Neurologists and the economics of MS treatment

Lighting candles, not cursing the darkness

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It is understandable that neurologists might "curse the darkness" that engulfs the economics of multiple sclerosis (MS) care. The price of MS disease-modifying therapies (DMTs) is shocking. In 2013, the average wholesale price of all MS DMTs in the United States clustered around $65,000 a year and prices continue to increase by more than 10% per year.[1] In response to skyrocketing DMT prices, insurance companies and specialty pharmacies create rules regulating coverage of MS treatments with little input from neurologists.[2] Neurologists must navigate Kafkaesque health insurance bureaucracies to obtain coverage for treatments we deem appropriate for our patients. By contrast, reimbursements for neurologists illustrate that we may be undervalued. In 2013, Medicare spent $820 million for a single MS DMT, glatiramer acetate, which nearly equaled the $939 million paid to all neurologists for their evaluation and management services.[3] Neurologists, the experts in the care of MS, have no influence over the rising cost of DMTs or the decisions made by the health insurance industry regarding coverage of therapies. Frustrated neurologists complain at meetings and via e-mail groups about medication cost and lack of influence, generating much heat but little light.

In this issue of *Neurology*®, Kister and Corboy[4] discuss 5 strategies to positively influence the cost of care for people with MS. Their purpose is to shed light on ways neurologists can devise medically sound, but cost-effective, strategies to treat MS.

Kister and Corboy first emphasize the need to avoid using DMTs to treat patients who do not have MS. This seems obvious but there is evidence that misdiagnosis of MS is not rare and often leads to inappropriate use of DMTs.[5] A second strategy is to be selective in the treatment of MS relapses. The authors emphasize that mild, nondisabling relapses do not need to be treated. When treatment is appropriate, the standard therapy is 1,000 mg of methylprednisolone administered IV for 3 to 5 days. The authors point out that orally administered high-dose methylprednisolone is also effective and costs much less. Even larger savings can be achieved by avoiding use of repository corticotropin (Acthar gel) to treat MS relapses. Despite there being no evidence that it is superior to methylprednisolone, some neurologists prescribe ACTHar gel, which has an average wholesale price of more than $40,000 to treat a single MS relapse.

As a third strategy, the authors suggest that the dosing of some MS DMTs could be reduced without affecting efficacy. They summarize studies suggesting that glatiramer acetate, fingolimod, and natalizumab can be given less frequently than the Food and Drug Administration (FDA)-approved schedules with similar efficacy and a substantial reduction in cost. Another strategy is the off-label use of less expensive immunotherapies. For instance, there is ample evidence indicating that the chimeric anti-CD20 monoclonal antibody, rituximab, is efficacious in treating relapsing MS, has a long-term safety record,[6,7] and is less expensive than the projected price of the humanized anti-CD20 monoclonal antibody, ocrelizumab, and the other DMTs approved by the FDA for relapsing MS. While not approved for MS, rituximab is being used successfully to treat MS at many MS clinics in the United States and elsewhere. Leflunomide is another example. It is a prodrug of the FDA-approved MS DMT, teriflunomide, and generic leflunomide costs $25 to $65 a month compared with the average wholesale price of teriflunomide of approximately $6,500 a month. Finally, Kister and Corboy question whether older patients who have had no evidence of active MS while on a DMT for 5 years or longer might be safely taken off their DMT.[8] If so, a substantial savings could be achieved by stopping the DMTs in this population.

Neurologists should now be implementing some of the strategies that Kister and Corboy suggest. We should accurately diagnose MS and not rush to prescribe MS DMTs for questionable cases. We should not be using repository corticotropin to treat MS relapses given its high cost compared with equally efficacious and considerably less expensive corticosteroid regimens. However, other strategies suggested in their article are not so straightforward.

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Using rituximab to treat relapsing MS is reasonable given the results of the phase 2 trial of rituximab and the impressive results in relapsing MS of another anti-CD20 monoclonal antibody, ocrelizumab.[6,9] However, insurance companies vary regionally in their willingness to approve the off-label use of rituximab despite the cost savings. For instance, while Corboy and his colleagues at the University of Colorado have been successful at obtaining approval for treating MS with rituximab, in Oregon we frequently receive denials from insurance companies for coverage of rituximab for MS. To take advantage of the cost savings of using rituximab off-label for treating MS will require insurance companies to cooperate. Alternatively, a noninferiority trial of rituximab vs ocrelizumab may be needed to show that rituximab is not less effective than ocrelizumab; however, noninferiority trials are usually expensive, and it is challenging to secure funding for such trials.

Other strategies recommended by Kister and Corboy will also require clinical trials, and the challenge will be funding this research. Pharmaceutical companies are unlikely to fund research that will lower their profits, such as alternative dosing schedules, the off-label use of generic immunotherapies, or other strategies to lower the price of DMT for MS. Neurologists will need to design these clinical studies and apply for funding for projects that seek to lower the cost of MS care. One example of success is the recent funding by the Patient-Centered Outcomes Research Institute of a neurologist-led multicenter trial to assess the safety of discontinuation of DMT in older, stable patients with MS. Neurologists should draw inspiration from successes such as this.

Kister and Corboy present useful strategies that could lower the cost of MS care without sacrificing efficacy, but they do more. They call for neurologists to light the way toward better and more cost-effective treatment of MS.

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