

January 31, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-9898-NC, Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: CMS-9898-NC, Requestion for Information; Essential Health Benefits

Dear Administrator Brooks-LaSure,

Thank you for the opportunity to provide information related to the use of step therapy in plans that provide Essential Health Benefits (EHB). The 84 undersigned patient and provider advocacy organizations are members of the Safe Step Act Ad Hoc Coalition, and many have operated on both the state and federal levels to advocate for step therapy reform.

Step therapy is a complex form of prior authorization (PA) in which health insurers require patients to try and fail one or more insurer-preferred medications before the insurer will cover the medication initially prescribed and agreed upon by the patient and their provider. Because it can take several months for patients to prove failure, medically inappropriate step therapy delays access to needed care and can result in devastating health outcomes.

***Are there significant barriers for consumers to access mental health and substance use disorder services, including behavioral health services that are EHB?***

Insurance-mandated step therapy presents a barrier for consumers to access treatments for several conditions, including mental health and substance use disorder treatments. A study on anti-depressant medication coverage in employer plans found that step therapy reduced medication adherence and, within a quarter following the implementation of step therapy, increased mental health-related outpatient, inpatient, and emergency room visits by nearly 20%.<sup>1</sup> The authors noted that “emergency room spending in the step therapy plans consistently exceeded the spending levels of the comparison group.”

***Are these strategies to reduce utilization and costs applied broadly or are they targeted to a specific area?***

A recent study on commercial plans found that nearly 40% of prescriptions were subject to step therapy and that protocols varied greatly from plan to plan, even for the same condition.<sup>2</sup>

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<sup>1</sup> The Effects of Antidepressant Step Therapy Protocols on Pharmaceutical and Medical Utilization and Expenditures. Tami L. Mark, Teresa M. Gibson, Kimberly McGuigan, and Bong Chul Chu, American Journal of Psychiatry 2010 167:10, 1202-1209

<sup>2</sup> Variation In Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans. Kelly L. Lenahan, Donald E. Nichols, Rebecca M. Gertler, and James D. Chambers. Health Affairs 2021 40:11, 1749-1757

### ***How are these tools effective or ineffective?***

Without certain guardrails, insurance-mandated step therapy can be ineffective at controlling costs, burdensome to providers, and harmful to patients. A 2021 study estimated that utilization management (UM) including step therapy is associated with over \$90 billion in annual costs to the healthcare system.<sup>3</sup> This estimate included the cost to insurers of implementing UM, the cost to providers of fighting UM, and the cost to patients of striving for continuity of care including paying out of pocket during periods when they are insured but lack coverage. In addition, the American Medical Association found that 88% of physicians describe the burden of PA as high or extremely high, 40% report having dedicated staff to manage PAs, and physicians report spending two business days per week on PAs.<sup>4</sup>

### ***To what extent do these tools curb or complicate access to medically necessary care?***

Insurance-mandated step therapy can significantly disrupt and delay a patient's ability to receive the care they need. Across the disease spectrum, researchers have found harmful consequences from these delays in care. Below are a few examples:

- In pediatric inflammatory bowel disease, any PA on the formulary was associated with a 12.9% increased likelihood of serious adverse events in private plans; Constant, [Pediatrics](#), 2022
- In Arthritis, PA was associated with increased corticosteroid use; Wallace, [Arthritis Care and Research](#), 2019
- In depression, step therapy reduced medication adherence and increased adverse events by 20% in employer plans; Mark, [American Journal of Psychiatry](#), 2010
- In psoriatic arthritis, any delay in care can result in irreversible joint deformity; Gottlieb, [Dermatologic Clinics](#), 2016
- In cancer, PAs in pediatric hematology and oncology led to essentially no alterations in care, but delayed care; Dickens, [Pediatric Blood Cancer](#), 2017

The authors of a 2016 Health Affairs article, [Does A 'One-Size-Fits-All' Formulary Policy Make Sense?](#), also framed the consequences:

- "Breast cancer patients with a treatment delay of three months or more had a 12 percent lower five-year survival rate compared with breast cancer patients with only a zero to three month delay." ([Richards 1999 the Lancet](#))
- "A four-week delay in receiving adjuvant chemotherapy has been associated with a significant decrease in disease-free survival and overall survival in colorectal cancer patients." ([Biagi 2011 JAMA](#))

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<sup>3</sup> Howell S, Yin PT, Robinson JC. Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. *Health Aff (Millwood)*. 2021 Aug;40(8):1206-1214.

<sup>4</sup> 2021 AMA prior authorization (PA) physician survey. <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

## **Recommendations**

The harm caused by insurance-mandated step therapy has sparked movements across the country to establish common-sense guardrails that protect patients. Generally speaking, these reforms would:

- Ensure health plans offer a transparent step therapy exceptions process accessible to patients and providers
- Establish medically reasonable circumstances when a health plan should grant an exception request
- Require health plans to respond to a step therapy exception request within 24-72 hours

To date, 35 states across the nation have passed step therapy reform laws.<sup>5</sup> However, many enrollees in plans that provide EHB remain without protections. To address this gap, **the undersigned strongly recommend that CMS update the exceptions process outlined in section (c) of 45 CFR §156.122 to clarify that it applies to utilization management, including insurance-mandated prior authorization and step therapy.**

Thank you for your consideration of our views on behalf of the patient and provider advocacy organizations representing millions of beneficiaries and their health care providers. For additional information, please contact Sarah Buchanan, National Psoriasis Foundation, at [sbuchanan@psoriasis.org](mailto:sbuchanan@psoriasis.org), and Alisa Vidulich, Arthritis Foundation, at [avidulich@arthritits.org](mailto:avidulich@arthritits.org).

Sincerely,

ADAP Advocacy Association  
Allergy & Asthma Network  
American Academy of Dermatology Association  
American Academy of Neurology  
American College of Gastroenterology  
American College of Rheumatology  
American Gastroenterological Association  
American Partnership for Eosinophilic Disorders  
American Society for Gastrointestinal Endoscopy  
American Urological Association  
Arizona Prostate Cancer Coalition  
Arthritis & Osteoporosis Center of SW Ohio  
Arthritis Foundation  
Asthma and Allergy Foundation of America  
Autoimmune Association  
Beyond Celiac  
Child Neurology Foundation  
Chronic Care Policy Alliance  
Chronic Disease Coalition

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<sup>5</sup> <https://www.steptherapy.com/step-therapy-legislation-by-state/>

Coalition of Hematology Oncology Practices  
Coalition of Skin Diseases  
Community Access National Network  
Connecting to Cure Crohn's and Colitis  
Crohn's & Colitis Foundation  
Cure SMA  
CURED Nfp (Campaign Urging Research for Eosinophilic Diseases  
Depression and Bipolar Support Alliance  
Derma Care Access Network  
Digestive Disease National Coalition  
Dup15q Alliance  
Epilepsy Alliance America  
Epilepsy Foundation  
Fabry Support & Information Group  
Foundation for Sarcoidosis Research  
Global Healthy Living Foundation  
Hawai'i Parkinson Association  
Headache and Migraine Policy Forum  
HealthyWomen  
Hope Charities  
ICAN, International Cancer Advocacy Network  
Infusion Access Foundation (IAF)  
International Foundation for Autoimmune & Autoinflammatory Arthritis  
International Foundation for Gastrointestinal Disorders (IFFGD)  
International Pain Foundation  
Louisiana Hemophilia Foundation  
Lupus and Allied Diseases Association, Inc.  
Mental Health America  
Multiple Sclerosis Association of America  
Multiple Sclerosis Foundation  
National Alliance on Mental Illness  
National Ataxia Foundation  
National Eczema Association  
National Infusion Center Association (NICA)  
National Organization for Rare Disorders  
National Organization for Tardive Dyskinesia  
National Organization of Rheumatology Management  
National Pancreas Foundation  
National Psoriasis Foundation  
Nevada Chronic Care Collaborative  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition  
Ohio Association of Rheumatology  
Oklahoma Society of Clinical Oncology, Inc.  
Pacific Northwest Bleeding Disorders

Parkinson's Foundation  
Partnership to Advance Cardiovascular Health  
Pennsylvania Society of Oncology & Hematology  
PlusInc  
Pulmonary Hypertension Association  
Rheumatology Association of Minnesota and the Dakotas  
Rheumatology Nurses Society  
Society of Dermatology Physician Assistants (SDPA)  
Society of Gastroenterology Nurses and Associates, Inc.  
South Carolina Advocates For Epilepsy  
Spondylitis Association of America  
STAR State of Texas Association of Rheumatologists  
Susan G. Komen  
Texas Rheumatology Care  
The American Society for Parenteral and Enteral Nutrition  
The Michael J. Fox Foundation for Parkinson's Research  
Tourette Association of America  
TSC Alliance  
U.S. Pain Foundation  
United Ostomy Associations of America