

POSITION STATEMENT

Availability of Disease Modifying Therapies (DMT) for Treatment of Relapsing Forms of Multiple Sclerosis



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Background Information

Multiple sclerosis (MS) is a chronic inflammatory condition that affects the central nervous system, causing substantial disability and increasing the risk of mortality. People living with MS experience symptoms such as optic nerve dysfunction and vision problems, muscle weakness and pyramidal tract dysfunction, bladder or bowel dysfunction, tremors, cognitive and emotional problems, and incoordination. MS affects about 400,000 Americans and is a leading cause of disability among young adults.

Available disease modifying therapies (DMT) uniquely target and are FDA-approved for relapsing forms of MS. Many DMT are approved as first line agents. The FDA approval has provided no recommendations, and there are no universally accepted algorithms, for which DMT to use in which order or in which individuals. There are a limited number of comparative efficacy trials of available DMT, and even fewer cost-benefit comparisons among them.

Description of Issue

Pharmacy costs for MS drugs are escalating. Health insurer/payers are increasingly implementing utilization management programs that address pharmacy costs, called "step therapy programs" for DMT to treat relapsing forms of MS. Step therapy programs often require an individual to start with a lower-cost treatment which they must fail to respond to or to tolerate before trying a higher-cost alternative, even if that lower cost option is less effective or not appropriate for a given individual. Step therapy programs are often defined solely on the basis of cost which limits the choice of an appropriate DMT for an individual with MS and his or her care team.

The AAN Position

The Academy urges access to all DMT for treating MS individuals when they have the potential to provide clinical benefit. If step therapy programs are used, these programs should be driven by evidence-based clinical and safety data, and not just cost. The Academy believes that the highly individualized decisions around use of DMT should be made by persons living with MS in consultation with their treatment team.

The Academy also recognizes the need for data-driven clinically-sound pharmacy and medical benefit plans, development of better clinical trial evidence including comparative (head-to-head) trials and cost-effectiveness analyses, and the role of policymakers in provision of accessible product pricing.

Rationale

MS is a chronic disease with no known cure, but physicians can help individuals with MS modify their prognosis and postpone disability using appropriate DMT. Many factors impact medical decision making about choice of DMT and when to switch among them, and these factors are almost never considered in step therapy programs. These factors include relative efficacies of DMT, various modes of action, side effects, schedules of treatment, and routes of administration. In addition, MS varies in its aggressiveness, affects each person differently, and an individual may or may not achieve a favorable clinical response to one or another of the DMT. Other factors impacting choice of DMT include: Lifestyle; availability of a care partner; difficulty with injections or availability of infusion facilities; other intercurrent illnesses such as chronic or frequent infections, liver disease, cardiac disease, macular disease, depression; and future plans for pregnancy.

The Academy recognizes that neurologists play an important role in containing health care costs. Professionals prescribing DMT should be well-educated in the accurate diagnosis and natural course of MS, the strengths and limitations of the currently available clinical trial evidence of MS therapies, and the need to maintain access to unbiased and independent expert opinion on the appropriate use of DMT in the context of disease management. This should include not only decisions about when to begin the use of MS DMT, but also decisions about when to discontinue DMT in the context of futility or lack of need. When adding all costs of health care, not just those directly related to paying for a medication, both reduction in relapses and disability will save substantial amounts of money over time.

Finally, the Academy encourages all efforts to reduce overall health care costs while strongly supporting the need to make prescription drugs for MS accessible and affordable for appropriate individuals. For that reason, the Academy urges policymakers to address the escalating prices of MS DMT to protect individuals' access to appropriate therapies.

Position Statement History

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This position statement was endorsed by the Consortium of Multiple Sclerosis Centers (CMSC) on February 10, 2015, the International Organization of MS Nurses (IOMSN) on February 17, 2015, and the MS Coalition on February 17, 2015.

¹ Grima DT, Torrance GW, Francis G, Rice G, Rosner AJ, Lafortune L. Cost and health related quality of life consequences of multiple sclerosis. *Mult Scler* 2000;6:91–8.

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