Management of Multiple Sclerosis: Building Consensus between Healthcare Providers and Payers

By John A. Welz, MPH

Proceedings of the MS Roundtable Held on July 13, 2012, in Washington, DC

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Multiple Sclerosis Disease State Review

Treating Multiple Sclerosis: The Healthcare Provider Perspective

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Management of Multiple Sclerosis: Building Consensus between Healthcare Providers and Payers

By John A. Welz, MPH

Overview

Healthcare provider (HCP) and payer viewpoints can be very different regarding the treatment and management of patients with chronic conditions. The HCP’s principal responsibility is to the individual, ensuring that every patient under his or her care receives the appropriate treatment necessary to optimize their patients’ health and quality of life. Although the well-being of individual patients remains the major focus, in recent years, HCPs have been forced to view healthcare delivery in a broader context, one that includes the financing side of the equation. The skyrocketing cost of healthcare in the United States is responsible for this change, and the burden is being felt by all stakeholders—patients, government, HCPs, payers, and employers. Payers, both private and government, are charged with managing healthcare utilization in the broader context, and, as a result, their perspective is increasingly guided by the value of healthcare services (ie, the value of services relative to cost). As healthcare costs continue to rise, so does the level of scrutiny placed on determining the value of services, be it a medical procedure, a prescription medication, a health management program, or any other healthcare service.

As in many chronic conditions, the cost of treating multiple sclerosis (MS) has escalated in recent years. This increase has been driven primarily by the cost of medications used to treat the condition. As a result, payers have begun to manage utilization in the category, and patients are being asked to shoulder a larger share of the treatment costs. In some cases, payer utilization management efforts have created friction between payers and HCPs.

The MS roundtable was convened to bring together a diverse group of stakeholders who either have treated patients with MS (ie, HCPs) or who were responsible for the reimbursement of treatment costs (ie, payers). Using an interactive approach to stimulate exchange of ideas between payers and HCPs, the roundtable sought to foster a better understanding of each group’s perspectives, roles, and responsibilities in the treatment or management of MS, seeking to find common ground within the broader value-driven paradigm that defines healthcare in the United States today.

Not surprising, program prework revealed that HCPs and payers had substantially different perspectives regarding the treatment and management of MS. For example, HCPs and payers differed in their perceptions of patient medication adherence (as measured by medication possession ratio [MPR]), with HCPs estimating that a greater percentage of patients were adherent to therapy. Payers possess the claims data allowing them to calculate MPR for defined populations and therefore quantitatively examine patient adherence.

Both payers and HCPs agreed that walking impairment was the most debilitating symptom associated with MS, and its impact was, in many cases, very substantial.

The roundtable program began with an overview of the MS disease state, including an interactive discussion with a review of MS subtypes, pathophysiology, disease course management, and symptom management. Subsequently, using a case-based format, the group was asked to focus on one area of symptom management—walking—and to discuss the impact of walking impairment, determine the need to treat, review the patient benefits of treatment, and work together to achieve consensus on an optimal approach to treatment and management from a value-based perspective.

Reference

Multiple Sclerosis Disease State Review

Multiple sclerosis (MS) is a progressive neuroimmunologic disease of the central nervous system, characterized by multiple areas of demyelination, myelin damage and scarring, loss of oligodendrocytes, and axonal and neuronal injury to the white matter of the brain and spinal cord. MS is a leading cause of medical neurologic disability in younger people affecting individuals in the prime of their lives, with age of diagnosis between 20 and 50 years of age. MS is at least two to three times more common in women than in men.

In the majority of patients, MS is characterized by periodic episodes of neurologic dysfunction called “exacerbations” or “relapses.” Exacerbations are highly variable in their duration, frequency, and severity. As a result, the clinical course of MS varies over time and disease prognosis is unpredictable.

There are four clinically distinct subtypes of MS:

• Relapsing-remitting MS (RRMS)
• Secondary progressive MS (SPMS)
• Primary progressive MS (PPMS)
• Progressive-relapsing MS (PRMS).

Each type is characterized by different patterns of symptom progression over time, as shown in Figure 1.

Approximately 85% of patients with MS are initially diagnosed with RRMS, which is characterized by clearly defined acute exacerbations with full recovery or partial residual deficit. In RRMS, the periods between exacerbations are characterized by lack of disease progression.

The clinical course of SPMS is always preceded by RRMS disease. After the initial relapsing-remitting course, the disease progresses at a variable rate that may include occasional exacerbations and plateaus. Of the 85% of patients who begin with RRMS, approximately 50% will convert to SPMS within 10 years of disease onset, and 8% of untreated relapsing patients develop secondary progressive disease within 20 to 25 years.

Of patients with MS, 10% are diagnosed with PPMS, which is characterized by the progression of disability from onset with no acute attacks or with occasional plateaus, remissions, or minor improvements. In PPMS, which affects approximately 5% of patients diagnosed with MS, there is progression from onset but with clear acute relapses either with or without recovery, with periods between relapses showing continued progression.

Treat ing Multiple Sclerosis

The treatment of MS involves a combination of pharmacologic and nonpharmacologic strategies.

Lifestyle choices can also serve to alleviate the effects of some of the symptoms of MS. Proper nutrition, exercise, and stress management are all important to maintaining wellness, even in the presence of a chronic illness such as MS.

Rehabilitation, which includes physical and occupational therapies, can contribute to improved mobility, activities of daily living, quality of life (QOL), and patient safety and independence for a broad range of impairments in MS. The National Multiple Sclerosis Society considers rehabilitation to be a necessary component of comprehensive, quality healthcare for people with MS, at all stages of the disease. Rehabilitative specialists work with patients to develop a carefully planned program of exercise, functional training, and activities designed to promote good health, general conditioning, and to reduce fatigue.

MS pharmacotherapy typically involves a multi-pronged approach. Whenever possible, clinicians seek to manage the course of RRMS and slow its progression through the use of disease-modifying therapies (DMTs). With the exception of fingolimod and mitoxantrone, DMTs are not indicated to treat other subtypes of MS. In addition, glucocorticosteroids are prescribed to mitigate the effects of acute exacerbations. Finally, several therapies are available to treat the symptoms of MS, which include bladder disturbance, fatigue, depression, pain, and gait disturbance, to name a few. Treating the symptoms of MS can have a positive effect on the patient’s QOL.

Although considerable medical advances have been made in the treatment of MS, there are currently no therapies available that are capable of repairing the central nervous system or restoring lost neurologic function.

Although considerable medical advances have been made in the treatment of MS, there are currently no therapies available that are capable of repairing the central nervous system or restoring lost neurologic function. However, DMTs can alter disease progression by reducing the number of relapses. DMTs for MS, beginning with the introduction of interferon beta-1b in 1993, fundamentally changed the treatment approach for MS. Since then, a number of additional disease-modifying agents have become available, and as of 2011, seven therapies were on the market. In 2010, the first oral
DMT for MS became available. For maximum long-term effectiveness, DMT therapy should be started as early as possible in the course of the disease.

Long-term adherence to DMT presents a significant challenge for patients with MS. Approximately 60% to 76% of patients with MS adhere to DMT for two to five years. However, approximately 50% of patients who discontinue DMT tend to do so within the first two years of initiating treatment.

High-dose methylprednisolone is the most frequently prescribed medication for the short-term management of acute exacerbations, and is effective in reducing inflammation in the central nervous system, and accelerating recovery from relapses. Methylprednisolone can be administered orally or intravenously. Because there is no clear benefit based on route of administration, many healthcare providers prescribe the oral formulation, which allows patients to be treated at home. Although high-dose steroids are effective in treating acute exacerbations, they have not demonstrated any improvement in long-term outcomes.

**Symptom Management**

Although DMTs have demonstrated efficacy in preventing relapses and in delaying disease progression in RRMS, and may delay the accumulation of physical disability, they are not indicated to treat disease-specific symptoms. In fact, some patients report that they feel worse when receiving immunomodulatory therapies. The symptoms of MS can be debilitating and can adversely affect the patient’s ability to maintain functionality and QOL. Therefore, treatment of symptoms...
is considered to be an important component of the overall management of patients with MS.14

For patients with MS, symptoms can occur at any time. Patients may experience problems with speech, cognition, sleep, and bowel and bladder function. Up to 90% of patients with MS report fatigue.15 In addition, the majority of patients with MS experience muscle weakness in their extremities and difficulty with coordination and balance. Most people with MS exhibit transitory abnormal sensory feelings, such as numbness, prickling, or “pins and needles” sensations. Additional symptoms may include pain, spasticity, dizziness or vertigo, heat sensitivity, and vision impairment.16-19 Left untreated, individual symptoms may worsen and precipitate other symptoms, thus producing a cycle of interrelated symptoms. For example, fatigue and depression can lead to decreased exercise which, in turn, can lead to increased spasticity and constipation. Bladder dysfunction can lead to a decrease in sleep time, which can affect cognitive function and can aggravate fatigue and depression.20

The symptoms of MS are described and assessed from the patient’s perspective, and symptom evaluation is largely dependent on patient self-report and clinician/patient interaction, which are difficult to quantify. Efficacy of symptomatic management strategies are often evaluated by patient self-report and not necessarily directly measurable using objective criteria.14

Many pharmacologic agents are available to treat the symptoms of MS. Medication selection is typically determined by the specific symptom or symptoms reported by the patient. Symptom management agents include, but are not limited to, baclofen for spasticity, oxybutynin and tolterodine for bladder dysfunction, amantadine and modafinil for fatigue, gabapentin and carbamazepine for neuralgia, and dalfampridine for walking impairment.8,21

**Walking Impairment: A Common and Debilitating Symptom of MS**

In a survey conducted by Heesen and colleagues (2008), walking was ranked as the most important function by the greatest proportion of patients with MS, regardless of disability type, severity, or disease duration (Figure 2).22 Patients were asked to rate 13 selected bodily functions in order of personal importance, including cognition, mood, vision, speech and communication, swallowing, upper-limb function, lower-limb function, bladder control, bowel control, sexuality, fatigue, sensory symptoms, and “other disabilities.” The survey population included patients with both short- and long-term disease duration, with 82 patients having MS for less than

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**Figure 2: Multiple Sclerosis Patient Function Rankings**

<table>
<thead>
<tr>
<th>Function</th>
<th>Percentage first rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walking</td>
<td>40</td>
</tr>
<tr>
<td>Visual function</td>
<td>35</td>
</tr>
<tr>
<td>Thinking and memory</td>
<td>30</td>
</tr>
<tr>
<td>Lack of pain</td>
<td>25</td>
</tr>
<tr>
<td>Power coordination of hands</td>
<td>20</td>
</tr>
<tr>
<td>Bladder control</td>
<td>15</td>
</tr>
<tr>
<td>Speech</td>
<td>10</td>
</tr>
<tr>
<td>Swallowing</td>
<td>5</td>
</tr>
<tr>
<td>Sexuality</td>
<td>5</td>
</tr>
<tr>
<td>Normal skin sensations</td>
<td>5</td>
</tr>
<tr>
<td>Mood</td>
<td>5</td>
</tr>
<tr>
<td>Bowel control</td>
<td>5</td>
</tr>
<tr>
<td>Awakeness and alertness</td>
<td>5</td>
</tr>
</tbody>
</table>

MS indicates multiple sclerosis.
Source: Reference 22.
Walking impairment can manifest early in the disease course of MS, and can have significant effects on patients, their families, employers, and the healthcare system.

Measurement of Walking Impairment

A number of different tools are used to measure walking impairment in patients with MS, including the timed 25-foot walk (T25FW), the 6-minute walk, and the 12-item MS Walking Scale (MSWS-12). Although all of these metrics have some utility in measuring walking impairment, they each have limitations.

The T25FW, which is often used in clinical practice, correlates independently with the Expanded Disability Status Scale (EDSS) across disability and MS type. However, because of a floor effect, it is less sensitive for detecting differences in mildly disabled patients. In addition, MS roundtable participants indicated that it may not be feasible for all practices to implement the T25FW because of space limitations.

The 6-minute walk correlates well with other measures of disability and is a better measure of walking endurance than the T25FW. However, to implement the 6-minute walk, a walkway of sufficient length is needed. In addition, because it is difficult for patients with moderate-to-severe disability to walk for six minutes, it is not appropriate for all patient populations with MS.

The MSWS-12, a patient-reported outcome measure, is more responsive than other walking-based measures, including the EDSS and the T25FW, and is used in clinical trials and clinical practice. However, as a self-reported measure, it may be perceived to be more subjective compared with observer-reported measures.

Ensuing discussions will focus on the utility of these measures, both in clinical practice and as utilization management criteria for payers.

Walking Impairment: Impact on Patients

Walking impairment can manifest early in the disease course of MS, and can have significant effects on patients, their families, employers, and the healthcare system.

A Harris Interactive survey of 1246 respondents with MS found that walking impairment occurs early in the onset of MS symptoms. Approximately two of three people with MS (65%) reported experiencing some type of trouble walking, inability to walk, and/or difficulty maintaining balance at least twice weekly. Among people with MS who have trouble walking, 70% found it to be the most challenging aspect of their MS. Of patients reporting some degree of walking impairment, 92% indicated that it had some impact on their ability to carry out daily tasks. In this survey, patients that experienced walking difficulty reported that it led to decreased self-esteem, decreased ability to travel, and adverse effects on their work life.

The Patient-Determined Disease Steps (PDSS) is a validated 9-point measure that is a patient self-report instrument comparable with the EDSS. In a cross-sectional research study conducted among US MediGuard.org members aged ≥18 years, in the population of MS patients with PDSS 3 and PDSS 4, walking impairment led to significantly more falls, despite the use of a walking device (P < .01). Reported visits to the hospital or emergency department and office visits for severe falls increased significantly, along with higher levels of walking impairment, especially for those using a walking device (P < .01).

Walking Impairment: Impact on Employers

Walking difficulty also negatively impacts work life for employed patients with MS. In a data analysis of the Harris Interactive survey assessing the negative impact on the lives of people with MS who experienced trouble walking, inability to walk, and/or difficulty maintaining balance at least twice weekly, 79% indicated that their work had been negatively affected by MS.

Even mild walking impairment can adversely affect employment status. An analysis of North American Research Committee on Multiple Sclerosis (NARCOMS) registry data from 8180 patients with MS,...
showed a significant association between unemployment and mild gait disability (P < .0001). The greatest loss of income occurs as patients transition from normal mobility to minimal walking impairment.

In another study estimating the probabilities of employment status transitions among persons with MS, worsening disability, as measured by PDDS or mobility score, increased the probability of transitioning to not working compared to those with improving or stable disability. Specifically, researchers assessed the probability of transition from working full-time or part-time to not working, stratified by a 1-year change in MS severity. For patients with worsening disability, the most frequent transition was from working part-time to not working.

For most patients, walking impairment occurs early in the onset of MS symptoms, and timely intervention gives patients the best opportunity to maintain optimal ambulation for as long as possible, given the progressive nature of MS. Conversely, lack of intervention may contribute to diminished QOL, reduced ability to work, and increased healthcare utilization.

### The Future of MS Treatment

A number of additional oral and injectable agents are currently being investigated for the treatment of MS, and patients and providers alike are hopeful that 1 or more of these new therapies will represent a major clinical advance in modifying the course of the disease. The future treatment landscape of MS is expected to involve more tailored therapies, perhaps including combination therapies, as clinicians have more agents available to treat both the disease and its symptoms. Although this evolution will give rise to new treatment options for clinicians, it also will result in more coverage and management issues for the health plan and the pharmacist.

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Treating Multiple Sclerosis: The Healthcare Provider Perspective

The treatment of multiple sclerosis (MS) involves pharmacotherapy to treat disease progression, symptoms, and acute exacerbations. Patients may also engage in a number of nonpharmacologic interventions, such as physical and occupational therapy.

Optimally, patients with MS are treated using an interdisciplinary approach, which may involve a number of different healthcare providers (HCPs) in patient care. Generally the neurologist leads the treatment team, and may refer services to physical therapists, psychiatrists, occupational therapists, and other allied health professionals on a patient-specific basis. In addition, some neurology practices employ nurse practitioners and physician assistants to assist with patient care. Other health system professionals, such as pharmacists and case managers, may also become involved in patient care. Because of the psychosocial aspect of MS, and the fact that many patients suffer from concomitant depression, mental health professionals may be members of the treatment team. Finally, there are a number of advocacy and support organizations that provide valuable resources to patients seeking to empower themselves in managing their illness.

Although all of these stakeholders are committed to providing the best possible patient care, their professional orientation, training, and philosophies toward treatment may differ. For example, neurologists focus on reducing relapses and limiting disease progression, whereas mid-level providers are more aware of patient symptoms and psychosocial issues. Rehabilitative specialists focus on nonpharmacologic approaches to treatment. Misaligned perspectives and lack of coordination may lead to missed opportunities to optimize care, as expressed by the following two panelists of the MS roundtable:

• Physical therapist: “In general, I have to say that neurologists are very slow to refer the patients to physical therapy in general. We see more referrals from the MS society and other providers than neurologists. But usually, if there's a significant decline in function through the relapse and so on, then we may see a physical therapy referral.”

• Nurse practitioner: “While the world has changed in terms of relapse management and disease modification, symptom management has always been a mainstay, and I don’t think we should lose sight of that. I think that one of the big problems that we have today is that there’s such a focus on those expensive disease-modifying therapies that many patients are falling by the wayside in terms of those important symptoms, such as walking, bowel, bladder, fatigue, cognition, using drugs that we know have worked.”

HCPs at the MS roundtable noted that there is substantial variability in the services available to patients with MS, depending on geography and the practice-specific level of care integration. As a result, smaller, community-based neurology practices, particularly those in rural areas, may not have the same access to the range of multidisciplinary clinicians and support services as larger, multiprovider, urban-based practices.

The clinical course of MS can be highly variable and involves management of disease progression as well as symptoms. As a result, the treatment of MS is complex. Because of this complexity, many neurologists consider the treatment of MS in general, and symptom management in particular, to be an art as well as a science. Neurologists and other members of the treatment team frequently rely on patient self-report and clinician/patient interaction to inform treatment decisions. Because of the interpatient and intrapatient variability in disease course and treatment response, regimens are often tailored to the needs of the individual patient. In other words, MS does not lend itself to a one-size-fits-all treatment approach.

In addition to the variability in the treatment of MS, the neurology community is fragmented. By and large, state neurology societies conduct their activities independent of the American Academy of Neurology. There are few consensus guidelines regarding disease-modifying therapies, and even fewer regarding symptom management. Furthermore, there is a lack of objective, universally accepted metrics available to measure functional status for some symptoms.

Because of the complexity of the treatment of MS and the inherent unpredictability of the disease, coupled with the special nature of the clinician/patient relationship, the course of treatment may vary over time, and successful treatment of MS can be difficult to quantify.

“While the world has changed in terms of relapse management and disease modification, symptom management has always been a mainstay, and I don’t think we should lose sight of that.”
As a nurse practitioner at the roundtable stated, “Nothing exists by itself in MS—it’s a very complicated disease—and it becomes a very costly disease for the caregiver. The time required is extraordinary, if you really want to do a good job.”

Payers are reacting to the increasing cost of the MS category, and as a result, neurologists and other treatment team clinicians are being forced to consider treatment in a broader context. HCPs are increasingly being impacted by business considerations in healthcare, primarily in the form of utilization management strategies implemented by third-party insurers. Because of their patient-centered focus, HCPs have difficulty understanding what value means to payers. A neurologist at the roundtable commented, “I know what patient value is. I think [HCPs] can all figure out what patient value means to us. I still don’t know what value is to [payers].”

Prior authorization (PA) is the most frequently used utilization management tool in treating MS. In the PA process, HCPs are asked to provide clinical justification before the insurer agrees to pay the cost of a prescription drug or a medical procedure.

Although most HCPs acknowledge the rising cost of healthcare and understand the rationale for PA implementation, they contend that the process is cumbersome and sometimes interferes with patient care. The HCPs represented on the roundtable panel expressed their desire for consistent, streamlined PAs, without superfluous or irrelevant questions, that adequately take into account their professional judgment and experience. HCPs may have a few or many payers whose PA requirements are different, which creates an additional challenge. Perhaps above all, HCPs seek to understand payer expectations so they can respond to utilization management requests in an appropriate, timely manner. Payer expectations may pose a particular challenge for smaller, community-based practices that may not have the resources or the infrastructure to keep abreast of changing requirements by multiple health plans. In the words of a neurologist on the panel, discussing the PA for an agent to treat walking impairment, “It would be useful if the PA criteria were completely transparent. On the initial PA [forms] that we receive, it doesn’t specify that we need to reassess patients after X months. That information needs to be on the form. And if we have any questions, we need open lines of communication with payers.”

Because of the complexity of the treatment of MS and the inherent unpredictability of the disease, coupled with the special nature of the clinician/patient relationship, the course of treatment may vary over time, and successful treatment of MS can be difficult to quantify.

In the end, HCPs state that their primary responsibility is to the patient. In that sense, they have a concrete goal, whereas payers represent broader societal and fiscal concerns. These concerns are more difficult to elucidate and describe, and are often driven by health policy at the state and federal levels.

By and large, the neurology professionals represented on the panel recognized the need to rein in healthcare spending, noting that the costs are increasingly being passed on to patients, not all of whom have the ability to pay, even if they are insured. In this regard, they are open to compromise with the payer community. Although there may be disagreement on the best way to support appropriate utilization of healthcare services, HCPs acknowledge that there must be systems in place to mitigate the burden of increasing healthcare costs on the patient in particular and on society in general.
Management of the Multiple Sclerosis Category: An Increasing Focus for Payers

As drug costs continue to outpace overall health-care spending, private health insurers are seeking innovative ways to manage pharmacy utilization. In keeping with this trend, pharmacy management of specialty categories such as multiple sclerosis (MS) has begun to change in recent years.

When evaluating a therapeutic category from an economic perspective, payers evaluate overall spending trends, then drill down to identify specific cost drivers. Unlike many other disease states, the cost of prescription medications is responsible for the majority of healthcare spending in the MS category.1 As a result, there are limited opportunities for medical cost offset compared with other chronic conditions, such as cardiovascular disease and diabetes, where complications frequently result in hospitalization. A medical director at the roundtable stated, “I think [MS] is on everyone’s radar screen because of cost. In addition to disease-modifying therapies, symptom management agents are also being looked at, because they add to the cost.”

In the past, most drugs to treat MS were managed under the medical benefit. However, now most private payers manage drugs for MS via specialty pharmacy providers (SPPs). Some plans operate their own SPPs, whereas others carve out specialty pharmacy to independent SPPs.

In the MS category, PA is the utilization management tool of choice for most payers. Payers acknowledge that their PA criteria are developed in response to the standards identified and agreed on by the broader medical community.

As a result of an explosion in the cost of drugs to treat certain conditions, specialty drug spending is expected to continue rising more rapidly than the cost of traditional drugs.1 In the MS category, this increase is primarily a result of two factors. In 2010, the first oral disease-modifying drug, fingolimod, was introduced to the marketplace with premium pricing. In response, manufacturers of many existing injectable drugs took large price increases. These price increases among the disease-modifying therapies, along with the introduction of branded symptom management agents, resulted in a substantial increase in per-member per-month spending for MS by private payers.1

In response, some payers are changing the way they are managing drugs covered under the medical benefit, by implementing prior authorization (PA) and other utilization management approaches traditionally associated with pharmacy. Other payers have moved agents for the treatment of MS (including orals) to specialty pharmacy distribution, allowing far more control over tracking and utilization management.

In the MS category, PA is the utilization management tool of choice for most payers. To develop PA criteria, clinical staff prepare and review drug monographs, which are compilations of relevant clinical and product information needed to support payer decision-making. Clinical subcommittees typically provide these monographs along with their recommendations to the Pharmacy & Therapeutics committee. Payers may consult with network neurologists to review PA criteria, but neurologists are usually not involved in the criteria development process. Rather, they are asked to review the criteria to ensure that they are reasonable and that they meet acceptable medical standards. Based on information provided by subcommittee members, the payer determines the coverage criteria for a given drug or therapeutic category.

Payers contend that utilization management measures are implemented to ensure appropriate utilization and not to arbitrarily penalize prescribers. Payers typically do not base coverage decisions on medical opinion; rather, they use empirical data as the basis for the development of objective, evidence-based criteria. Independent, peer-reviewed information is the preferred source. At the roundtable, a medical director stated, “In order to determine whether a drug works or doesn’t work, there should be some evidence-based measure, not some subjective evaluation to try and determine whether it works or not.”

The development of PA criteria for certain drugs for the treatment of MS has posed a considerable challenge to payers, and walking impairment provides a good representative example. Payers contend that the lack of universally acceptable clinical practice guidelines to measure walking impairment has hindered their ability to develop consistent PA criteria acceptable to the neurology community. In the absence of consensus, payers are forced to use product labeling for their PA criteria. However, product labeling is normally based on clinical trial data, and the measurement criteria used in clinical trials often differs from the criteria used in clinical prac-
tice. For example, in walking impairment, payers typically use the T25FW in their PA criteria, although payers and providers agree that it has significant limitations. Because of a floor effect, the T25FW is less sensitive for detecting differences in mildly disabled patients. Also, many community neurology offices do not have a walkway of sufficient length to conduct a T25FW. However, in the absence of a universally accepted, practical surrogate measure for walking, most payers default to the T25FW because of its use in the clinical trial setting. As a pharmacy director at the roundtable noted, “We don’t have a good surrogate, so we go back to the product label. In the clinical trials, the 25-foot time walk was used. It’s far from perfect, but it’s the best surrogate we have. Therefore, we accept the 25-foot timed walk along with physician attestation.”

Payers acknowledge that their PA criteria are developed in response to the standards identified and agreed on by the broader medical community. Therefore, they would consider revising their utilization management criteria if the neurology community agreed on consensus guidelines that were appropriately vetted. A medical director at the roundtable pointed out, “We don’t have anyone in the community to come to us and say, ‘You should be changing it to this.’ If there’s another methodology around to assess the patient for performance and evaluation, we will consider it. If [the neurology community] agrees on it, then we’ll consider adopting it.”

Therein lies the payers’ willingness to compromise—utilization management criteria are perceived as fluid and can be adapted to suit medical and community standards. However, in alignment with long-term federal policy initiatives supporting an evidence-based (and more recently, value-based) approach to developing medical standards, payers stand firm on the need for objective, measurable criteria that can be applied to everyone.

References

Achieving Consensus between Healthcare Providers and Payers

Through a structured, interactive approach designed to facilitate collaborative discussion, the MS roundtable sought to identify areas of common ground between healthcare providers (HCPs) and payers in making clinically appropriate, value-based patient management decisions. HCPs and payers represented on the panel discussed their responsibilities, goals, and challenges in an open forum that encouraged the candid exchange of ideas.

At the onset of the program, each group identified their respective positions, acknowledging that their perspectives toward patient care and management were very different. HCPs focus on providing the best possible care to their individual patients. In this regard, they want payers to trust their professional judgment about clinical decisions, rather than impose restrictions that sometimes appear to be arbitrary and subjective. On the other hand, because they represent insured populations, payers take a value-based, fiscally sensitive approach to managing coverage decisions.

As the exchange of ideas continued, the two groups began moving closer to consensus. HCPs acknowledged that healthcare financing was a critical societal issue, noting that their patients frequently struggle with the burden of escalating healthcare costs. HCPs also recognized that they had a responsibility to be mindful of the cost of care, not only to the patient, but also to the insurer. As an example, they cited the prudent use of discontinuing a therapy in the absence of clear patient benefit from both a safety and cost perspective. A neurologist at the roundtable commented, “We don’t want patients to continue to use [MS agents] indefinitely without clear benefit, just because there’s nothing else, and because it’s on the market and available….We don’t want to contribute to an unending cycle of unnecessary spend.”

Likewise, payers began to appreciate the HCP perspective, conceding that no one was more qualified to make clinical decisions than the direct providers of healthcare. Payers also acknowledged the importance of the subjective component of patient care, agreeing that the clinician’s expertise and judgment were critical.
However, this subjective element is difficult to quantify, and therefore limits payers’ abilities to measure the quality of patient care. This is especially true in MS, because of the lack of consensus clinical guidelines and the fragmentation of the neurology community. As a pharmacy director at the roundtable explained, “It comes down to the well-selected patient. We’re just trying to make sure that we don’t waste money, as opposed to saving money but not covering something. Usually, the input of the physician is very important in making that decision.”

In the end, HCPs and payers were able to find sufficient common ground to work together on several real-world, case-based patient-management scenarios. In this consensus-building exercise, where patient benefit was not always clear cut, payers relied on the judgment of HCPs to help guide their management decisions. HCPs readily accepted the responsibility, appreciated the reliance on their professional judgment, and, acknowledging the cost issue, indicated their willingness to discontinue therapy in the absence of patient benefit. As a result of these discussions, HCPs and payers were able to achieve consensus regarding treatment decisions and subsequent management of the patient.

In our opinion, this interactive approach provided a constructive forum for stakeholders with differing points of view to candidly share their positions, ideas, and potential solutions. Through their interaction, each group achieved an enhanced understanding of the other group’s perspectives, and a better appreciation of their role in the care and management of patients with MS. It may be valuable to apply the concept at the regional level, bringing together community HCPs and payers to discuss the issues and challenges that may be specific to their respective geographical areas.

The author of this publication believes that this interactive consensus-building approach, which was tested on a micro scale, demonstrated proof of concept for the MS disease state, is potentially transferable to other disease states, and serves as an effective model to initiate multi-stakeholder interaction.