April 13, 2020

Administrator Seema Verma
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: Prior Authorization and Step Therapy Processes

Dear Administrator Verma,

On behalf of the millions of Americans living with chronic, disabling, and life-threatening medical conditions, the undersigned patient and provider organizations have joined together to express our concern regarding the ongoing burdensome prior authorization (PA) requirements administered by Medicare Advantage and Part D Plans. During this time of a pandemic, physicians have less resources and time at their disposable to manage multiple PAs. With so much uncertainty patients should not be worried about whether or not they can access a necessary treatment or service. Therefore, we call on the Centers for Medicare and Medicaid Services (CMS) to encourage Medicare Advantage and Part D plans to relax PA and step therapy standards for medically necessary prescribed or ordered treatments and services during national pandemics.

You recently stated at a meeting of the American Medical Association that "Prior-authorization requirements are a primary driver of physician burnout ,... and, even more importantly, patients are experiencing needless delays in care that are negatively impacting the quality of care." We appreciate CMS recognizing that when processes are not in place to quickly review and approve requests for treatments, tests, services and supplies that may be medically necessary for the beneficiary, it can adversely affect access to medically necessary patient care. The COVID-19 pandemic has highlighted the negative effect of prior authorization (PA) and step therapy on the delivery of care, particularly this impact on delayed care. CMS should consider tools it can use in the future to alleviate this burden during emergency situations.

During this time of a pandemic, physicians are quickly adapting and implementing new technology to ensure they can continue to see patients. At the same time, they are working to ensure they can continue to operate their businesses; the burden is especially heavy on small and solo practices right now. A recent survey administered by the American Academy of Dermatology Association (AADA) found that PA requirements have added to dermatologist office costs an average of \$40,000 per year. At a time of when practices are worried about keeping their doors open, it is not the time for them to worry about going through PA processes to ensure their patients have necessary access to medications. We recommend CMS immediately advise Medicare Advantage and Part D plans to relax PA and step therapy standards for prescribed or ordered treatments during national pandemics.

We are concerned that any formulary changes that occur during this pandemic will severely limit patient access to needed, effective therapies and put patients at risk for worsening disease, severe flares, or worse, preventable complications. Often, patients must schedule to meet with their health care provider, complete lab work and discuss other therapeutic options if forced to

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switch to a different treatment. In the current environment office visits are much more challenging and could further delay the patient accessing the necessary treatment. Importantly, it is not advisable for a patient to have to visit a pharmacy multiple times right now due to a PA. On top of delaying care, the patient is put in even more at risk in this setting. Especially during this public health emergency, we recommend that stable patients continue to be on their prescribed treatments and any PA requirements are relaxed.

Supply chains are threatened with drug shortages when overburdened or disrupted. If a patient's treatment is compromised due to a drug shortage, they should be not be burdened with having to go through a PA for that treatment. Continued access is important during this time of social distancing and limited access to healthcare services.

Physicians are focusing on patients who require urgent or necessary care and PA creates another hurdle to the patient trying to access this care. PA and appeals policies should not unduly burden physicians or patients or prevent them from achieving optimal outcomes. Delays can cause irreparable harm to patients in need of specific procedures. PA policies that place a third party, with no knowledge of the complexity or full history of a patient's condition, in a decision-making position are not only inappropriate, but they also impede patients' access to the most effective procedure. Additionally, physician offices may be short staffed or have limited resources now to process a PA for a time-sensitive, medically necessary service. We recommend CMS advise Medicare Advantage to relax PA standards for necessary medical services during national pandemics.

This access issue is widespread, which is why we brought together a broad range of specialties as well as patient advocates. We respectfully request that CMS address these access issues as soon as possible so that patients can have access to these affordable and effective treatments and services. We look forward to additional opportunities to work together on this issue and to provide feedback that may help guide policy development. Please contact Ashley John, Manager in Advocacy and Policy at ajohn@aad.org or (202) 609-6332 if you have any questions or if we can provide additional information. Thank you for your attention to our concerns.

Sincerely,

Allergy & Asthma Network
Alliance for Patient Access
American College of Cardiology

American Academy of Dermatology Association

American Academy of Family Physicians

American Academy of Ophthalmology

American College of Allergy, Asthma and Immunology

American College of Mohs Surgery

American College of Rheumatology

American Gastroenterological Association

American Osteopathic Association

American Society for Dermatologic Surgery Association

American Society for Mohs Surgery

American Society of Hematology

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American Urological Association Arthritis Foundation Association of Black Cardiologists Cutaneous Lymphoma Foundation Derma Care Access Network Dermatology Nurses' Association (DNA) Foundation for Ichthyosis & Related Skin Types, Inc. Genetic Alliance Headache & Migraine Policy Forum International Pemphigus Pemphigoid Foundation Lupus Foundation of America Medical Group Management Association National Eczema Association National Psoriasis Foundation **PXE** International Siegel Rare Neuroimmune Association The Sturge-Weber Foundation Tuberous Sclerosis Alliance Vitiligo Support International