

May 29, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Verma:

On behalf of the 50 undersigned patient and provider organizations, we would like to thank you for actions the Centers for Medicare and Medicaid Services (CMS) has taken during the novel coronavirus (COVID-19) pandemic to support beneficiary access to care and ask that additional action be taken to extend these flexibilities to include step therapy requirements. Over the past several months, CMS has implemented a number of protections to ensure beneficiaries have access to health care despite the enormity of the COVID-19 pandemic. This is particularly important for beneficiaries with chronic conditions who require regular access to medical care and medications. CMS' 'Patients Over Paperwork' initiative works to "cut the red tape" to reduce burdensome regulations in healthcare. Now more than ever, these new flexibilities help ensure care for patients during the pandemic and that care is not delayed "due to administrative red tape."¹

While we recognize the unprecedented amount of action CMS has taken, we feel that further measures are needed to address the use of step therapy by Medicare Advantage (MA) and Medicare Prescription Drug Plan (PDP) sponsors. As you know, under step therapy protocols, a patient may be required to try – and fail – one or more medications before being granted coverage for the drug originally prescribed by their health care provider. Step therapy protocols are often used as a utilization management tool to keep prescription drug spending low. Plans with unclear exemption processes or lengthy response timelines can place great administrative burden on providers by requiring multiple follow-ups with the plan, the beneficiary, and beneficiary's pharmacy. Across the country, many patients are unable to see their doctors in person and some 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.

¹ <https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid>

In the April 21st memorandum to MA and PDP sponsors, CMS addressed the issue of prior authorization by stating that sponsors “can also choose to waive or relax PA requirements at any time for other formulary drugs in order to facilitate access with less burden on beneficiaries, plans and providers.” CMS went on to say “we encourage plans to consider utilizing this flexibility.” Unfortunately, this section of the document makes no reference to step therapy.

Because step therapy can and does create a burden on providers and is an impediment to beneficiary access during these challenging times, we ask that CMS further update this guidance to provide explicit flexibilities to MA and PDP sponsors to waive the use of step therapy requirements and to similarly encourage use of such flexibilities. This action would speak explicitly to step therapy and place it on par with prior authorization more broadly. As we are only requesting the CMS permit this flexibility, plan sponsors would not be compelled to take actions that they are unwilling to take. We note that CMS has already amended the April 21st memorandum with two clarifying FAQs, so an avenue exists for CMS to permit plans to reconsider step therapy usage during the emergency.

We thank you for the actions CMS has already taken to lessen provider administrative burden and facilitate beneficiary access to care during the PHE. We reiterate our request that the agency provide plans with explicit authority and encouragement to waive the use of step therapy protocols during this time. If you or others at CMS have any questions or if you would like to connect directly, please contact Patrick Stone of the National Psoriasis Foundation at pstone@psoriasis.org. Thank you for your consideration.

Sincerely,

Alabama Rare
Allergy & Asthma Network
Alliance for Balanced Pain Management
Alliance for Patient Access
Alpha-1 Foundation
American Academy of Dermatology Association
American Academy of Ophthalmology
American Cancer Society Cancer Action Network
American College of Rheumatology
American Gastroenterological Association
American Liver Foundation
Arthritis Foundation
Association for Clinical Oncology
Cancer Support Community
Chronic Disease Coalition
Derma Care Access Network
Digestive Disease National Coalition
Dystonia Medical Research Foundation

Epilepsy Foundation
Fabry Support & Information Group
Global Healthy Living Foundation
Good Days
Hemophilia Federation of America
International Foundation for Gastrointestinal Disorders
Interstitial Cystitis Association
Lupus and Allied Diseases Association, Inc.
Lymphatic Education & Research Network
METAvivor
Michigan AHEC
National Alliance on Mental Illness
National Eczema Association
National Health Council
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
Patient Services, Inc.
Pulmonary Hypertension Association
Restless Legs Syndrome Foundation
Scleroderma Foundation
The American Society for Parenteral and Enteral Nutrition
The Marfan Foundation
The Oley Foundation
Tourette Association of America
U.S. Hereditary Angioedema Association
U.S. Pain Foundation
United Ostomy Associations of America