IOMSN Briefing:

Approaches to Treatment Access and Consistent Care in Patients With Multiple Sclerosis

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Abstract

In the management of relapsing forms of multiple sclerosis (MS), challenges to optimal outcomes extend beyond clinical and radiological milieu. Like other diseases, especially those that are heterogeneous, complex, and chronic with an autoimmune basis, the best outcomes may be associated with full access to a wide array of therapeutic options. Research has shown that there are clinical benefits for patients with relapsing forms of MS who are able to persist with their therapies. However, as the MS treatment landscape shifts, barriers such as insurance coverage may preclude full access to treatment options such as specific medications. Although this situation may be constantly shifting and challenging, there are strategies that prescribers, practice staff, and patients can use to facilitate overcoming these barriers.

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The need for multiple treatment options in multiple sclerosis

The complexity and heterogeneity of multiple sclerosis (MS) challenge the healthcare community to provide individualized and effective treatment. Evidence-based practice indicates that the selection of therapeutic interventions should be tailored to the dynamics of the disease and individual therapeutic responses.[1]

MS is a chronic debilitating disease of the central nervous system (CNS) characterized by extensive diversity in clinical attributes, genetics, pathogeny, and responsiveness to treatments.[2] This variation extends beyond the disease itself, as patients with MS are a heterogeneous population in terms of race/ethnicity, age, gender, geography, and comorbidities.[3]

No single pathway, reliable biomarker, diagnostic test, or specific treatment has yet been identified as effective for all patients with MS.[4]

Emerging evidence in MS involves disease-modifying therapies (DMTs) that are associated with a reduction in relapse rate and a delay in disease progression. This disease modification underscores the urgency of identifying and maintaining an effective treatment for individual patients with MS.[4-6]

> **“Routine formulary changes may yield immediate cost savings, but net costs may increase downstream due to disruptions in patient care. Insurance-driven medication changes have also been shown to negatively affect patient adherence to medical treatment and also disease outcomes.”[13,17,21]**
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> *—Mark N. Rood, MD, et al*

Response to approved MS therapeutic agents varies significantly across the MS population.[2] A systematic review comparing the effectiveness and safety of DMTs for MS was recently completed by the Drug Effectiveness Review Project (DERP), an independent collaboration of state Medicaid and public pharmacy programs. This MS-specific review included 10 head-to-head trials, 17 observational studies, and 4 systematic reviews that assessed efficacy and safety within the class. The review found that direct evidence from several head-to-head trials was conflicting on disease progression outcomes. Studies comparing DMTs yielded inconsistent results for risk and benefit.[7]

Shared decision making between the prescriber and patient that incorporates the consideration of a patient’s unique circumstances is of great importance to appropriate treatment selection.[8]

The potential consequences of restricting therapeutic options

In the treatment-access arena, prescription benefit restrictions implemented for the purpose of reducing costs may include step edits, prior authorizations, quantity limits, and increased cost sharing.[9] Comparative effectiveness research (CER) has emerged as a key tool for outlining the advantages and disadvantages of DMTs for MS.[10,11] CER can provide physicians with valuable information to assist them in selecting the most appropriate therapeutics for their patients with MS. For payers, data from CER can inform decisions regarding the level of coverage for MS therapies.[9]

Studies in other chronic therapeutic areas have revealed that restrictive formulary policies may in fact lead to increased hospitalizations and healthcare utilization that offset decreased pharmacy payments. These may include policies that classify drugs as nonpreferred, off-formulary, or other tiered programs, or that require prescribers to switch both new and existing patients to a preferred or on-formulary agent.[12,13] In addition, a multisite study of limited formularies demonstrated that suboptimal therapy or breakthrough disease may result in increased prescription costs and increased office, urgent care, and hospital utilization.[14]

The reasons that some patients with MS discontinue their therapy tend to be complex and multidimensional.[15] Dealing with the disease, its myriad treatments, financial planning and insurance coverage can be overwhelming.[5] Specialists in MS treatment recognize that promoting adherence to MS therapy should be recognized as a treatment goal in its own right.[16] Restrictions to benefits and formularies have been shown in a multitude of studies to be associated with lower drug adherence and/or poorer patient outcomes across many different chronic diseases.[17,18]

The association between treatment access and treatment continuity and adherence

When patients participate in their therapeutic treatment decisions, a correlation has been shown to exist with treatment adherence. Both treatment adherence and treatment persistence have been shown to lead to long-term cost savings for payers and patients.[19,20]

Poor adherence to long-term therapy across numerous chronic therapeutic areas compromises effectiveness, adversely impacting both patient quality of life and health economics. Numerous factors influence a patient’s ability to adhere to treatment, including social and economic factors, the healthcare team/system, characteristics of the disease and symptomology, disease therapies, insurance coverage disruption, and patient-related factors. Addressing the issues related to each of these factors is necessary if patients’ adherence to therapies is to be maintained or improved.[22]

> **“When making treatment decisions, it is important to look at the specific aspects of a particular patient’s disease activity. Then it is essential to monitor the patient to see how they respond to the treatment which is initiated. This allows us to make the best decisions about what may be the most appropriate therapy for that individual.”[27]**
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> ***—Bruce Cohen, MD, Northwestern University***
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> from Kelman M, ed. Benefits and risks of MS therapy, treatment optimization, and future directions: an expert interview with Bruce Cohen, MD. *Medscape Neurology & Neurosurgery.* 2006;8(2).

There is concern that higher patient out-of-pocket costs may affect patient compliance or utilization.[23] In a retrospective cohort study based on claims of members of BlueCross and BlueShield plans in the Midwest and South (2006-2008), among members with MS who were required to pay more than $200 per prescription, more than 1 in 4 experienced treatment disruption of MS therapies within 90 days.[18,24]

In patients with MS, a change in routine has been associated with increased anxiety and stress—which may be related with relapse triggers.[25] Research has indicated that treatment disruption in patients with MS can lead to an increase in symptoms and a greater frequency of relapses.[26]

The role of healthcare practitioners and patients in access support

Observational studies have shown that, although healthcare providers want to make prescribing choices based on therapeutic and evidence-based success, they can often feel restricted by treatment access and cost barriers.[17] Healthcare providers and their patients with MS can play an active role in helping increase access to therapeutic options in MS. They can share their concerns and needs with payers, employers, government decision makers, and national and international non-profit or for-profit organizations like the National MS Society and the MS Coalition. Clinical decisions fall within the purview of the healthcare provider. By communicating the need to maintain therapeutic options, patients and healthcare providers can contribute to building an environment in which financial implications do not impede them from making the most appropriate therapeutic choices.

Communicating the Need for Broad Formulary Access

The following customizable templates offer a straightforward way to communicate concerns about prescription coverage and formulary restrictions to employers, health plans, pharmacy benefit managers, and government representatives.

Visit IOMSN.org/dmtaccess to download these resources

HCP Office	Health Plan or Pharmacy Benefit Manager	**HCP Practice Staff to Health Plan/PBM** Healthcare providers can adapt these templates to request that a patient maintain or receive new coverage for a specific prescription medication based on the patient’s clinical profile.
Patient	Health Plan	**Patient to Health Plan** Patients can personalize these letters to request that their new or current prescription receive coverage by their health plan.
HCP	Employer	**HCP to Employer** Healthcare providers may wish to write directly to their patient’s employer (or the employer of their patient’s beneficiaries) to communicate the importance of ensuring that specific medications are covered by current and future health plans.
Patient	Government Representative	**Patient to Government Representative** Patients can use this template to express the importance of broad prescription coverage at national and regional health plans and legislation that encourages broad formulary choices.

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