

September 10, 2021

The Honorable Charles Schumer
U.S. Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mitch McConnell
U.S. Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Nancy Pelosi
U.S. House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin McCarthy
U.S. House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515

Dear Leader Schumer, Leader McConnell, Speaker Pelosi, and Minority Leader McCarthy:

The undersigned 43 patient and provider advocacy groups ask that you include policies that support access to health care and protections from barriers that impede patient access to prescription medications as part of the upcoming reconciliation package. Specifically, we ask that this package include guardrails on the use of step therapy protocols in ERISA health plans.

As you know, step therapy is a protocol used by health insurance companies that requires patients to try and fail on one or more insurer preferred medications before they will provide coverage for the medication initially agreed upon by the patient and their provider. Step therapy is widely used by health plans, and protocols vary greatly from plan to plan, even for the same disease state. When a step therapy protocol is inappropriate for a patient, it delays needed access to care and can result in devastating health outcomes. Anecdotes of patients undergoing preventable and irreversible surgeries, or even dying, as a result of badly implemented step therapy is common among many of the patient communities we represent.

Both Congress and the Biden Administration have expressed interest in addressing prescription drug costs and other policies that limit patients' access to the medications they need to treat their chronic conditions. However, insurer utilization management policies that also limit patient access to treatment should be addressed as well. Including step therapy protections for patients in the reconciliation package will help ensure patients have timely access to the most medically appropriate treatment.

We urge Congress to include the following step therapy protections for ERISA health plans in the upcoming reconciliation package:

- Establish a clear exemption process for patients and providers to request an exception to a step therapy protocol
- Outline five exceptions to fail first protocols:
 - Patients already tried and failed on the required drug
 - Delayed treatment to the initially prescribed drug would lead to severe or irreversible consequences
 - The required drug is contraindicated or has caused/is likely to cause an adverse reaction
 - Required will prevent a patient from working or fulfilling activities of daily living
 - Patient is stable on their current medication

- Require a group health plan respond to an exemption request within 72 hours in all circumstances, and 24 hours if the patient's life is at risk.

These protections are clearly articulated in pending bipartisan and bicameral legislation, known as the Safe Step Act (H.R. 2163/S. 464), first introduced in 2017. Currently, over 30 states have passed patient friendly step therapy protections. These state laws apply to state regulated insurance plans such as the individual marketplace. We are asking Congress to enact these protections for federally regulated ERISA health plans, ensuring all patients, regardless of who regulates their health plan, have access to the right treatment at the right time.

If you have any questions or would like to discuss this important policy further, please direct your staff to contact Hannah Lynch, Associate Director of Federal Government Relations and Health Policy at the National Psoriasis Foundation, at hlynch@psoriasis.org. Thank you for your consideration of this critical patient access concern.

Sincerely,

Allergy & Asthma Network
Alliance for Balanced Pain Management
Alliance for Patient Access
American Academy of Dermatology Association
American Academy of Neurology
American Autoimmune Related Diseases Association
American College of Rheumatology
American Gastroenterological Association
American Liver Foundation
American Society for Gastrointestinal Endoscopy
Arthritis Foundation
Association of Black Cardiologists
Cancer Support Community
Color of Crohn's and Chronic Illness
Crohn's & Colitis Foundation
Cure SMA
Derma Care Access Network
Digestive Disease National Coalition
Dystonia Advocacy Network
Dystonia Medical Research Foundation
Global Healthy Living Foundation
Hemophilia Federation of America
Infusion Access Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
International Foundation for Gastrointestinal Disorders
International Myeloma Foundation
ITSAN Non Profit
Lupus and Allied Diseases Association, Inc.

Multiple Sclerosis Association of America

National Alopecia Areata Foundation

National Eczema Association

National Pancreas Foundation

National Psoriasis Foundation

NICA

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

Partnership to Advance Cardiovascular Health

Project Sleep

Pulmonary Hypertension Association

Spondylitis Association of America

The Headache and Migraine Policy Forum

Tourette Association of America

US Hereditary Angioedema Association

Vision Health Advocacy Coalition