. Accessed October 2025. https://ascopubs.org/doi/pdf/10.1200/OP.2024.20.10_suppl.18

THE IMPACT ON PATIENTS, PRACTICES, AND PROVIDERS

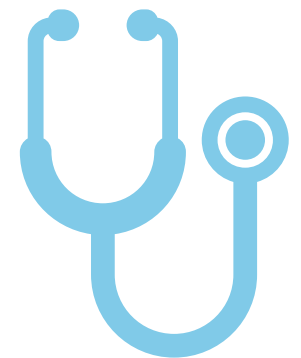
Step therapy restrictions can have a negative impact on patients, including^{1,2}

- Delayed access to the most effective treatment
- Severe side effects
- Irreversible disease progression
- Ignoring a patient's unique circumstances and medical history
- Requiring a drug produced by a company that does not offer patient financial assistance, resulting in financial toxicity
- Limiting patient preference
- Impacting goals of care



These restrictions can also negatively impact practices and providers^{3,4}

- Increased administrative burden
- Limited clinical autonomy and undermining evidence-based practice
- Loss of individualized treatment plan development
- Staffing challenges, including shortages
- Potential provider burnout
- Wasted health resources
- Patient relationship strain



Reference(s): 1. Safe Step Act, S 652/H.R. 2630. Flyer. StepTherapy.com; July 2023. Accessed August 2025. <https://steptherapy.com/wp-content/uploads/2023/07/Flyer-Safe-Step-Act.pdf>
2. McBride A. Step therapy in oncology: It's complicated. *ACCC Buzz*. November 18, 2019. Accessed October 2025. <https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2019/11/18/step-therapy-in-oncology-it-s-complicated?> 3. American Medical Association. AMA survey indicates prior authorization wrecks havoc on patient care [press release]. American Medical Association. Accessed October 2025. <https://www.ama-assn.org/press-center/ama-press-releases/ama-survey-indicates-prior-authorization-wrecks-havoc-patient-care> 4. Rddad Yossef. "It's Anxiety-Provoking": Step Edits Drive Complexity, Costs, and Physician Burnout in Oncology. *Oncology News Central*. Published October 8, 2024. Accessed October 2025. <https://www.oncologynewscentral.com/article/its-anxiety-provoking-step-edits-drive-complexity-costs-and-physician-burnout-in-oncology?>

5 EXCEPTIONS TO FAIL FIRST PROTOCOLS

1

Patient already tried and failed on the required drug. A patient has already tried the medicine and failed before.

2

Delayed treatment will cause irreversible consequences. The drug is reasonably expected to be ineffective, and a delay of effective treatment would leave to severe or irreversible consequences.

3

Required drug will cause harm to the patient. The treatment is contraindicated or has caused/is likely to cause an adverse reaction.

4

Required drug will prevent a patient from working or fulfilling Activities of Daily Living. The treatment has or will prevent a participant from fulfilling their occupational responsibilities at work or performing Activities of Daily Living. Activities of daily living (ADLs) mean basic personal everyday activities such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).

5

Patient is stable on their current medication. The patient is already stable on the prescription drug selected by his or her provider, and that drug has been covered by their previous or current insurance plan.

Thank you धन्यवाद Děkujeme Mange
takk Vă multumesc Gracias Vielen
Dank شكراً Teşekkürler Děkojame jur
спасибо Merci 谢谢 Obrigado ありが
ございました cảm ơn bạn Paldies 감사합
Hartelijk dank Thank you धन्यवाद Dě
Mange takk Vă multumesc Gracias
Vielen Dank شكراً Teşekkürler Děkojar

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