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Commentary

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Practices of US health insurance companies concerning MS therapies interfere with shared decision-making and harm patients

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Abstract

The US Food and Drug Administration has registered 13 multiple sclerosis (MS) disease-modifying therapies (DMTs). The medications are not interchangeable as they vary in route of administration, efficacy, and safety profile. Selecting the appropriate MS DMT for individual patients requires shared decision-making between patients and neurologists. To reduce costs, insurance companies acting through pharmacy benefit companies restrict access to MS DMTs through tiered coverage and other regulations. We discuss how policies established by insurance companies that limit access to MS DMTs interfere with the process of shared decision-making and harm patients. We present potential actions that neurologists can take to change how insurance companies manage MS DMTs. ***Neurol Clin Pract* 2016;6:177–182**

It is a typical day. Our nurse comes to us with a problem. One of us has prescribed dimethyl fumarate, an oral disease-modifying therapy (DMT) for multiple sclerosis (MS), and the patient's Medicaid managed care organization (MCO) has denied coverage; the MCO wants a different oral drug, fingolimod, prescribed. However, the MCO will not cover the cost of cardiac monitoring on the first day the patient takes the drug, even though the manufacturer and the Food and Drug Administration (FDA) require monitoring. Resolving this problem will require several hours of the physician's and our staff's time writing appeals, calling the MCO, and having a peer-to-peer telephone call. Meanwhile, the patient must await treatment.

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Our purpose is to give voice to concerned neurologists over the intrusion of insurance companies into our care of people with MS.

Increasingly, we find ourselves altering the care we provide our patients because of rules regarding coverage of MS DMTs and spending hours dealing with insurance companies that refuse to cover treatments that we have prescribed. This is not unique to Oregon. We recently polled 17 colleagues who care for people with MS in Alabama, Alaska, California, Connecticut, Florida, Illinois, Kansas, New Mexico, New York, Ohio, Pennsylvania, and Washington. All 17 believed that the policies of insurance companies concerning MS DMT interfered with the care they provided their patients. They estimated that their staff spent 20–30 hours per month addressing problems related to insurance coverage for MS drugs. The neurologists indicated that they usually spent 1–1.5 hours per week on insurance denials. These experiences are consistent with our own and suggest the widespread effects of insurance company policies on the care of people with MS.

Our purpose is to give voice to concerned neurologists over the intrusion of insurance companies into our care of people with MS. Our concerns are not just about the wasted hours of appealing arbitrary and uninformed decisions by insurance companies. Insurance companies are interfering with the shared decision-making of patients and their physicians that is at the center of compassionate and ethical health care. This interference can harm patients.

Case vignette

A 45-year-old woman with MS since age 29 years started interferon-β-1a (IFN-β-1a) IM at age 31. She took IFN-β-1a IM from 2001 to 2013. Because of her needle phobia, her husband gave her the weekly injection. This required them to adjust their work schedules, as her employment required frequent travel. Despite interferon therapy, she had a clinical relapse in 2011, and brain MRI revealed gadolinium-enhancing lesions in 2008, 2011, and 2013. In 2011, natalizumab was discussed as a treatment option. However, the patient was serum JC virus antibody positive, and the patient and her neurologist decided against switching to natalizumab because of the risk of progressive multifocal leukoencephalopathy. The patient and her neurologist also discussed switching to the oral DMT, fingolimod, when it became available, but the patient decided against switching because of concerns about cardiac side effects and uncertainty about the long-term risks of the drug. In 2013, the patient and her neurologist decided to switch her to dimethyl fumarate to gain better control of her disease and avoid the problems associated with an injectable DMT. However, her insurance company denied coverage of dimethyl fumarate, indicating that "the member does not meet the following criteria: No documented contraindication or intolerance or allergy or failure of a 1 month trial of Copaxone [glatiramer acetate]." The neurologist subsequently had a peer-to-peer review with the company's medical director. He would not approve dimethyl fumarate without a trial of glatiramer acetate despite the results of a pivotal trial suggesting superiority of dimethyl fumarate over glatiramer acetate[1] and the patient's inability to perform self-injections. The neurologist wrote a letter appealing the denial but never received a response. The patient believed she could not do daily injections of glatiramer acetate. After further delays in therapy that were stressful for the patient, she qualified for a Biogen-sponsored program through which she obtained dimethyl fumarate at no cost. She has had excellent control of her MS disease activity since going on dimethyl fumarate, and her quality of life has improved since stopping the injectable DMT.

This case illustrates the complexity of decision-making regarding MS DMT and how rigidly applied rules concerning MS DMT access by an insurance company can obstruct appropriate treatment. Do actions such as this by insurance companies interfere with shared decision-making between neurologists and their patients and can they harm patients?

Shared decision-making and prescribing MS DMTs

Over the past 30 years, there has been increasing emphasis on shared decision-making as the optimal way to make complex and important medical decisions.[2] Shared decision-making requires that physicians advise their patients about the risks and benefits of various treatment options and then seek to understand the values and health goals of their patients. Patients are actively engaged in making the final decision about treatment. This model of physician–patient decision-making represents a marked change in the paternalistic model that was prevalent in medical care prior to the 1970s.[3] There is considerable evidence that shared decision-making improves patient compliance and health outcomes.[4] Moreover, it is an accepted ethical imperative that patients are engaged in making decisions about treatments and shared decision-making honors this ethical imperative.[5]

Relapsing MS varies considerably among patients; disease severity ranges between those who have mild, indolent disease to those with highly active and rapidly disabling disease. In the United States, there are 13 FDA-approved therapies in 7 different classes of medication for relapsing MS.[6] These medications differ in route of administration, mechanisms of action, side effect profiles, and efficacy, and are not interchangeable. The high variability in the disease course among patients coupled with the large number of FDA-approved therapies renders selection of a MS DMT for a given patient highly complex. Decisions about MS DMTs are also complex as they involve consideration of the attitudes of patients about their MS, their lifestyle, and tradeoffs between the risks and benefits of the various therapies. To complicate the process further, there is uncertainty about the comparative efficacy and safety of MS therapies because there are few head-to-head clinical trials. Given the large number of treatment options, neurologists and their patients can usually find an approach that will control the patient's MS while meeting the patient's personal goals and preferences.[6] This is best accomplished through shared decision-making between patients and their neurologists.

The current MS DMT approval process is flawed

Despite the large number of MS DMTs and the complexity of the decision-making, insurance companies, acting through pharmacy benefit management (PBM) companies, commonly limit treatment options. The costs of MS DMT have skyrocketed in recent years,[7] and these medications now cost between $60,000 and $75,000 a year. Given the high price of these therapies, PBMs seek to manage costs by placing restrictions on their use and establishing tiers of therapy that govern what they will cover. Preferred pricing and rebate arrangements made between insurers and the pharmaceutical companies drive restrictions on access and these financial arrangements are not transparent. Policies concerning coverage of MS drugs vary from company to company and create a confusing and frustrating environment in which physicians and their patients must navigate.

Health insurance companies deny coverage of treatments that patients and their neurologists have decided upon based on rules that the insurance companies have established with little or no input from neurologists and people with MS. In addition, the seemingly arbitrary rules established by the insurance carriers for DMT approval go well beyond FDA-approved indications and labeling for the MS DMTs, restricting patient access unilaterally. Peer-to-peer reviews usually involve a discussion between a highly experienced neurologist and a non-neurologist with little or no experience treating MS who works for the health insurance company. Such reviews are not truly peer-to-peer and peers who are employees of insurance companies have an inherent conflict of interest.

PBMs often claim that they base their coverage policies on analysis of efficacy and safety data of the available treatments.[8] However, if this were the complete story, major differences in criteria for approval of MS DMTs among insurance companies should not occur. In our region, one private insurance carrier requires that IFN-β-1a IM, glatiramer acetate, and dimethyl fumarate are tried prior to approval of fingolimod, teriflunomide, or IFN-β-1b. A second private insurer requires that glatiramer acetate and IFN-β-1a IM or IFN-β-1a SC

Restrictions on access created by insurance companies often render shared decision-making between the patient and neurologist an exercise in futility.

be tried prior to approval of any of the oral DMTs. Differences also exist in the criteria for transitioning a patient from first tier therapies to natalizumab. These variances suggest that objective review of medical literature is not the primary basis for guiding decisions about which medications to cover preferentially. What drives this variance is the opaque proprietary financial arrangements made between PBMs and pharmaceutical companies for preferential pricing and rebates.

Do insurance companies interfere with shared decision-making about MS DMTs?

As discussed above, decisions about MS DMT for individual patients are complex and should involve formally or informally shared decision-making between patient and physician. Restrictions on access created by insurance companies often render shared decision-making between the patient and neurologist an exercise in futility. Insurance companies enter into this process by unilaterally deciding coverage and patient cost-sharing levels. There is no meaningful dialogue among insurance companies, patients, and their physicians. While PBMs may argue that they are not interfering with the decisions patients and their physicians make, refusal to cover expensive treatments and high cost-sharing for patients limits the treatment options available to most patients.[9]

The approach of insurance companies to MS DMTs stands in stark contrast to the approach of neurologists. Through shared decision-making, we seek to individualize treatment and engage patients in the decision. This approach recognizes the marked variability in disease activity among patients and respects the differences in their lifestyles, health care goals, and risk aversion. The policies of insurance companies controlling access to MS DMT are created without input from neurologists and people with MS, do not allow for the variability in disease activity among patients, and do not respect the autonomy of patients in making health care decisions. The policies of insurance companies regarding MS DMT clearly interfere with shared decision-making, a process considered necessary to ethical health care.

Can the practices of insurance companies regarding MS DMTs harm patients?

Neurologists encounter daily a myriad of obstacles to timely and appropriate treatment of their patients with MS. The first DMT chosen by the patient and the neurologist can be denied. Step-therapy programs are often illogical, sometimes requiring trials of several different interferons, all with similar tolerability and efficacy profiles, or a trial of a second injectable DMT in a person who cannot perform self-injections, before approving an oral drug. There are major obstacles to communication between the prescribing neurologist and decision-makers at the insurance company, with lack of response to appeal letters, cumbersome phone trees, and an unreasonable expectation of the time that a neurologist can spend contacting multiple insurance carriers for multiple patients. There are major obstacles to communication between the insurance carrier and the patient as well. DMT denial letters refer patients to lengthy policy documents that are not readily digested even by a well-informed patient. These administrative obstacles delay appropriate treatment of patients and create anxiety in people already concerned about their illness.

The delays in initiating appropriate treatment are not merely inconveniences but can harm patients. MS treatment is most effective when initiated early, and delays in MS treatment

approval and gaps in therapy while awaiting drug approval can result in recrudescence of MS disease activity.[6] Trying several ineffective therapies when the preferred therapy has been denied can result in poor MS disease control and permanent loss of function. Short-term and long-term toxicity of MS DMT can vary considerably depending on a patient's comorbidities, and a poor drug choice may result in permanent harm. Forcing patients to use a MS DMT with a side-effect profile unacceptable to them results in poor adherence to therapy, which can also lead to increased MS disease activity and disability. Studies have shown that many patients with MS would prefer an oral DMT to an injectable DMT,[4,10] and forcing patients to take an injectable medication before allowing an FDA-approved oral therapy is unjustified. The intrusion of insurance companies into the complex decision-making needed to select the proper MS DMT for a given patient and the resulting delays put patients at risk of harm from continued disease activity or side effects.

Possible solutions going forward

If insurance companies use flawed processes to determine coverage of MS DMT and their policies disrupt shared decision-making and harm patients, is there anything that neurologists can do?

First, neurologists need to deliver the same message to insurance companies. We need to acknowledge the legitimacy of the goal of insurance companies to control costs, but we also must insist that insurance companies engage neurologists and people with MS in establishing their policies. These policies cannot be rigidly applied to all patients and need to acknowledge the variability in disease severity and patient preference. In addition, decisions regarding MS DMT coverage need to be made in a timely and efficient manner to avoid harm to patients.

Second, neurologists, the American Academy of Neurology (AAN), the Consortium of Multiple Sclerosis Centers, the National Multiple Sclerosis Society (NMSS), the Multiple Sclerosis Coalition, and other patient advocacy groups need to lobby for state and federal government legislation to ensure fair access to MS DMT and require transparency regarding the financial arrangements between insurance and pharmaceutical companies. The AAN recently released the "Position Statement on the Availability of Disease Modifying Therapies (DMT) for Treatment of Relapsing Forms of Multiple Sclerosis," which supports making prescription drugs for MS accessible and affordable and urges policymakers to address escalating MS drug prices.[11] The NMSS recently announced a request for research proposals to investigate the relationship between MS DMT cost and policies of payers concerning coverage.[12] These are steps in the right direction. In addition, the interference of insurance companies with medical decision-making and the resulting limitations to medication access are not unique to MS drugs. MS advocacy groups should partner with other medical specialty groups to maintain access to life-altering drugs for all patients.

Finally, we need to advocate for lower costs for MS drugs. The root cause of the conflict between neurologists and insurance companies over approval of MS therapies is the high cost of the treatments, which have risen dramatically in recent years without good explanations.[7] We should model efforts by oncologists to address high drug costs.[13]

We have made tremendous advances in treating relapsing MS. Shared decision-making and the availability of a large number of DMTs allows us to select treatments that are effective and meet the individual goals of patients. This level of individualized and ethical treatment will only be possible if insurance companies alter their approach to setting policies on MS DMT coverage.

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Dr. Bourdette conceived of the manuscript, contributed concepts, and participated in writing the manuscript. Dr. Hartung contributed concepts and participated in writing the manuscript. Dr. Whitham contributed concepts and participated in writing the manuscript.

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D.N. Bourdette has served as a consultant for Teva Pharmaceuticals, Biogen, and Genentech; serves as Section Editor for *Current Neurology and Neuroscience Reports*, an Associate Editor for *Autoimmune Diseases*, and on the Editorial Board of *Neurology*®; has a use patent pending for the treatment of multiple sclerosis with cyclic peptide derivatives of cyclosporine and a patent pending for a thyromimetic drug for stimulating remyelination in multiple sclerosis; and receives research support from the Department of Veterans Affairs, the National MS Society, and Biogen. D.M. Hartung serves as a consultant for Providence Health Systems and receives research support from AHRQ and CDC/NIDA. R.H. Whitham serves on the Independent Data Monitoring Committee for a clinical trial sponsored by Chugai Pharmaceutical Co. Full disclosure form information provided by the authors is available with the **full text of this article at Neurology.org/cp**.

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