To the Editor:

I read with interest the recent article in JMCP by Miller et al., “Approaches to the Management of Agents Used for the Treatment of Multiple Sclerosis: Consensus Statements from a Panel of U.S. Managed Care Pharmacists and Physicians.” As an experienced neurologist and multiple sclerosis (MS) specialist, I believe that consensus commentary can be very relevant in these increasingly complex times in MS therapeutics, especially in view of very limited evidence-based treatment guidelines. Whereas I feel that most of the consensus comments (Table 3) are in keeping with modern MS practices, I have a concern pertaining to consensus comment 21 (regarding dalfampridine use).

Consider the following, not-infrequent clinical scenario: a patient with either secondary-progressive MS without relapses or primary-progressive MS who, because of his or her nonrelapsing status, is not or is no longer taking one of the U.S. Food and Drug Administration (FDA)-approved disease-modifying agents (DMAs; none have clearly demonstrated benefits in nonrelapsing forms of MS). This individual may very likely demonstrate significant ambulation limitations due to MS, and therefore could be a good candidate for symptomatic ambulation improvement with dalfampridine—quite independent of whether or not that individual is concurrently receiving an approved DMA. Taken at face value, consensus statement 21 would disapprove of such an individual receiving possible symptomatic improvement with dalfampridine.

Although dalfampridine is typically prescribed to a person with MS who happens also to be taking a DMA, the 2 are independent treatments with independent benefits that are not related to or dependent on each other. Importantly, at the point where a person with nonrelapsing MS may no longer be an optimal candidate for an approved DMA treatment, that same person may still be an optimal candidate for FDA-approved use of dalfampridine.2,3

Given the limitations inherent in any questionnaire process, the respondents to the consensus survey may not have considered the latter, less frequent, but nonetheless very important scenario. Nonetheless, consensus statement 21 makes a sweeping recommendation that, for reasons outlined above, is not universally accurate or necessarily appropriate. Exercising consensus statement 21 could, perhaps inadvertently and unintentionally, deprive a significant number of patients with MS an important, often beneficial, and FDA-approved symptomatic treatment option.

J. Theodore Phillips, MD, PhD, FAAN, MS Research Program Director, Baylor Institute for Immunology Research
ted.phillips@baylorhealth.edu

DISCLOSURES

The author reports receiving speaker or consulting honoraria from Acorda, Biogen Idec, Genzyme, Novartis, Sanofi-Aventis, and Teva.

REFERENCES


The Authors Respond:

We thank Kern et al. and Phillips for their constructive critiques of our article. While they have highlighted the inherent limitations of developing consensus statements by payers for payers, we feel that they have slightly, but importantly, misinterpreted the purpose of our work. As stated in our article, the multiple sclerosis (MS) consensus statements were intended “to serve as a practical reference tool for health plans, to be used in conjunction with clinical evidence, when designing benefits and coverage policies for MS agents.” We appreciate the not-infrequent clinical scenario described by Phillips and the feedback concerning the limitations of consensus statement 21. We agree that a patient with either secondary-progressive MS without relapses or primary-progressive MS who is no longer taking 1 of the disease-modifying agents needs a symptomatic treatment option. However, the consensus statements published in our article were never meant to be used by managed care decision makers in the absence of clinical judgment, and nowhere in our article is it implied that they were. In addition, the claim by Kern et al. that our article implies that management decisions in the MS category should be made “without the counsel of clinical experts” is not valid. In fact, we noted in the Limitations section of the article that “practicing neurologists and the specialists who treat patients with MS may have different opinions than pharmacy and medical directors of health plans.” While we agree and acknowledge in our article that the consensus statements do not incorporate MS expert clinical input, we disagree that this fact renders the conclusions less robust.

Additionally, we wish to further inform readers about the work that is in progress to bridge the gap between clinical and payer resources in MS. As stated in the last sentence of our article: “Future opportunity exists to seek commentary on this reference from neurology experts and to update the statements as new agents enter the market.” Specifically, the organization