A Payer Point of View on the Changing Multiple Sclerosis Treatment Spectrum, With Kenneth Snow, MD

KENNETH SNOW, MD
Medical Director
Aetna

***AJMC®*: What clinical endpoints are most influential when determining access for multiple sclerosis (MS) treatments?**
SNOW: Plans are really looking for "hard clinical outcomes" and outcomes that can be measured. Examples include annualized relapse rates, number of exacerbations, evidence of disease progression, and loss of function.

***AJMC®*: Over the past few years, there have been a few studies demonstrating the link between brain atrophy and disability progression in patients with MS. Can you discuss the importance of brain atrophy as a clinical measure in MS and how it may evolve in the next couple of years?**
SNOW: Brain atrophy is certainly an interesting potential marker; however, it is way too early to base coverage decisions on brain atrophy data. At this point, brain atrophy data have not reached the level to be a primary decision determinant. For brain atrophy data to be used in clinical practice settings, better tools need to be available for clinicians to measure them. Currently, no standard has been established with regards to assessing/monitoring brain atrophy.

***AJMC®*: How do lack of consensus guidelines affect coverage considerations? Would consensus guidelines be helpful or a hindrance in policy development?**
SNOW: Well-researched and -referenced evidence-based consensus guidelines would certainly be useful for managed care professionals when making formulary decisions. On the contrary, guidelines based only on expert opinion would not be useful in policy development.

***AJMC®*: How would you define treatment failure, and what criteria must be met for a patient to be allowed to switch disease-modifying therapies (DMTs)?**
SNOW: Treatment failures are determined by pre-established criteria versus by physician attestation. Criteria for determining treatment failure includes 1 of the following: (1) two or more exacerbations within 1 year; (2) one severe exacerbation with incomplete recovery in a year; (3) increased number or size of lesion(s) on magnetic resonance imaging (MRI) scans; and 4) worsening of disability.

***AJMC®*: Are patients with aggressive disease at baseline allowed to be started on an oral agent or 1 of the newer injectable products or are they required to begin therapy with 1 of the first-generation injectable products?**
SNOW: When patients are diagnosed with MS, we do not differentiate initial therapy based on initial presentation (such as Expanded Disability Status Score [EDSS], number of lesions, and symptomatology) or prognostic factors (including age at diagnosis, ethnicity, and race). All patients are required to initiate therapy with 1 of the first-generation injectable products. The rationale for this decision is that there is no proof that the oral agents or newer injectable products produce better outcomes compared with the first-generation injectable products.

***AJMC®*: How have plans managed first-dose monitoring with fingolimod?**
SNOW: Plans generally cover all approved monitoring (including first-dose monitoring requirements) and testing required for fingolimod. We rely on the prescribing physician to provide "any and all appropriate care and oversight that they deem necessary" for patients receiving fingolimod.

***AJMC®*: When making formulary decisions, do you consider neuroprotective properties of products?**
SNOW: When evaluating products for formulary inclusion, we consider all aspects of the product, including evidence related to neuroprotection. The positive and negative aspects of products help us to determine coverage and/or preferred status. As mentioned previously, we do not consider just 1 aspect, but all are considered together when making formulary decisions.

***AJMC®*: What is the role of quality of life (QoL) and patient-reported outcome (PRO) data when making coverage decisions, both in general and specifically related to MS?**
SNOW: Generally speaking for all disease states, QoL and PRO data are considered "somewhat" useful, because their usefulness is limited. In the MS space, more weight is placed on QoL and PRO data because these data do overlap with level of disability. There are limitations to QoL and PRO data. First, there is no universal scale that defines QoL and PRO data in terms of "good" and "bad." Second, it is very difficult to compare QoL and PRO data between patients.

***AJMC®*: Data suggest that enforcing formulary restrictions and utilization management criteria in the MS space has been difficult for payers. Can you explain why this is possibly the case and whether this can or will change in the future?**
SNOW: I agree that enforcing formulary restrictions and utilization management criteria in the MS space has been very difficult for payers. There are several reasons for this issue, including:

1. Lack of evidence-based, well-researched, and well-referenced consensus guidelines.
2. Lack of accepted clinical practice by physicians (physician preferences versus guideline-based decisions).
3. Different routes of administration of the currently available DMTs (for example, subcutaneous injection, intramuscular injection, intravenous infusions, and oral administration).
4. Efficacy must be assessed over the long term, because responses are not observed in short term; likewise, it also takes time for treatment failures to be observed.
5. Treatment failures can have long-term and irreversible complications.

These issues can be responsible for contested decisions, which managed care tries to avoid. Again, evidence-based, well-researched, and well-referenced consensus guidelines could benefit plans when enforcing formulary restrictions and utilization management criteria in the MS space.

***AJMC®*: What are the unmet needs in MS?**
SNOW: Current unmet needs are as follows:

1. None of the currently approved products cures MS. They only decrease relapse and progression. Products with improved efficacy are needed in this space.
2. Products with improved safety profiles are also needed, especially products not associated with catastrophic adverse events such as progressive multifocal leukoencephalopathy and secondary cancers.
3. Better knowledge of products in this space. The relative efficacy of the products is not fully understood, because few head-to-head trials exist. Again, evidence-based, well-researched, and well-referenced consensus guidelines would certainly be useful in helping managed care professionals understand the relative safety/efficacy of products in this space.