April 28, 2021

Steve Miller, MD
Chief Clinical Officer, Express Scripts
1 Express Way
St. Louis, MO 63121

Snezana Mahon, PharmD
Vice President & General Manager Clinical Product Management
1 Express Way
St. Louis, MO 63121

Re: National Preferred Formulary Exclusion List

Dear Dr. Miller and Dr. Mahon,

On behalf of the Movement Disorders Policy Coalition and the movement disorders community, I am writing to express concern regarding Express Scripts' 2021 National Preferred Formulary Exclusion List placement of Parkinson's and tardive dyskinesia medications. The coalition's members are concerned that the decision to exclude these therapies – specifically, Gocovri, Ongentys, Xadago, Zelapar, and Ingrezza – from coverage has a detrimental impact on patient-centered care for those living with movement disorders. We urge you to reverse the policy as currently set.

The Movement Disorders Policy Coalition (MDPC) serves as a platform from which stakeholders, including health care providers and patients, can provide input on policy decisions impacting patient-centered care for those living with movement disorders. As a coalition of twenty stakeholder groups across the movement disorders space, MDPC advocates at the federal, state, and health plan level for key health reforms that increase access to personalized care for patients with movement disorders including Parkinson's disease, tardive dyskinesia, essential tremor, dystonia, ataxia, Tourette syndrome, spasticity, and Huntington's disease.

Parkinson's Disease Exclusions

Parkinson's disease is a relentlessly progressive neurodegenerative condition that affects approximately one million Americans. The disease causes a heterogenous constellation of symptoms, including slowed movement, tremor, stiffness, and poor balance as well as cognitive changes, gastrointestinal issues, and mental health challenges. For instance, Parkinson medication induced dyskinesia, involuntary, abnormal movements in one body part or over the entire body, affect the majority of Parkinson's patients over time. Another challenge, OFF time, occurs when medication is no longer working optimally, causing a resurgence of symptoms. Some patients experience a gradual wearing off of their medication before the next dose is due for administration; or, they find the dose not taking effect as quickly as usual. For other patients, the OFF episode may happen suddenly and unexpectedly. More than 90 percent of patients

reported experiencing OFF episodes, according to a survey conducted by Michael J. Fox Foundation.[1]

There is still no cure for Parkinson's disease, but fortunately, there are a growing number of treatments available to help manage the debilitating symptoms. These medications address challenges like OFF time, medication induced dyskinesia, and other symptoms, and importantly, also vary in formulation and method of administration. These differences in therapies allow patients and providers to tailor treatment to individual needs, such as allowing for fewer doses or pills per day. This is incredibly important for many people with Parkinson's, because the disease often causes swallowing difficulty and choking. Access to a wide array of therapies is critical for treatment of Parkinson's patients due to the heterogeneity of the Parkinson's population and the variation in symptoms and disease experience.

We are concerned that Express Scripts' decision to exclude a number of Parkinson's medications such as Gocovri, Ongentys, Xadago, and Zelapar effectively denies patient access to appropriate, and proven FDA-approved therapies. This creates onerous and unreasonably burdensome limitations for patients and clinicians and results in fewer options for Parkinson's patients who need access to the full range of therapies in order to successfully manage their disease.

Tardive Dyskinesia Exclusions

In addition to its Parkinson's disease exclusions, Express Scripts has excluded Ingrezza, an FDA-approved therapy for treatment of tardive dyskinesia (TD). TD is an involuntary, sometimes irreversible movement disorder that can occur due to necessary use of antipsychotics, commonly prescribed to treat bipolar disorder, schizophrenia, and depression, or other medications.

The more than 500,000 people in the U.S. with TD experience involuntary, repetitive movements of their face, limbs, or torso that can be uncomfortable, painful, and disabling. The condition has a significant impact on individuals' ability to do activities of daily living. Moreover, people with TD frequently face stigma that can lead to embarrassment or withdrawal and can worsen mental health symptoms.

Fortunately, two therapies have been approved in recent years to treat tardive dyskinesia, providing patients, for the first time, with FDA-approved options to treat the debilitating symptoms of TD; however, Express Scripts has excluded one of these from coverage, providing just one FDA-approved therapy. We are concerned that this decision limits access to an appropriate therapy for patients and providers.

Value of Treatment Options

For movement disorders patients managing complex disease symptoms and treatment regimens, access to all appropriate medications is particularly important. Placing barriers between patients and the therapies that their healthcare provider prescribes interferes with patient care and undermines the primacy of the physician-patient relationship, a relationship that serves as the

[1] https://www.michaeljfox.org/foundation/news-detail.php?capturing-and-elevating-the-patient-voice

backbone of our healthcare system. We urge you to implement a patient-centered approach by reconsidering the decision to exclude important movement disorders therapies from coverage.

Allowing access to the full range of therapies will provide more opportunities for a patient-centered care approach, one that allows for tailored treatment of each patient and their individual disease management needs. A patient-centered approach focuses on the ability to change course, as needed, and allows patients the opportunity to access innovative medications that could drastically improve their quality of life.

On behalf of the Movement Disorders Policy Coalition and the undersigned organizations, we urge you to reverse placement of Gocovri, Ongentys, Xadago, Zelapar, and Ingrezza on the 2021 National Preferred Formulary Exclusion List thereby ensuring patients can access the therapies their health care providers deem most appropriate. Doing so will support timely access to appropriate care for those with movement disorders and support a patient-centered system of care.

Thank you for your consideration. If we can answer any questions or provide further information, please contact us at jcooper@allianceforpatientaccess.org or 202-499-4114.

Sincerely,

The Movement Disorders Policy Coalition

Co-Signing Organizations:
Alliance for Patient Access
American Brain Coalition
American Parkinson Disease Association
Brian Grant Foundation
Caregiver Action Network
Davis Phinney Foundation
Depression and Bipolar Support Alliance
Hawaii Parkinson's Association
HD Reach
Houston Area Parkinson Society
Mental Health America
Michigan Parkinson Foundation
National Alliance on Mental Illness
National Council for Behavioral Health
National Organization for Tardive Dyskinesia
Parkinson Association of the Rockies
Parkinson's Foundation
Parkinson & Movement Disorder Alliance
Parkinson's Resources of Oregon
Power for Parkinson's
The Michael J. Fox Foundation for Parkinson's Research
The Parkinson Alliance