October 2, 2026

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Safe Step Coalition and the 123 undersigned organizations submit these comments in response to your request for information on "Health Care Coverage That Works for Everyone." The overarching goal of our comments is to propose policy changes designed to ensure timely access to the treatment plan designed by patients and their clinicians.

The Safe Step Coalition (hereinafter referred to as "the Coalition") is a broad alliance of patient advocacy organizations, medical professional societies, and clinician groups that aims to reform the insurance practice known as step therapy. Our Coalition represents millions of patients with life-threatening, complex, chronic conditions and the health care professionals who care for them. The Coalition exists to prevent delays in access to clinician-prescribed treatments and advance proposals that would establish patient protections through a fair, timely exceptions process for step therapy.

For many patients and caregivers, the practical experience of health insurance coverage is shaped less by formal benefit design than by whether prescribed therapy can be approved, adjudicated, dispensed, or administered in a timeframe consistent with clinical need. Delays in starting or continuing a needed therapy or treatment can lead to symptom exacerbation, avoidable disease progression, and disruptions that are difficult to reverse once treatment momentum is lost.[1,2] The stakes are especially high when a therapy is time-sensitive, when a patient is stable on their existing treatment, or when failure to access a treatment may alter the course of the patient's disease.

We commend the Committee for considering diverse policy options to improve the way health insurance works in the United States and to ensure that it is affordable for everyday Americans. We recommend that the Committee consider the following issues when designing a future health insurance framework:

- Prior authorization reforms should protect patients and promote operational workability
- Insurance plans should be required to establish a clear, standardized process to request an exemption from step therapy

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[1] Kyle MA, Keating NL. Prior authorization and association with delayed or discontinued prescription fills. J Clin Oncol. 2024;42(8):951-960. https://doi.org/10.1200/JCO.23.01693.

[2] Henry T. Prior Authorization Delays Care and Increases Health Care Costs. American Medical Association. August 12, 2024. Accessed September 15, 2026 from https://www.ama-assn.org/practice-management/prior-authorization/prior-authorization-delays-care-and-increases-health-care.

- Approaches should support continuity of care

Prior Authorization Reforms Should Protect Patients and Promote Operational Workability

For many people living with chronic diseases, disabilities, rare conditions, cancer, or other serious illnesses, prior authorization can be among the most consequential forms of utilization management.[3,4] Prior authorization, once a rare requirement, has become increasingly common and more stringent. Between 2009 and 2019, Medicare Advantage plans increased their use of prior authorization for 12 of 15 service categories, including diagnostic procedures (45.7% vs. 63.7%), diabetic supplies/services (42.3% vs. 60.3%), and psychiatric services (42.7% vs. 57.0%).[5] In 2024, Medicare Advantage insurers denied, on average, 7% of prior authorization requests and this increased to an average of 12% in 2025.[6,7] Most critically, prior authorization denials are often overturned upon appeal, proving that the care was medically necessary.[8] These delays in care due to prior authorization denials lead to preventable negative health outcomes.[9,10]

We encourage the Committee to require policies that strengthen patient protection, reduce duplicative burden, and promote implementation that is operationally workable for plans, clinicians, pharmacy benefit managers, and other entities participating in the process. Ultimately, the value of any new framework will depend on whether it functions reliably under real-world conditions, including when patients move across benefit pathways, change plans, coordinate among multiple clinicians, or rely on caregivers to navigate the process. For that reason, the Coalition encourages the Committee to implement reforms

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[3] Wang Y, Levy JF, Mattingly TJ 2nd, Anderson G. Prior authorization and associated delays and denials of branded medication dispensation. JAMA Health Forum. 2026;7(4):e260760. DOI: 10.1001/jamahealthforum.2026.0760.

[4] Murphy J, Beauchamp N, Sun KJ, et al. Adverse effects of health plan prior authorization on clinical effectiveness and patient outcomes: A systematic review. Am J Med. 2026;139(1):24-32.e1. DOI: 10.1016/j.amjmed.2025.08.018

[5] Neprash HT, Mulcahy JF, Golberstein E. The extent and growth of prior authorization in Medicare Advantage. Am J Manag Care. 2024;30(3):e85-e92. DOI: 10.37765/ajmc.2024.89519

[6] Biniek JF, Sroczynski N, Freed M, Neuman T. Medicare Advantage Insurers Made Nearly 53 Million Prior Authorization Determinations in 2024. KFF. January 28, 2026. Accessed on September 3, 2026 from: https://www.kff.org/medicare/medicare-advantage-insurers-made-nearly-53-million-prior-authorization-determinations-in-2024/

[7] Long M, Biniek JF, Lo J, et al. Prior Authorization Metrics Provide New Insights into Insurer Practices, but Gaps Remain. KFF. August 13, 2026. Accessed on September 3, 2026 from: https://www.kff.org/patient-consumer-protections/prior-authorization-metrics-provide-new-insights-into-insurer-practices-but-gaps-remain/

[8] Long et al., Prior Authorization Metrics.

[9] Baidoun B, Cares K. Delays in the administration of biologic therapies and adverse outcomes in pediatric patients with inflammatory bowel disease: A retrospective study. Inflamm Bowel Dis. 2025;31(Suppl 1):S61. DOI: 10.1093/ibd/izae282.144

[10] 2025 AMA prior authorization (PA) physician survey. American Medical Association. 2025. Accessed June 6, 2026. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

that produce measurable improvements in operational usability, continuity of care, and reduced patient and clinician burden, including:

- Require standard electronic prior authorization claims submission and processing through a framework that reduces delay for all medications (including both drugs covered under the medical benefit and those covered under the pharmacy benefit)
- Promote implementation approaches that reduce duplicative documentation requests and minimize manual workarounds
- Require automatic approval when payers fail to meet applicable review deadlines
- Require continuity of care protection that maintains access to existing therapy during pending appeals or patient transitions between health plans
- Prohibit prior authorization frameworks that are more restrictive than the relevant and current clinical practice guidelines
- Require prior authorization denials to be reviewed by appropriately qualified specialists with relevant expertise in the disease or condition for which the treatment is being requested
- Denials should trigger an automatic appeal and require the payer to provide communications that are sufficiently specific, timely, and operationally useful to support prompt correction, resubmission, and exception requests
- Strengthen public reporting and metrics so that prior authorization data are meaningful and interpretable for patients, advocates, clinicians, plans, and regulators

Insurance Plans Should Be Required to Establish a Clear, Standardized Process to Request an Exemption from Step Therapy

Step therapy (also known as “fail first") requires patients to try an insurer-preferred treatment and prove that it has failed to sufficiently treat their condition before they get access to the treatment originally prescribed by their clinician. While the problems associated with step therapy closely align with those caused by prior authorization, the remedies are separate and distinct. Implementing the recommendations mentioned above will not, by itself, solve the issue of step therapy.

Many of our patients suffer from chronic, progressive, or degenerative diseases. Effectively managing these diseases requires a highly personalized long-term strategy overseen by a specialized clinician. When insurers impose step therapy, they override clinician-prescribed treatment plans, forcing patients to cycle through alternative medications regardless of their clinical needs or the potential danger to the patient. For example, a large insurer imposed a new step therapy protocol at the start of the 2026 plan year that required patients to “step through” between 9 to 13 different medications, using each for 3 months, before obtaining coverage for a newer advanced therapy.[11] If a patient worked through each

[11] UPMC implemented the new step therapy protocol for guselkumab (Tremfya) at the start of the 2026 plan year (Policy Number RX.PA.403). The patient was required to trial each preferred drug for 3 months before moving to the next step. Patients with Crohn’s disease had to try and fail 9 products, for a total of

required step, it would take more than 2 years before the patient would gain access to their clinician-prescribed treatment. For patients with degenerative diseases, the time spent cycling through these ineffective therapies often leads to severe health consequences. The dangers of unmitigated step therapy protocols include:

- Irreversible Disease Progression: Step therapy delays access to targeted advanced therapies that are superior in halting disease progression. Active, unmitigated disease significantly increases the risk of disease progression, loss of function, permanent disability, or even death.[12,13,14]
- Direct Contradiction of Clinical Guidelines: Fail-first protocols often directly conflict with the clinical practice guidelines for many disease states, requiring more steps than are recommended by clinical evidence.[15]
- Compounded System Costs: Step therapy fails as a cost-cutting tool. Forcing patients to use less safe or ineffective drugs can lead to preventable emergency room visits, prolonged hospitalizations, surgeries, and other health complications that require intensive health interventions.[16] Multiple studies have shown that the delays caused by step therapy led to increased health system costs, often within the same plan year.[17,18,19]

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27 months elapsed time, before accessing guselkumab. Patients with ulcerative colitis had to try and fail 11 medications, for a total of 33 months elapsed time, before accessing guselkumab. Patients with plaque psoriasis had to try and fail 13 medications, for a total of 39 months elapsed time, before accessing guselkumab. Patients with psoriatic arthritis had to try and fail 14 medications, for a total of 42 months elapsed time, before accessing guselkumab.

[12] Mark TL, Gibson TM, McGuigan K, Chu BC. The effects of antidepressant step therapy protocols on pharmaceutical and medical utilization and expenditures. Am J Psychiatry. 2010;167(10):1202-1209. DOI: 10.1176/appi.ajp.2010.09060877

[13] Richards MA, Westcombe AM, Love SB, et al. Influence of delay on survival in patients with breast cancer: A systematic review. Lancet. 1999;353(9159):1119-1126. DOI: 10.1016/s0140-6736(99)02143-1.

[14] Constant BD, de Zoeten EF, Stahl MG, et al. Delays related to prior authorization in inflammatory bowel disease. Pediatrics. 2022;149(3):e2021052501. DOI: 10.1542/peds.2021-052501.

[15] Lenahan KL, Nichols DE, Gertler RM, Chambers JD. Variation in use and content of prescription drug step therapy protocols, within and across health plans. Health Aff. 2021;40(11):1749-1757. DOI: 1-.1377/hlthaff.2021.00822

[16] Joy S, Mire RD. Mitigating the negative impact of step therapy policies and nonmedical switching of prescription drugs on patient safety: A position paper of the American College of Physicians. American College of Physicians. Updated 2020. Accessed May 4, 2026. https://www.acponline.org/sites/default/files/acp-policylibrary/policies/step_therapy_nonmedical_switching_prescription_drugs_policy_2020.pdf

[17] Farley JF, Cline RR, Schommer JC, et al. Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications. Clin Ther. 2008;30(8):1524-1539. DOI: 10.1016/j.clinthera.2008.08.009

[18] Panzer PE, Regan TS, Chiao E, Sarnes ME. Implications of an SSRI generic step therapy pharmacy benefit design: An economic model in anxiety disorders. Am J Manag Care. 2005;11(12 Suppl):S370-S3709. PMID: 16236019

[19] Murawski MM, Abdelgawad T. Exploration of the impact of preferred drug lists on hospital and physician visits and the costs to Medicaid. Am J Manag Care. 2005;11:SP35-42. PMID: 15700908

- Clinician Administrative Burden: Appealing step therapy protocols imposes an unsustainable administrative burden on medical practices, redirecting limited clinical staff away from direct patient care in order to manage insurer paperwork.[20] [21]

Supporters of step therapy often argue that it prevents unnecessary care or direction to higher-cost medications when cheaper options suffice.[22] However, there is clear, documented evidence of insurance plans requiring clinically stable patients off their medication to repeat the arduous, mentally and physically taxing, and medically harmful process of step therapy.[23,24] Stable patients can be faced with new step therapy requirements when they switch insurance carriers, when their existing plan changes the formulary, and even at the start of the plan year when a patient's plan updates its utilization management requirements.

Therefore, we recommend that the Committee require all insurance plans to establish a clear, standardized process for patients and clinicians to request an exception to step therapy. Plans should be required to respond to exception requests within 72 hours of receipt under normal circumstances and within 24 hours in case of a medical emergency. Plans should be required to grant a step therapy exception to patients who meet one or more of the following criteria:

- The patient already tried the insurance-preferred drug(s) and it did not work
- Delayed access to the originally prescribed treatment will cause irreversible health consequences
- The insurance-required drug(s) will cause harm to the patient
- The insurance-required drug(s) will prevent a patient from attending school, working or fulfilling activities of daily living
- The patient's condition is stable on their current medication

To ensure that this process is standardized, that patients and clinicians have sufficient information to make informed decisions, and that continuity of care is prioritized, we recommend that the Committee:

- Creates a standardized process across all health insurance plans for step therapy exceptions that requires all payers to:
    - Allow the patient or clinician to present their clinical rationale for the request
    - Use standard forms and instructions for step therapy exceptions
    - Request the same information (e.g., medication and medical history) to be submitted to support the exception request

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[20] https://gastro.org/advocacy-and-policy/policies-a□ecting-gi/regulatory-relief-for-gastroenterologists/
[21] 2025 AMA prior authorization (PA) physician survey
[22] Sachs RE, Kyle MA. Step therapy's balancing act – Protecting patients while addressing high drug costs. NEngl J Med. 2022;386(10):901-904. DOI:10.1056/NEJMp2117582
[23] Rubin DT. Restarting Biologic Agents After a Drug Holiday. Gastroenterol Hepatol (N Y). 2019 Nov;15(11):612-615. PMID: 31802986; PMCID: PMC6883732.
[24] Step Therapy. Arthritis Foundation. Accessed May 4, 2026. https://www.arthritis.org/advocate/issuebriefs/step-therapy

    - Use the same set of criteria for determining when an exception request meets the standardized policy
    - Provide exception denials that include patient-specific information detailing the payer's clinical rationale for denying the request (e.g., national medical society's guidelines, peer-reviewed clinical literature), the alternative treatment covered by the plan, and a description of the right to an appeal
- Requires all insurance plans to provide the following information, in plain language, using a standardized format, and in an easy to access location, to patients and clinicians:
    - Patient-specific utilization management requirements, including which treatments, services, and prescription drugs have step therapy requirements, prior authorization requirements, and/or formulary restrictions
    - Patient-specific cost-sharing information for each treatment, service, and prescription drug
    - For prescription drugs and services subject to step therapy, a clear description of the exact step therapy requirement(s) for each applicable service/drug
    - References to the documented, conclusive clinical evidence that the insurance-required medication/treatment is as effective and safe as the initial, clinician-prescribed medication
    - Clear description of the criteria used to determine the appropriateness of a step therapy exception
    - Effective dates of step therapy policies
- Support continuity of care by requiring a new health insurance plan to apply the previous payer's determination that a patient has satisfied step therapy requirements and creating clear eligibility standards for continuity in coverage by:
    - Mandating that insurance programs provide continuity of coverage for their existing patients, even if the payer expands or alters their step therapy protocols
    - Mandating patient eligibility for continuity in coverage by their new payer, even if the prior payer required fewer or different steps than the new payer
    - Mandating that plans recognize the completion of their own step-therapy process across all benefit categories, sites of care, and across plan years

To continually evaluate the effectiveness of new policies, we also recommend that the Committee design future systems with public reporting in mind. Therefore, we believe that, at a minimum, insurers should be mandated to publicly report available data (as allowed under existing patient privacy protections) on the following variables:

- Medications, diagnostic tests, and/or procedures that are subject to step therapy
- The health indication that the medication/test/procedure is used to treat
- Total number of step therapy exception requests received by the payer
- The results of all step therapy exception requests (approvals, denials)
- Reasons for exception request denials

- Total number of exception denials overturned on appeal

Framework Should Support Continuity of Care

Although we highlighted specific recommendations that support continuity of care as it relates to step therapy in the above section, we think it is important to more broadly encourage the Committee to design approaches that consider how the proposed insurance framework can better support continuity of care for patients already established on therapy.

For many patients, the problem is not solely the initial insurance approval, but the repeated disruption that occurs when treatment must be reauthorized in ways that do not reflect the patient's established clinical history or prior evidence of medical necessity.[25] This concern is particularly important when patients experience changes in coverage, payer or processor, or transitions between sites of care. A patient who has already demonstrated clinical need for a particular therapy, already established treatment stability, or already satisfied earlier prior authorization and step therapy requirements should not be required to repeatedly reconstruct the same evidentiary record simply because administrative responsibility has shifted. The Coalition therefore encourages the Committee to consider how policy changes can better support recognizing established treatment history and prior determinations where appropriate.

Additionally, the proposed insurance framework should support coordination across prescribing, dispensing, administration, and follow-up care. For many patients with complex or ongoing needs, relevant clinical information is dispersed across multiple actors and systems, including treating clinicians, pharmacies, specialty pharmacies, infusion providers, plans, pharmacy benefit managers, and caregivers. The framework's value will depend in part on whether those actors can access current, consistent information on prior authorization status, step therapy protocols, required documentation, decision timing and outcomes, and approval duration.

Conclusion

The Coalition believes medical decisions should remain in the hands of clinicians and their patients, not insurance companies. For millions of Americans, timely access to targeted therapy is the difference between achieving clinical remission and suffering irreversible disease progression. We urge the Committee to protect beneficiaries by reining in aggressive prior authorization and step therapy protocols. We also implore you to establish a fair, swift, and transparent step therapy exemption process and support patient continuity of care.

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[25] American Medical Association, "Fixing Prior Auth: We Must Ensure Continuity of Care," accessed June 14, 2026, https://www.ama-assn.org/practice-management/prior-authorization/fixing-prior-auth-we-must-ensure-continuity-care

On behalf of the Safe Step Coalition, we thank the Committee for the opportunity to provide input, and we look forward to collaborating with you to improve health care for patients living with chronic diseases. Should you have any questions or if we can be of assistance, please contact Liz Siembida with the National Psoriasis Foundation, at lsiembida@psoriasis.org or Hayley Dempsey with the Arthritis Foundation, at hdempsey@arthritis.org.

Sincerely,

ADAP Advocacy Association
AiArthritis
Aimed Alliance
Allergy & Asthma Network
Alliance for Aging Research
Alliance for Headache Disorders Advocacy
Alliance for Patient Access
Alpha-1 Foundation
ALS Association
American Academy of Neurology
American Association of Orthopaedic Surgeons
American College of Gastroenterology
American College of Osteopathic Family Physicians
American College of Rheumatology
American Gastroenterological Association
American Migraine Foundation
American Partnership for Eosinophilic Disorders
American Psychiatric Association
American Society for Gastrointestinal Endoscopy
American Society for Parenteral and Enteral Nutrition
Arizona United Rheumatology Alliance
Arthritis Foundation
Association for Clinical Oncology
Association of Gastrointestinal Motility Disorders (AGMD)
Asthma and Allergy Foundation of America
Autoimmune Association
Biomarker Collaborative
Cancer Support Community
CancerCare
Caregiver Action Network
Celiac Disease Foundation
Chronic Care Policy Alliance
Coalition of Hematology and Oncology Practices
Coalition of Skin Diseases

Coalition of State Rheumatology Organizations
Coalition of Wisconsin Aging and Health Groups
Community Access National Network
Community Liver Alliance
Crohn's & Colitis Foundation
CURED Nfp
CURED Nfp Campaign Urging Research for Eosinophilic Diseases
Depression and Bipolar Support Alliance (DBSA)
Derma Care Access Network
Dia de la Mujer Latina Inc
Digestive Disease National Coalition
Dravet Syndrome Foundation
Eosinophilic & Rare Disease Cooperative
Epilepsy Alliance America
Epilepsy Foundation of America
Exon 20 Group
Facial Pain Association
Foundation for Sarcoidosis Research
Gastroparesis Patient Association (G-PACT)
Gastroparesis: Fighting for Change
Girls With Guts
Global Healthy Living Foundation
HCNE (Headache Cooperative of the Northeast)
Headache Cooperative of the Pacific
HealthyWomen
Hematology/Oncology Pharmacy Association
Hemophilia Federation of America
HIV+Hepatitis Policy Institute
Hope Charities
Hope in Pain dba Migraine Meanderings
IBDMoms
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
International Foundation for Gastrointestinal Disorders
International Pain Foundation
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LUGPA
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
MET Crusaders
Metro Maryland Ostomy Association, Inc.

Movement Disorders Policy Coalition
Multiple Sclerosis Foundation
Myasthenia Gravis Association
Nami Nevada
National Alliance of State Prostate Cancer Coalitions
National Alopecia Areata Foundation
National Bleeding Disorders Foundation
National Eczema Association
National Headache Foundation
National Health Council
National Infusion Center Association
National Multiple Sclerosis Society
National Organization of Rheumatology Management
National Patient Advocate Foundation
National Psoriasis Foundation
Nevada Chronic Care Collaborative
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
NRG1 Energizers
Organization for Latino Health Advocacy
Parkinson's Foundation
PDL1 Amplifieds
Pennsylvania Society of Oncology and Hematology
PlusInc
Prevent Blindness
PROSTATE CANCER EDUCATION COUNCIL
RARE Foundation
Rheumatology Alliance of Louisiana
Rheumatology Society of New Mexico
Sjogren's Foundation
Society for the Study of Celiac Disease
Society for Women's Health Research
Society of Dermatology Physician Associates
Society of Gastroenterology Nurses and Associates, Inc. (SGNA)
Spondylitis Association of America
Sturge-Weber Foundation, The
Susan G. Komen
Tennessee Rheumatology Society
Texas Rheumatology Care
The Coalition for Headache and Migraine Patients (CHAMP)
Tourette Association of America
TSC Alliance
U.S. Pain Foundation
United Ostomy Associations of America, Inc.
Wisconsin Rheumatology Association

ZERO Prostate Cancer