



January 16, 2018
Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8016

Submitted electronically to www.regulations.gov
Re: CMS-4182-P

Dear Administrator Verma:

The National Multiple Sclerosis Society (the Society) appreciates this opportunity to comment on proposed policy and technical changes for Medicare prescription drug plans for year 2019. While the proposal touches on many aspects of Part D and Medicare Advantage operations, this response is limited to those parts of the proposal most directly relevant to Medicare beneficiaries living with multiple sclerosis (MS) and their families. It is on their behalf that we applaud the agency's interest in exploring refinements to plan operations and benefits to help reduce out-of-pocket costs for beneficiaries, though we urge caution in the adoption of certain measures which can have unintended consequences for beneficiaries with certain conditions such as MS.

About MS

MS is an unpredictable, often disabling disease of the central nervous system, which interrupts the flow of information within the brain, and between the brain and body. Symptoms range from numbness and tingling to blindness and paralysis. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted. Health coverage and access to healthcare are of critical importance to people with MS. Lack of access can result in exacerbations of the disease; earlier onset of disability; premature departure from the workforce; and greater cost to the individual, his/her family and the healthcare system at large.

Further, the cost of MS treatment is high and increasing, resulting in significant burdens for both public and private payers, employers and those living with the disease. A 2013 study comparing people diagnosed with MS to those without the disease highlighted the harsh realities of life with MS. Those with MS were shown to be at significantly higher risk of being unemployed (60%); had income



that was lower by over \$6700 per year; required \$24,000 more in direct medical expenditures (\$32,051), or roughly five times as much; were twice as likely to be divorced or separated; and had significantly lower quality adjusted life years ⁱ At present, the average annual cost of the currently available MS disease modifying therapies is approximately \$85,000, and the cost of these drugs accounts for roughly 75% of the annual cost of MS treatment overall. ⁱⁱ

Research shows that early and ongoing treatment with a disease-modifying therapy (DMT) is the best way to slow the course of disease and disability from relapsing forms of MS, and protect the brain from damage due to MS lesions. ⁱⁱⁱ MS can also be accompanied by a variety of life altering symptoms such as bladder problems, vision problems, and issues with gait, spasticity, and extreme fatigue. It can take years for a person living with a chronic health condition like MS to find the most effective course of treatment for their set of symptoms. Any change to a treatment plan that is not made for medical reasons must be understood as potentially harmful, and can put the patient's health at risk. In addition, changing a person's medication can sometimes cause adverse reactions or side effects.

MS and Medicare

Transitioning into Medicare, learning to navigate the program, and overcoming cost barriers to treatment are among the most frequent reasons such individuals seek our assistance. These challenges can be particularly burdensome for beneficiaries with cognitive impairment resulting from their disease, often leading to earlier than expected retirement, and reliance on disability insurance and Medicare long before one's 65th year. Others with low or fixed incomes are also especially vulnerable to changes, limits or disruptions in their coverage regardless of their level of physical or cognitive impairment.

To help Medicare beneficiaries with MS take best advantage of their annual Open Enrollment opportunities, the Society now offers one-to-one and no-cost telephone counseling sessions with staff specialized in health insurance and Medicare, including expertise in plan features, formulary design, look-up tools and more. Among the most common complaints we hear from these beneficiaries are the dramatic rise in out-of-pocket costs for MS drugs due to higher co-insurance in Medicare plans than employer-sponsored insurance, lack of access to copay assistance programs available to Medicare beneficiaries under current law, and the lack of annual caps on out-of-pocket costs for beneficiaries in Original Medicare. As a result, our anecdotal evidence suggests the number of



people with MS, including an unknown number in Medicare who are no longer adherent to their treatment plan, is increasing.

Tiered Rx Benefits

We are concerned about CMS' proposals regarding tiered benefit designs, as they could reinforce common misconceptions about MS treatments and their cost implications for beneficiaries. Unfortunately for people with MS, Medicare drug plan formularies often reflect the presumption that the existing DMTs are of equal value and effectiveness in treating the disease, regardless of evidence to the contrary. In fact, as described and supported in ['The Use of MS Disease Modifying Therapies: Principles and Current Evidence'](#), only the interferon beta agents are sufficiently comparable to warrant a presumption of interchangeability and lower cost-sharing as an inducement for preferential treatment on a formulary. The remaining 13 approved therapies are characterized by significant differences in their mechanism of action, potential side effects, warnings and precautions.^{iv}

This reality explains the lack of applicability of most MS drug treatments to widely-supported value-based insurance designs and other cost-cutting measures generally, as well as our inability to support CMS' proposals regarding tiered benefits in this proposal specifically. Instead, we urge continued exploration and thoughtful regard for improving benefit designs and meaningful exceptions to high cost-sharing.

Mid-Year Substitutions

CMS proposes to allow plans to make mid-year changes to their formularies if they are substituting a therapeutically equivalent newly-approved generic for a brand name drug. While we appreciate the objective of this policy, we must warn that current law regarding cost-sharing during the coverage gap can result in even higher cost-sharing for generics than brand products. When Medicare beneficiaries are in the coverage gap, brand name drugs must be covered at a 50% discount while generic drugs do not.^v Therefore, we strongly recommend the policy be amended to include a cost-sharing exception to assure beneficiaries in the coverage gap prescribed a generic not pay more than they would for the original brand product.

We have been disappointed by this and other cost implications as the first generic DMTs have emerged. Allowing plans to substitute a new generic for a



brand name prescription drug in the middle of the plan year could result in some beneficiaries being forced to pay more for the therapeutically equivalent generic drug when they were stable on the brand name drug beforehand.

Pass-Through of Rebates at Point of Sale

We are pleased to see that CMS is interested in exploring the possibility of passing rebates and pharmacy price concessions along to consumers at the point of sale. The Society recently launched the [Make MS Meds Accessible Campaign](#) to address the complexities and challenges of the prescription drug supply chain from all sides and with the participation of all stakeholders. The goals of the Society's campaign clearly align with CMS' proposal regarding rebates and who should benefit from them. Passing rebates through to consumers is a step in the right direction toward a more fair and transparent supply chain, but we must emphasize that rebates are just one component of the much larger issue of prescription drug costs. This policy should be pursued, but we implore CMS to continue to explore how other policy options can help reduce the cost of prescription drugs in the United States. While this proposal has the potential to reduce beneficiaries' out-of-pocket costs for their drugs, we believe that more could be done to drive down the price of the high-cost specialty medications that people who are living with MS rely on.

The Society promotes greater transparency and accountability for stakeholders in the prescription drug supply chain to make the system more patient-centered overall. The prices charged for MS medications, price negotiations between manufacturers and payers and decisions resulting from them are outside of the public realm. The Society believes the public would be better served if greater understanding of price and rebate negotiations, and stakeholders' roles in them, was also more transparent. When rebates are exchanged between a manufacturer and a health plan, the enrollees that rely on the most expensive specialty medications are effectively subsidizing the rest of the health plan's risk pool with the rebate dollars derived from those specialty medications. We believe that this is inherently unfair, and believe the people who are benefiting from rebates should be the ones taking the rebated medications.

The use of rebates obfuscates the flow of money in the supply chain and makes it unclear what the relationships are between each of the actors, which contributes to this lack of transparency. We believe that CMS should continue to explore the best methods to pass on rebates to consumers and to ensure that the supply chain is transparent for consumers.



Thank you for this opportunity to comment. For additional information on these comments or other aspects of Medicare coverage and MS, please contact Senior Director of Health Policy Kim Calder (Kimberly.Calder@nmss.org).

Sincerely,

A handwritten signature in black ink that reads "Bari Talente". The signature is written in a cursive, flowing style.

Bari Talente, Esq.
Executive Vice President of Advocacy

ⁱ Malachy Bishop, Ph.D., Principal Investigator and colleagues, Final Report to National Multiple Sclerosis Society '*Optimizing MS Care: Multiple Sclerosis Patients' Perspectives and Priorities for their MS Care*', 2017

ⁱⁱ Jonathan D.Campbell, Vahram Ghushchyana, R.Brett McQueen, Sharon Cahoon-Metzgerb, Terrie Livingston, Timothy Vollmer, John Corboy, Augusto Miravallec, Teri Schreiner, Victoria Porter, Kavita Naira. *Burden of multiple sclerosis on direct, indirect costs and quality of life: National US estimates*. Science Direct

ⁱⁱⁱ MS Coalition monograph, '*The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles & Current Evidence*', Updated March 2017.

^{iv} Ibid, page 9.

^v Medicare.gov webpage 'Costs in the Coverage Gap', <https://www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html>, (January 16, 2018).