



May 25, 2022

The Honorable Lina Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

RE: Pharmacy Benefit Managers' Impact on Affordable and Accessible Care for Movement Disorders Patients

Chairperson Khan:

On behalf of the Movement Disorders Policy Coalition and the movement disorders community, I am writing to provide comment on the role that pharmacy benefit managers (PBMs) play in determining the therapies that movement disorder patients can access. The coalition and our members are concerned that PBMs' current practices have a detrimental effect on patient access, and we thank you for the opportunity to weigh in.

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 stakeholder groups across the movement disorders space, MDPC advocates at the federal, state, and health plan levels for key health reforms that increase access to personalized care for patients with movement disorders including Parkinson's disease, essential tremor, Tourette Syndrome, dystonia, tardive dyskinesia, ataxia and Huntington's disease.

Pharmacy Benefit Managers (PBMs)

Pharmacy benefit managers assist health insurers, Medicare Part D programs, and large employers manage their prescription drug programs. As such, they play a large role in determining the cost and availability of these medicines to both plans and their beneficiaries. Currently, three PBM entities control almost 80% of the market.¹ This market domination has allowed these companies to play an outsized role in working with health insurers to guide the treatment options that patients and providers can access. It is also noteworthy that each of these PBMs offers its health insurance clients the option of a national formulary of covered medications. These one-size-fits all plans capture a large percentage of covered individuals, furthering PBMs' influence and control.

Implications for Access

PBMs use formulary design, formulary exclusions, and utilization management tools to determine which medications are covered and the cost that they will have to beneficiaries.

¹ <https://www.hirc.com/PBM-market-landscape-and-imperatives#:~:text=Three%20Major%20Players%20Control%2080,the%20total%20PBM%20market%20share.>

Formulary Design

PBMs construct formularies to control what medications patients can access. Often, medications are split into multiple tiers that PBMs use to determine how much each patient will pay for a particular medication. For example, in some 4-tier benefit designs, medications on levels one and two are preferred formulary medications and typically have a lower copayment. However, medications listed as level three are non-preferred medications and usually have a higher copay. Finally, level four medications are specialty treatments and have the highest copay or frequently, a coinsurance requirement that requires a patient to pay a percentage of the medication's cost. Many of the medications prescribed for movement disorder patients, particularly innovative therapies, are listed on higher tiers, causing patients to pay higher out-of-pocket costs. This can create a significant access barrier.

Rebates are another common tool used by PBMs. PBMs negotiate with pharmaceutical companies to secure the best deal for their customers, the health plans. In practice, these negotiations often center around the payment of a rebate from the manufacturer to the PBM, a discount off the list price that the PBM keeps. A sufficient rebate has the potential to incentivize the PBM to cover medications with higher list prices. However, patients whose medications are on specialty tiers with co-insurance must still pay their percentage based on the list prices, rather than the negotiated price. This leaves patients with higher out-of-pocket costs, even as the PBM profits. When PBMs negotiate with manufacturers on behalf of insurance companies to cut costs, patients often do not reap the benefits. Patients' costs remain high while PBMs profit from their negotiations with manufacturers.

Formulary Exclusions

In some cases, PBMs exclude or remove a previously covered medication from the formulary outright, preventing beneficiaries from accessing those treatments. This tactic is increasing in prevalence; in 2012, Caremark excluded fewer than 50 drugs from its formulary.² However, in 2022, the three largest PBMs, Caremark, Express Scripts, and OptumRX each exclude between 400-500 drugs from their formularies.³ These exclusions affect coverage broadly, completely preventing providers and patients from accessing appropriate, FDA-approved medications.

Exclusions can also force non-medical switching. When a PBM chooses to exclude a previously included treatment, patients are often non-medically switched to a new treatment, regardless of their health status. This means that a stable patient may be forced on to an entirely new treatment without their physician's consideration. This new treatment may not work for the patient or may introduce new, difficult-to-manage, or even life-threatening side effects. They may also lead to other downstream costs, including additional lab tests, appointments, and emergency department visits. Further, these exclusions may change year over year, forcing patients to make constant changes to their formerly stable routines. These changes are implemented based on what is most profitable to the payer, meaning that patients' health is not the deciding factor.

Utilization Management Tools

PBMs also advise health insurers on which utilization management tools to include in the pharmacy benefit. Prior authorization, step therapy, and non-medical switching all place barriers between patients and their treatments. As these tools proliferate, policymakers must ensure a clear exception pathway, timely reviews, and a simple appeals process.

² <https://www.drugchannels.net/2022/04/five-takeaways-from-big-three-pbms-2022.html>

³ Ibid.

A newer utilization management tool, copay accumulator programs, targets patients who rely on manufacturer coupons to assist with their out-of-pocket obligations. With these programs, the health insurer accepts the coupon payment but does not count it toward the patient's annual out-of-pocket deductible cost. This practice leaves patients with higher out-of-pocket costs over the long-term, as their yearly deductible is not met as quickly. And often, patients are not aware of this harmful practice until it is too late, leaving them with unexpected expenses. To ensure appropriate access to care, all payments made on behalf of a patient should be counted on their behalf. This will ensure that patients meet their deductibles in the expected amount of time, allowing for a decreased financial burden and higher rates of treatment adherence.

Implications for Movement Disorder Patients

For movement disorders patients managing complex disease symptoms and treatments, access to all appropriate, FDA-approved medications is particularly important. One example of a population acutely affected is those with Parkinson's disease, a progressive neurodegenerative condition for which there is no cure. 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, they vary in formulation and method of administration. These differences in therapies allow patients and providers to tailor treatment to individual needs and symptom presentation, such as allowing for fewer doses or pills per day. Further, Parkinson's disease often causes swallowing difficulty and choking, making the option to administer treatment without swallowing a pill a necessity. However, PBMs' decisions often create difficulty in gaining coverage for new medications to treat Parkinson's. This is just one example of the impact of PBMs' impact on the movement disorders community. Access to a wide array of therapies is critical for treatment of movement disorders patients due to the heterogeneity of the movement disorders population and the variation in symptoms even among individual disease states.

As previously mentioned, an increase in drug exclusions is proliferating. It is specifically affecting movement disorders patients, who often rely on higher-cost specialty drugs that are becoming more commonly excluded from formularies. For example, Express Scripts currently excludes a half dozen FDA-approved movement disorders therapies. Many other movement disorders therapies are on higher tiers, resulting in higher costs for patients. This example demonstrates that these issues are not insular; they often combine to create a complicated web of barriers and in some cases, non-coverage, for patients who require specialized treatment.

Movement disorder patients are harmed by a one-size-fits-all approach, as their unique, heterogeneous symptoms necessitate individualized treatment. PBM-induced barriers for movement disorders patients, impede patient-centered care and undermines the primacy of the physician-patient relationship, which is well-positioned to determine the best type of treatment of movement disorders.

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

Conclusion

On behalf of the Movement Disorders Policy Coalition and the undersigned organizations, we urge you to consider PBMs' negative effect on drug affordability and treatment access for movement disorders patients. Coverage of a full range of therapies will allow for a patient-centered care approach, ensuring

that movement disorders patients and their providers are able to access the treatments that will best suit patients' individual needs.

Thank you for your consideration. If we can answer any questions or be of further assistance, please reach out to contact us at jcooper@allianceforpatientaccess.org or (202) 499-4114.

Sincerely,



Josie Cooper
Executive Director
Movement Disorders Policy Coalition

Cc: Commissioner Alvaro Bedoya

Commissioner Noah J. Phillips

Commissioner Rebecca Slaughter

Commissioner Christine S. Wilson

Co-Signing Organizations:

Alliance for Patient Access

Caregiver Action Network

Clinical Neurological Society of America

Depression and Bipolar Support Alliance

Dystonia Medical Research Foundation

Hawai'i Parkinson Association

HD Reach

International Essential Tremor Foundation

National Ataxia Foundation

National Organization for Tardive Dyskinesia

Parkinson's Foundation

Parkinson & Movement Disorder Alliance

The Michael J. Fox Foundation for Parkinson's Research