

May 24, 2022

The Honorable Robert Scott  
Chair, Education & Labor Committee  
U.S. House of Representatives

The Honorable Patty Murray  
Chair, Senate Committee on Health, Education,  
Labor, & Pensions, U.S. Senate

The Honorable Virginia Foxx  
Ranking Member, Education & Labor  
Committee, U.S. House of Representatives

The Honorable Richard Burr  
Ranking Member, Senate Committee on Health,  
Education, Labor & Pensions, U.S. Senate

Dear Chair Scott, Ranking Member Foxx, Chair Murray, Ranking Member Burr, and Members of the House Education & Labor Committee and Senate Health, Education, Labor, & Pensions Committee:

On behalf of the 75 undersigned patient and provider advocacy groups, we urge you to support timely access to needed medical treatments as part of your plans for a mental health package and to address provider burnout. Specifically, we ask that such legislation include step therapy reform in ERISA health plans, as outlined in the Safe Step Act (HR 2163/S 464).

Step therapy is a protocol used by health insurers that requires 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. Step therapy is widely used by health plans – a recent study on commercial plans found that almost 40% of prescriptions were subject to step therapy and that protocols varied greatly from plan to plan, even for the same condition.<sup>1</sup> Because it can take 2-3 months for patients to prove failure, medically inappropriate step therapy delays access to needed care and can result in devastating health outcomes for the patient.

As with other chronic illnesses, medication is an important treatment option for people with mental illnesses as well as those suffering from substance use disorder (SUD).<sup>2,3</sup> However, insurance-mandated step therapy can reduce medication adherence, increase serious adverse events, and increase costs:

- 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>4</sup> The authors noted that “emergency room spending in the step therapy plans consistently exceeded the spending levels of the comparison group.”

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<sup>1</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

<sup>2</sup> Medications: Step Therapy. National Alliance on Mental Illness, <https://www.nami.org/Advocacy/Policy-Priorities/Improving-Health/Medications-Step-Therapy>

<sup>3</sup> NIDA. "Treatment Approaches for Drug Addiction DrugFacts." National Institute on Drug Abuse, 17 Jan. 2019, <https://nida.nih.gov/publications/drugfacts/treatment-approaches-drug-addiction> Accessed 29 Apr. 2022.

<sup>4</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

- A study among Medicaid patients found that the impact of delays in needed care among patients with a mental illness and/or substance use disorder (SUD) included an emergency visit, psychiatric hospitalization, increase in suicidal or violent ideation or behavior, homelessness, or incarceration in prison or detention in jail.<sup>5</sup> This study also found that step therapy was associated with a 4.7 times greater likelihood of a mental health medication access problem.
- Alcohol and drug use is a leading cause of death in the U.S., and health plans spend 1% or less of their health expenditures on treatment – in part because of utilization management like step therapy which discourage patients from pursuing access to needed care.<sup>6</sup>

In addition, patients with other illnesses are more likely to have comorbid mental illness. Comorbid mental illness is also associated with greater healthcare utilization and costs. It is important to ensure that **all patients** have timely access to needed care to limit disease progression, reduce utilization, and reduce costs.

- Among Alberta chronic illness patients, co-occurring mental illness was associated with higher healthcare utilization and costs.<sup>7</sup>
- About 1 in 5 US adults with arthritis have symptoms of anxiety or depression, especially among those living with chronic pain or other co-occurring chronic conditions according to the CDC. “Not only are symptoms of anxiety and depression common among US adults with chronic conditions, but these symptoms also have also been associated with reduced response to treatment and poorer quality of life.”<sup>8</sup>
- Among patients with inflammatory bowel disease, depression was associated with more aggressive disease,<sup>9</sup> and comorbid mental illness associated with higher surgical costs.<sup>10</sup>
- The prevalence of depression in patients with psoriasis may be higher than 50%. Studies have shown that psoriasis patients experience physical and mental disability just like patients with other chronic illnesses such as cancer, arthritis, hypertension, heart disease, and diabetes.<sup>11 12</sup>

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<sup>5</sup> Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings from Ten States  
Joyce C. West, Ph.D., M.P.P., et al. *Psychiatric Services* 2009 60:5, 601-610

<sup>6</sup> American Society for Addiction Medicine. Third Party Payment for Addiction Treatment.  
<https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2020/04/22/third-party-payment-for-addiction-treatment>

<sup>7</sup> Sporinova, Barbora et al. “Association of Mental Health Disorders with Health Care Utilization and Costs Among Adults with Chronic Disease.” *JAMA network open* vol. 2,8 e199910. 2 Aug. 2019,  
doi:10.1001/jamanetworkopen.2019.9910

<sup>8</sup> CDC: The Arthritis-Mental Health Connection. October 2021.  
<https://www.cdc.gov/arthritis/communications/features/arthritis-mental-health.htm>

<sup>9</sup> Kochar, Bharati et al. “Depression Is Associated with More Aggressive Inflammatory Bowel Disease.” *The American journal of gastroenterology* vol. 113,1 (2018): 80-85. doi:10.1038/ajg.2017.423

<sup>10</sup> Szigethy, Eva et al. “Mental Health Costs of Inflammatory Bowel Diseases.” *Inflammatory bowel diseases* vol. 27,1 (2021): 40-48. doi:10.1093/ibd/izaa030

<sup>11</sup> Dowlatshahi, E. A., Wakkee., Arends, L. R., & Nijsten, T. (2014). The prevalence and odds of depressive symptoms and clinical depression in psoriasis patients: a systematic review and meta-analysis. *Journal of Investigative Dermatology*, 134(6), 1542-1551

<sup>12</sup> Mentor A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 3. Guidelines of care for the treatment of psoriasis with topical therapies. *J Am Acad Dermatol* 2009 April; 60(4): 643-659

Given the abysmal health outcomes among patients subject to medically inappropriate step therapy, unsurprisingly utilization management exacerbates provider burnout which is already a national problem due to the COVID-19 pandemic. According to the American Medical Association, 88% of physicians describe the burden of prior authorization (PA) high or extremely high, 40% report having dedicated staff to manage PAs, and physicians report spending two business days per week on PAs.<sup>13</sup> The American College of Gastroenterology (ACG) recently reported that PA is “harming patients and overwhelming practices.”<sup>14</sup>

The Safe Step Act (HR 2163/S 464) would improve patient outcomes, reduce costs, and improve provider experience by ensuring that employer plans offer a medically reasonable and expedient step therapy exceptions process. This bill, first introduced in 2017, is modeled after legislation that has passed in over 30 states. These state laws apply to state-regulated plans including the individual marketplace, and such patient protections must be extended to federally regulated ERISA health plans.

As patient and provider advocacy organizations representing millions of beneficiaries and their health care providers, we urge you to include step therapy reform in legislation that addresses mental health and/or provider burnout. If you would like to discuss this important policy further, or if you have any questions, please contact Alisa Vidulich, Policy Director at the Arthritis Foundation, at [avidulich@arthritis.org](mailto:avidulich@arthritis.org). Thank you for your consideration of this critical patient access concern.

Sincerely,

ADAP Advocacy Association  
Aimed Alliance  
Allergy & Asthma Network  
Alliance for Patient Access  
American Academy of Dermatology Association  
American Academy of Neurology  
American Academy of Ophthalmology  
American College of Rheumatology  
American Gastroenterological Association  
American Partnership for Eosinophilic Disorders  
American Society for Gastrointestinal Endoscopy  
American Society for Parenteral and Enteral Nutrition  
Arizona Peer and Family Coalition  
Arizona Prostate Cancer Coalition, Inc.  
Arizona Psychiatric Society  
Arthritis Foundation  
Association of Black Cardiologists  
Caregiver Action Network  
Child Neurology Foundation  
Chronic Disease Coalition  
Coalition of Skin Diseases

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<sup>13</sup> 2021 AMA prior authorization (PA) physician survey. <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

<sup>14</sup> ACG. Prior Authorization: Harming Patients and Overwhelming Practices. <https://webfiles.gi.org/links/policy/PriorAuthorizationHarmingPatientsandOverwhelmingPractices.pdf>

Coalition of State Rheumatology Organizations  
Community Access National Network (CANN)  
Connecting to Cure Crohn's and Colitis  
Crohn's & Colitis Foundation  
CURED Nfp (Campaign Urging Research for Eosinophilic Disease)  
Depression and Bipolar Support Alliance  
Digestive Disease National Coalition  
Epilepsy Alliance America  
Epilepsy Foundation  
Fabry Support & Information Group  
Georgia AIDS Coalition  
Gilda's Club South Florida  
Hawai'i Parkinson Association  
HD Reach  
HealthyWomen  
Hope Charities  
ICAN, International Cancer Advocacy Network  
International Foundation for AiArthritis  
International Foundation for Gastrointestinal Disorders (IFFGD)  
International Pain Foundation  
Louisiana Hemophilia Foundation  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
Movement Disorders Policy Coalition  
Multiple Sclerosis Association of America  
Multiple Sclerosis Foundation  
National Alliance of State Prostate Cancer Coalitions  
National Council for Mental Wellbeing  
National Eczema Association  
National MS Society  
National Organization for Rare Disorders  
National Organization for Tardive Dyskinesia  
National Pancreas Foundation  
National Patient Advocate Foundation  
National Psoriasis Foundation  
National Psoriasis Foundation  
Nebraska Pharmacists Association  
Nevada Chronic Care Collaborative  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition  
Parkinson's Foundation  
PlusInc  
Society of Dermatology Physician Assistants  
Spondylitis Association of America  
State of Texas Association of Rheumatologists  
Susan G. Komen  
The Arc of Nebraska  
The Leukemia & Lymphoma Society  
The Michael J. Fox Foundation for Parkinson's Research

Transplant Recipients International Organization (TRIO)  
TSC Alliance  
U.S. Pain Foundation  
United Ostomy Associations of America  
VHL Alliance  
ZERO - The End of Prostate Cancer

CC:

Speaker Nancy Pelosi  
Majority Leader Charles Schumer  
Minority Leader Mitch McConnell  
Minority Leader Kevin McCarthy  
House Committee on Education and Labor Members  
House Committee on Energy & Commerce Chairman Frank Pallone, Jr.  
House Committee on Energy & Commerce Ranking Member Cathy McMorris Rodgers  
House Committee on Energy & Commerce Chairwoman, Health Subcommittee Anna Eshoo  
House Committee on Energy & Commerce Ranking Member, Health Subcommittee Brett Guthrie  
House Committee on Energy & Commerce Committee Members  
Senate Committee on Health, Education, Labor, and Pensions Members