



PROTECTING PATIENT ACCESS TO TREATMENTS FOR NEURODEGENERATIVE DISEASES

A White Paper from the **Physicians Neurodegenerative Disease Working Group**

Physicians
Neurodegenerative
Disease Working Group

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Millions of Americans and their families deal with the debilitating effects of neurodegenerative diseases such as Alzheimer's, Parkinson's, and Huntington's.

For years, failed attempts to find treatments that would slow, stop, or cure these illnesses have discouraged researchers and patients. Although there are no cures for these progressive conditions, there are now treatments that can improve symptoms and quality of life, and there are promising new therapies in development.

Yet as patients and physicians look forward to these breakthrough treatments, a new concern looms: Will health plans and coverage policies allow patients to access long-awaited treatments for neurodegenerative diseases?

NEURODEGENERATIVE DISEASES

Neurodegenerative diseases are a significant health problem in the United States. More than 5 million Americans live with Alzheimer's¹ and 1 million Americans live with Parkinson's.² Thirty thousand individuals have Huntington's and another 200,000 have a risk of developing it.³ These potentially terminal conditions progressively

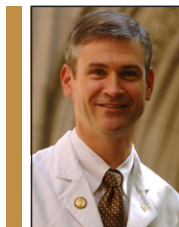
diminish the mental and physical abilities of those suffering from them.

Families are deeply impacted by neurodegenerative diseases. In addition to the psychological toll, there is a very real financial cost. Last year, 15.9 million family members and friends provided 18.1 billion hours of unpaid care to loved ones stricken with Alzheimer's and other forms of dementia. Caretakers lose an average of \$15,000 in annual income as they are forced to reduce work hours or quit their jobs to meet the needs of loved ones.⁴

The Alzheimer's Association estimates the aggregate cost of health care, long-term care, and hospice for patients suffering from that neurodegenerative condition alone amounted to \$200 billion in 2012. If current trends continue, that figure could rise to \$1.1 trillion by 2050.⁵

THE FIGHT FOR TREATMENTS

Researchers are working to understand the cause of these diseases and to develop effective treatments, but it is a slow, expensive process. It typically takes more than a decade to develop and test a new drug, and the average cost of successfully bringing a prescription drug to market is now estimated at \$2.6 billion.⁶



“While researchers are meticulously exploring new treatments for neurodegenerative diseases, families across the country are watching their loved ones slowly succumb to progressive and debilitating diseases. This community of patients, spouses, and children is deeply hopeful for new and effective treatments.” David Charles, MD

Creating treatments for neurodegenerative diseases can be especially challenging. Drugs to treat Alzheimer's have one of the highest failure rates of any disease area: 99.6 percent, compared to 81 percent for cancer.⁷

The Food and Drug Administration (FDA) recognizes that patients can benefit from an efficient yet thorough review of new medications, biologics, medical devices, and diagnostic tests. In light of these challenges, the FDA may fast track approval of new treatments that would treat serious medical conditions or fill an unmet medical need. The FDA may also apply breakthrough therapy status, accelerated approval, and priority review to cut the time required to bring treatments to patients.⁸

For example, the FDA granted fast-track approval to pimavanserin, the first FDA-approved treatment for hallucinations and delusions associated with Parkinson's disease psychosis. Psychosis is a debilitating condition that often forces patients who are living at home to transition to assisted living or a nursing home. The medication also received breakthrough therapy status.

HEALTH PLAN BARRIERS TO TREATMENT

Even with FDA strategies to expedite the approval process, the cost of developing new treatments for neurodegenerative diseases almost guarantees that they will be expensive. In an effort to control their costs, health plans may implement strategies to limit the number of patients who can access these treatments or pass costs on to patients.

Cost Sharing & Specialty Tiers

Cost sharing is one health plan tool for limiting patients' access to high-cost treatments for neurodegenerative diseases or other serious, long-term illnesses. Various levels of cost sharing exist in plans offered through Affordable Care Act

exchanges, employers, or the federal government. These include the placement of expensive treatments on specialty tiers and high out-of-pocket payment requirements.

Specialty tiers represent the highest classification in a tier system, with Tier 1 being the lowest cost and Tier 4 or 5 the highest.⁹ Specialty tiers typically include specialty drugs, roughly defined as medications that cost \$600 or more per month. In 2013, specialty drugs accounted for 30 percent of total U.S. drug costs, according to one pharmacy benefit manager study; that number is expected to increase to 50 percent by 2018.¹⁰



“In reality, health plans are part of a patient’s care team. As with physicians,

nurses, caretakers, and the patients themselves, health plan officials are making decisions that directly affect patient health.

That means they should be held to the same level of transparency and accountability as other care team members. Their criteria for deciding whether a patient can get a specific medication or test should be straightforward. They should be forthcoming and specific about which health plan physician is responsible when my patients are denied the care or treatment they need. But this is seldom the case.”

Robert Yapundich, MD

While lower tiers may require patients to pay a fixed co-payment, health plans may require patients needing a treatment from the specialty tier to pay a percentage of the drug's cost, sometimes as much as 25-33 percent.¹² Insurance companies know that this high out-of-pocket expense, which they term "co-insurance," will simply put these treatments beyond the reach of many patients.

High out-of-pocket costs increase the risk that patients will not be able to adhere to the treatment prescribed by their doctor.

A 2010 study in the *Journal of Managed Care Pharmacy* found that oncology patients taking prescription drugs with an out-of-pocket cost exceeding \$200 per month were three times more likely not to fill their prescriptions than those with medications that cost \$100 or less.¹³ Patients and caregivers, particularly seniors on fixed incomes, can be forced to choose between taking their medications or paying for food, rent, and utilities.

Moreover, non-adherence can be costly. Patients who do not stick to their prescribed medication regimen are at risk for more serious health problems and may require more frequent office and emergency room visits or expensive hospital stays. One study estimates the direct and indirect costs of non-adherence across the medical spectrum in the United States totaled \$337 billion in 2013.¹⁴

Providers may be tiered as well. In tiered health plans, hospitals and providers are ranked according to the cost of the care they provide. As with specialty tiers for medications, tiers for providers and hospitals may drive patients to select the least costly option as opposed to the provider or facility that best meets their health care needs.¹¹

Medicare Challenges

Cost sharing can pose particular challenges for patients with neurodegenerative diseases who are covered under Medicare. The coverage gap in most Medicare Part D plans (commonly called the "donut hole") puts a limit on how much insurance will pay for prescriptions. In 2016, that amount is \$3,310, after which patients pay up to 45 percent of the plan's cost for covered brand-name drugs.¹⁵ According to the Affordable Care Act's design, the donut hole will be phased out by 2020, offering coverage relief for some neurodegenerative patients and other seniors.

Medicare Part D patients are also prevented from using co-pay coupons to help cover the cost of prescriptions. A federal anti-kickback law made this illegal, out of concern that coupons would induce Medicare consumers to buy more expensive brand-name drugs instead of cheaper generics.¹⁶ In practice, however, the restriction may have the unintended consequence of preventing these patients from receiving helpful assistance for the drugs they require.

Discriminatory Policies & The Affordable Care Act

When health plans purchased under the Affordable Care Act use policies that limit specific patient groups' access to treatment, those plans may violate the law's non-discrimination provision. For example, in 2014 the AIDS Institute filed a complaint with the U.S. Department of Health and Human Services Office for Civil Rights, charging four health plans in Florida with discrimination because their cost-sharing requirements discouraged people with HIV/AIDS from enrolling. As a result of the suit, the Florida Office of Insurance Regulation set maximum limits on cost sharing for HIV medications in marketplace plans.¹⁷

Other government agencies have taken up this issue as well. Beginning in 2017, the state of California will prohibit insurers from placing all or most of the drugs for a specific condition in the highest cost tier.¹⁸ The U.S. Department of Health and Human Services has also signaled to insurers that this practice may be discriminatory.¹⁹

COST CONTROLS & PATIENT ACCESS

Health plans that impose requirements on patients and physicians designed to limit the payer's short-term costs often fail to recognize the long-term costs these strategies can trigger. These practices can include prior authorization or reauthorization requirements and "fail first," or step therapy, requirements.

Prior Authorizations

Prior authorization or reauthorization dictates multiple requirements that a patient and physician must satisfy before the patient can receive a prescribed treatment. This can include requiring a patient to first take an "off-label" medication, one not approved specifically for the patient's condition. If a patient gets approval, it typically comes with a timeline after which the patient and physician may then have to apply for reauthorization.

Prior authorization frequently includes "fail first," or step therapy, policies. These require patients to first try a less expensive or generic medication. Often these therapies are suboptimal or inadequate, leading patients to suffer in order to prove to insurance companies that their preferred therapies do not work. Payers sometimes require multiple "fail first" steps before approving the

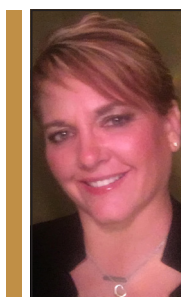
original therapy prescribed. "Fail first" policies are becoming more common; their use by health plans rose from 27 percent in 2005 to 67 percent in 2014. These policies frequently do not take into consideration factors such as a patient's medical situation or history.²⁰

Prior authorization is time consuming for health care providers and confusing for patients, many of whom do not have the support system or know-how to navigate the insurance companies' paperwork and policies. It can delay or deter patients' access to vital treatments. Reauthorization policies are particularly onerous for progressive neurodegenerative diseases, which by their very nature require lifelong treatment.

Non-Medical Switching

Patients may also face the threat of non-medical switching, whereby insurers force patients to abandon effective therapies for less costly ones. This can occur as health plans change their formulary of approved medications, incentivize pharmacists or physicians to switch medications, or limit the use of co-pay coupons that make treatments affordable for patients. Non-medical switching also occurs when health plans place therapies on specialty tiers with exorbitant cost-sharing requirements, potentially encouraging patients to opt for a more affordable treatment.

Non-medical switching can cut costs but may do so at the expense of a patient's health. As with prior authorizations and step therapy, non-medical switching undercuts the physician's ability to manage a patient's condition.



"The prior authorization process can be time consuming, a burden to the typical neurology practice. The administrative tasks of completing an authorization request or submitting an appeal can tie up the office personnel and physician, reducing the time they have for quality patient care.

The result? Some physicians may feel pressured to prescribe the health plan's preferred drug as opposed to doing right by the patient, simply to minimize the administrative burden."

Donna Spencer, MBA

OTHER ACCESS CHALLENGES

Some challenges to access for patients with neurodegenerative diseases stem from the application of requirements that may not make sense given the patient population and new treatment options.

For example, Medicare requires gradual dose reduction of antipsychotics for patients in nursing homes and long-term care facilities. These requirements are designed to prevent the overuse and misuse of antipsychotics, but they were put into place before the advent of a treatment designed specifically for treating psychosis in Parkinson's patients. Policymakers should now consider whether such requirements are appropriate for all antipsychotics used by Parkinson's patients in long-term care facilities.

BARRIERS TO CARE

Health plan policies can also complicate access to doctors, specialists, and health care facilities.

Narrow networks of health care providers can leave large groups of patients, such as those with neurodegenerative conditions, with only a handful of specialists to treat them.

As a result, seeing a geriatric psychiatrist, movement disorders specialist, or other specialist may require long waits and excessive travel, all while a patient's condition worsens. In addition to narrow networks, patients may find that a general lack of trained specialists further complicates access to care.

Complications can also arise for patients who need to transition to long-term care facilities. The use of antipsychotic medications can lower a nursing home's ratings, effecting a bias that can work against patients with neurodegenerative



“Access to physical therapy, occupational therapy, and speech therapy are also critical

for many patients with neurodegenerative conditions.

But some health plans may limit a patient's number of visits or offer narrow networks of health care providers, impeding access to allied health care providers.”

Rachel Dolhun, MD

diseases who need a long-term care environment but also require antipsychotic medications to control their symptoms.

CONCLUSIONS

Families and patients battling neurodegenerative diseases have struggled for years, suffering through an irreversible, degenerative disease that often results in patients' permanent loss of brain tissue. They deserve timely, affordable, and straightforward access to long-awaited treatments. They also deserve the right to make their own decisions about their healthcare, in partnership with their trusted and knowledgeable physicians. There are several ways we can help get them the access and care they need.

State legislatures must continue to address current barriers to patient access, such as prior authorization, “fail first,” non-medical switching, and high cost-sharing, all of which can impede access to treatment for patients with neurodegenerative diseases. Re-examining the impact of restrictions on Medicare Part D patients, such as the inability to use co-pay coupons to reduce

prescription drugs costs, could also be helpful. Additionally, engaging with health plan directors and Medicare and Medicaid officials can shape policies that protect patients' access to care and treatment.

Patients with neurodegenerative diseases and their caregivers look to

their physicians as trusted advisors over the course of a progressive and debilitating disease. The experiences and insights of those physicians must now inform policy and public dialogue on access issues so that patients can receive the care and treatments they need.

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JOIN AFPA'S PHYSICIANS NEURODEGENERATIVE DISEASE WORKING GROUP

AfPA's Physicians Neurodegenerative Disease Working Group seeks to ensure that policymakers hear the perspectives of clinicians who treat patients with Alzheimer's, Parkinson's and Huntington's diseases, as well as related conditions, as they consider issues impacting access to medical therapies. Working group members include psychiatrists, neurologists, movement disorder specialists, and other health care providers and advocates. Together, these members collaborate in the development of educational resources and participate in advocacy initiatives that promote informed policymaking. To learn more, visit www.AllianceforPatientAccess.org.



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