

April 20, 2020

The Honorable Nancy Pelosi
Speaker of the House
United States Congress
H-232 The Capitol
Washington, DC 20515

The Honorable Kevin McCarthy
Majority Leader
United States Congress
H-204 The Capitol
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
United States Senate
S-230 The Capitol
Washington, DC 20510

The Honorable Chuck Schumer
Minority Leader
United States Senate
S-220 The Capitol
Washington, DC 20510

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

As you consider additional legislation to respond to the coronavirus (COVID-19) pandemic, we write as patient and provider advocacy groups urging Congress to include protections from barriers that impede patient access to prescription medications. Specifically, **we urge that the next relief measure include guardrails on the use of step therapy protocols in Medicare Advantage, Medicare Prescription Drug Plan, Medicaid Managed Care and ERISA health plans.**

Thanks to recent efforts by Congress and the Administration, patients have already received a number of protections to ensure they have access to health care despite the enormity of the COVID-19 pandemic. Previously enacted statutory or regulatory changes have significantly expanded the use of telehealth, reduced face-to-face provider requirements, enabled providers to seamlessly practice across state lines, and lifted restrictions allowing patients to receive care at out-of-network or non-contracted facilities. Regarding prescription drugs, Medicare drug plans must now offer 90-day fills or refills and have been given the ability to waive prior authorization requirements for any drug that may be developed to treat the coronavirus.

While these measures have been critical in ensuring patients have access to health care and their medications in this time, further steps should be taken. We urge Congress to take additional action to support access to care by ensuring appropriate use of step therapy in Medicare Advantage (MA), Medicare Prescription Drug (PDP), Medicaid Managed Care (MCO) and ERISA plans by taking the following three actions:

- Institute step therapy guardrails and protections for all MA, PDP and Medicaid MCO plans during the public health emergency (PHE).
- Institute similar step therapy guardrails and protections for ERISA plans governed by the Department of Labor during the extent of the public health emergency.
- Enact these same protections outside of the public health emergency for at least one year after end date of the PHE.

Step Therapy Protections During the PHE

Step therapy protocols often significantly delay patients from accessing the medications prescribed by their doctors. Such impediments to care are challenging under normal circumstances and are exponentially more daunting during a public health crisis where our health care system is under an enormous strain. Across the country, patients are unable to see their doctors in person and physicians are being forced to cut staff, in particular, administrative staff. In a pandemic where there is limited staff, resources, and time, providers and patients simply do not have the bandwidth to go through the challenging process of obtaining exemptions to step therapy protocols. For patients, these protocols can result in delayed treatment, increased disease activity, loss of function, and potentially irreversible disease progression. Americans cannot afford to be put at risk of hospitalization right now, especially when hospitals are low on resources and those with chronic conditions are already at higher risk of contradicting COVID-19.

We urge Congress to institute the following step therapy protections effective immediately during the PHE:

- Require all MA, PDP, Medicaid MCO and ERISA plans that have step therapy policies to make those policies clear, readily accessible, and visible to all members.
- Require all plans to provide timely responses to requests for step therapy exemptions, including both regular and emergency requests.
- Enumerate a specific set of criteria that would warrant an exemption from any step protocol. Examples would include situations in which a patient has been stable on a drug for an extended period of time and where switching medications would jeopardize this stability, when a drug is contraindicated or when a patient has already tried and failed a drug they are being asked to step through.

These protections are clearly articulated in pending bipartisan and bicameral legislation, known as the **Safe Step Act (H.R. 2279 and S. 2546)**, which together have the support of more than 150 members of Congress. Instituting step therapy guardrails and protections during the PHE is aligned with previous actions taken to prevent disruption of patient care, such as requiring 90-day medication fills and facilitating care in multiple sites. Additionally, states such as Louisiana have included a prohibition on step therapy in their emergency rules responding to the current crisis. The consequences of a delay in access to care during this pandemic, paired with a decrease in providers ability to handle the administrative process involved with step therapy justify the need for prompt action around these reforms.

Step Therapy Protections Beyond the PHE

While protecting patients during the emergency period is of utmost importance, we must also recognize that the nation is facing a protracted and painful economic recovery given the extent of the pandemic's impact. This means that for most Americans, the end of the PHE will not translate to an immediate return to normalcy. Recognizing this reality, it is essential that Americans – particularly those impacted by chronic disease or other conditions that require regular access to medications – not face any undue impediments to access their treatments.

As noted above, the Safe Step Act (H.R. 2279 and S. 2546) would institute similar guardrails for ERISA plan members. These laws and pending legislation have been widely embraced because of their balanced approach and desire to see step therapy used appropriately. While we continue to work aggressively to permanently enact the protections as outlined in the Safe Step Act, we are mindful of the current crisis and urge Congress to extend the step therapy protections enumerated above for at least one year from the end of the PHE.

We thank you for the steps that have already been taken to protect patients during this global pandemic and urge Congress to include commonsense step therapy protections in the next relief legislation.

For more information or to discuss further, please direct your staff to contact Patrick Stone of the National Psoriasis Foundation at pstone@psoriasis.org. Thank you for your consideration.

Sincerely,

Allergy & Asthma Network
Alliance for Balanced Pain Management
Alliance for Patient Access
ALS Association
American Academy of Dermatology Association
American Academy of Neurology
American College of Rheumatology
American Diabetes Association
American Gastroenterological Association
American Liver Foundation
Arthritis Foundation
Association for Clinical Oncology
Cancer Support Community
Caregiver Action Network
Chronic Disease Coalition
Crohn's & Colitis Foundation
Depression and Bipolar Support Alliance
Derma Care Access Network
Dystonia Medical Research Foundation
Epilepsy Foundation
GBS|CIDP Foundation International
Good Days
Hawai'i Parkinson Association
Headache and Migraine Policy Forum
Hemophilia Federation of America
Hypersomnia Foundation
International Foundation for Gastrointestinal Disorders
Interstitial Cystitis Association
ITSAN Non Profit
Lupus and Allied Diseases Association, Inc.

Lymphatic Education & Research Network
Mental Health America
Movement Disorders Policy Coalition
National Alliance on Mental Illness
National Alopecia Areata Foundation
National Eczema Association
National Infusion Center Association
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Pancreas Foundation
National Patient Advocate Foundation
National Psoriasis Foundation
NephCure Kidney International
Project Sleep
Pulmonary Hypertension Association
Scleroderma Foundation
The Marfan Foundation
Tourette Association of America
United for Charitable Assistance
US Hereditary Angioedema Association
U.S. Pain Foundation
Vision Health Advocacy Coalition