June 11, 2026

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

Re: Request for Information on Step Therapy in Proposed Rule for Interoperability Standards and Prior Authorization for Drugs

Submitted via regulations.gov

Dear Administrator Oz,

On behalf of the Safe Step Ad Hoc Coalition and the 116 undersigned organizations, we implore you to ensure that patients have appropriate and timely access to the therapies they need to properly manage their health care. Below we outline our recommendations on needed reforms to the insurance practice known as step therapy, or "fail-first," in response to the Centers for Medicare and Medicaid Services (CMS) request for information on step therapy.

The Safe Step Ad Hoc Coalition is a broad alliance of patient advocacy organizations, medical professional societies, and provider groups whose goal is to reform the insurance practice known as step therapy. Our coalition represents millions of patients with life-threatening, complex, chronic conditions and the physicians who care for them. The coalition exists to prevent delays in access to physician-prescribed treatments and advance proposals that would establish patient protections through a fair, timely exceptions process for step therapy.

Step therapy is a complex prior authorization protocol that requires patients to try a Pharmacy Benefit Manager (PBM)- or insurer-preferred treatment and prove that it has failed before providing access to the treatment selected by the patient and their provider. Despite claims that step therapy saves money, there is mounting evidence that step therapy savings to the prescription drug benefit are eclipsed by spending in the medical

benefit even *within the same plan year*,[1,2,3] while causing serious delays in care that have led to lost body function, reduced medication adherence, diminished patient trust in their provider, and even death.[4,5,6]

While we commend CMS for examining how technology can make step therapy protocols more transparent and streamlined, we caution against assuming this is sufficient to reform this practice and ensure patients avoid negative consequences.

Specifically, the coalition urges CMS to consider the following:

Require Plans to Implement a Step Therapy Exceptions Process. There is little incentive for PBMs or insurance companies to preemptively exempt a patient from step therapy while they are still allowed to profit from steering patients to ineffective medications. Treatment selection for many complex, chronic, or life-threatening conditions is becoming increasingly individualized as physicians learn more about disease processes, patients' unique medical histories, and the evolving landscape of treatment options. Step therapy protocols may inappropriately override these individualized treatment plans when insurer-preferred treatments do not align with physician-directed, guideline-concordant care.[7]

Therefore, we recommend that CMS issue additional rulemaking to require all health insurance plans under its jurisdiction to offer a clear, medically reasonable, and expedient exceptions process to step therapy. This exceptions process should require plans to respond to emergent requests within 24 hours and within 72 hours for normal requests. Exceptions to step therapy should be allowed in the following five circumstances:

- The patient already tried the insurance preferred drug, and it has failed or is reasonably expected to be ineffective
- Delayed treatment will cause irreversible health consequences

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[1] 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

[2] 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

[3] 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

[4] 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

[5] 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.

[6] 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.

[7] 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

- The insurance preferred drug is contraindicated or will likely cause harm to the patient
- Required drug will decrease the patient's ability to work, attend school, or fulfill activities of daily living
- The patient is stable on their current medication

Require Recognition of Previous Payer's Step Therapy Determination. Patients currently receiving treatment should not be required to repeat step therapy protocols, restart prior authorization processes, or undergo nonmedical treatment switching due solely to coverage transitions or plan changes. Requiring patients to undergo step therapy again at a new payer leads to significant downstream harm, increased health care utilization, and ultimately increases costs.[8] Therefore, we strongly urge CMS to undergo additional rulemaking that requires new payers to apply the previous payer's determination that a patient has satisfied step therapy and grant immediate access to the prescribed medication. Requiring payer-to-payer transfer of prior authorization and step therapy determinations preserves continuity of care and prevents avoidable treatment disruption. Additionally, CMS should clarify that patients cannot be forced to repeat the same step therapy requirement once it has already been completed, regardless of payer.

We believe that the Safe Step Act (S. 2903/H.R. 5509) provides a strong model for policy development as it establishes a standardized exceptions process, protects continuity of care, and allows physician-directed override standards when step therapy is clinically inappropriate or reasonably expected to be ineffective.

Standardize the Step Therapy Exceptions Process Across Payers. We recommend CMS implement a clear, standardized process to step therapy exception requests. The process should:

- Allow the provider to present their clinical rationale for the request
- Utilize a single standard form and instructions across all payers
- Require the same information (e.g., medical and medication history) to be submitted to support the exception request to all payers
- Require plans to transparently provide clinical rationales and other supporting evidence for all step therapy protocols
- Require all payers to use the same set of criteria for determining when an exception request meets the standardized policy
- Require expedited review timelines for step therapy exception requests

[8] 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-policy-library/policies/step_therapy_nonmedical_switching_prescription_drugs_policy_2020.pdf.

- Require denials to include 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 appeal.

Leverage Technology to Streamline Step Therapy Exceptions. Technology will play a critical role in creating a standardized and streamlined process for step therapy exceptions. However, we caution CMS against the belief that interoperability and electronic data exchange alone is sufficient to prevent harmful delays. Technology solutions should support continuity of care and reduce administrative burden, not automate repeat authorization requirements.

To ensure that the technology solution is created with both patients and providers in mind, we recommend that CMS create a technology platform that ensures step therapy information and the exceptions process are standardized across payers. This includes the use of standardized forms for submitting exception requests, a standardized set of supporting documentation for the exception request, and standardized criteria for determining the appropriateness of the exception.

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

Sincerely,

ADAP Advocacy Association
AiArthritis
Aimed Alliance
Allergy & Asthma Network
Alliance for Aging Research
Alliance for Headache Disorders Advocacy
Alliance for Patient Access
Alliance of Specialty Medicine
Alpha-1 Foundation
American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology / Association
American Academy of Neurology
American Association of Orthopaedic Surgeons
American Association on Health and Disability
American College of Gastroenterology
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Rheumatology

American Gastroenterological Association
American Liver 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
AURA
Autoimmune Association
Brain Injury Association of Nebraska
Cancer Support Community
CancerCare
Caregiver Action Network
Chronic Care Policy Alliance
Chronic Disease Coalition
Coalition of Hematology Oncology Practices
Coalition of Skin Diseases
Coalition of State Rheumatology Organizations
Community Access National Network
Community Liver Alliance
Crohn's & Colitis Foundation
Cure SMA
CURED Nfp
Depression and Bipolar Support Alliance (DBSA)
Derma Care Access Network
Dravet Syndrome Foundation
Epilepsy Alliance America
Epilepsy Foundation of America
Foundation for Sarcoidosis Research
Gastroparesis: Fighting for Change
Gilda's Club South Florida, Inc.
Global Healthy Living Foundation
G-PACT (Gastroparesis Patient Association for Cures and Treatments)
HealthyWomen
Heart Failure Society of America
Hematology/Oncology Pharmacy Association
Hemophilia Federation of America
Hidradenitis Suppurativa Coalition
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network

Infusion Access Foundation
International Foundation for Gastrointestinal Disorders (IFFGD)
International Pain Foundation
International Rett Syndrome Foundation
Kentuckiana Rheumatology Alliance
Lakeshore Foundation
LUGPA
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Mental Health America
Metro Maryland Ostomy Association, Inc
Multiple Sclerosis Foundation
Muscular Dystrophy Association
Myasthenia Gravis Association
NAMI Valley of the Sun
National Alliance of State Prostate Cancer Coalitions
National Alopecia Areata Foundation
National Bleeding Disorders Foundation
National Eczema Association
National Headache Foundation
National Infusion Center Association
National Organization for Tardive Dyskinesia
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
Oklahoma Society of Clinical Oncology, Inc.
Oncology Nursing Society
Organization for Latino Health Advocacy
Pennsylvania Society of Oncology and Hematology
PlusInc
Pulmonary Hypertension Association
Rheumatology Alliance of Louisiana
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Society of New Mexico
Sjögren's Foundation
Society for Women's Health Research
Society of Dermatology Physician Associates
Society of Gastroenterology Nurses and Associates, Inc. (SGNA)
South Carolina Advocates For Epilepsy
Spondylitis Association of America
Susan G. Komen

Tennessee Rheumatology Society
The Arizona Clinical Oncology Society
TSC Alliance
U.S. Pain Foundation
United Ostomy Associations of America, Inc.
Winchester Hospital Endoscopy Center
Wisconsin Association of Hematology and Oncology
Wisconsin Rheumatology Association
WomenHeart
ZERO Prostate Cancer