



July 23, 2021

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human  
Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Ali Khawar  
Acting Assistant Secretary  
Employee Benefits Security Administration  
U.S. Department of Labor  
200 Constitution Ave NW  
Washington, DC 20210

Rachel D. Levy  
Associate Chief Counsel  
Internal Revenue Service  
Department of the Treasury  
1500 Pennsylvania Avenue, NW  
Washington, D.C. 20220

Laurie Bodenheimer,  
Associate Director, Healthcare and Insurance  
Office of Personnel Management  
1900 E Street, NW  
Washington, DC 20415-1000

Carol A. Weiser  
Benefits Tax Counsel  
U.S. Department of Treasury  
1500 Pennsylvania Avenue, NW  
Washington, D.C. 20220

RE: Attention: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC)

Dear Secretary Becerra, Acting Assistant Secretary Khawar, Ms. Levy, Ms. Bodenheimer and Ms. Weiser:

On behalf of the nearly one million individuals in the U.S. living with multiple sclerosis (MS), the National Multiple Sclerosis Society (Society) is pleased to comment on this request for information (RFI) regarding Reporting on Pharmacy Benefits and Prescription Drug Costs. We understand that the Departments and Office of Personnel Management (OPM) will be collecting data with the intent to analyze trends in overall spending on prescription drugs and other health care services by plans and issuers with the intent of publishing the analysis to enable plans and issuers to negotiate fairer rates and lower costs for participants, beneficiaries, and enrollees.

We applaud the Administration's interest in competition to help lower prescription drug costs and in policy changes expanding access to health coverage as helpful steps in promoting affordability and access to treatment. We view the implementation and enforcement of reporting requirements

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regarding pharmacy benefits, prescription drug costs, and rebates as additional tools in support of this positive trend. We also appreciate the Departments' and OPM's interest in financial assistance from drug manufacturers and are hopeful that responses to questions in the RFI about them will provide needed transparency on the flow and use of these funds from drug manufacturers to plans, pharmacy benefit managers (PBMs), pharmacies, charities, or other entities. While many of the specific questions posed in the RFI are focused on data and operational practices outside of the expertise of the Society, we are pleased to provide comments on the costs of MS disease modifying therapies (DMTs), the impact of those costs to people affected by MS, the role of financial assistance, and copay assistance in providing access to these treatments.

MS is an unpredictable, often disabling disease of the central nervous system that disrupts the flow of information within the brain, and between the brain and body. Symptoms vary from person to person and range from numbness and tingling, to walking difficulties, fatigue, dizziness, pain, depression, blindness, and paralysis. Most people are diagnosed between the ages of 20 and 50, when they are in their prime working years. Many will be forced out of the workforce due to the disabling and unpredictable effects of their disease. The progress, severity, and specific symptoms of MS in any one person cannot yet be predicted but advances in research and treatment are moving us closer to a world free of MS.

The Society's vision is a world free of MS and our mission is that we will cure MS while empowering people affected by MS to live their best lives. Growing evidence shows that early and ongoing treatment with a Food and Drug Administration (FDA) approved DMT is the best way to manage the MS disease course, prevent accumulation of disability, and protect the brain from damage due to MS. There are now more than twenty DMTs on the market, including generic options, and these medications have transformed the treatment of MS over the last 25 years. The full range of MS DMTs represent various mechanisms of action and routes of administration with varying efficacy, side effects and safety profiles. No single agent is 'best' for all people living with MS<sup>i</sup> and, as MS presents differently in each person, every person's response to a DMT will vary. Further, most of the MS DMTs are not therapeutically interchangeable.

In 2016, in reaction to increasing cost of MS DMTs and the resulting access challenges people with MS face, the Society released [comprehensive recommendations to Make MS Medications Accessible](#). Our recommendations call on all stakeholders across the healthcare and drug supply chain system to work together to make medications more affordable, and the process for getting them simple and transparent<sup>ii</sup>. We know that there is no single solution that can fully reverse the trend toward ever-increasing drug costs and payer policies that inhibit or delay access to medically necessary therapies.

### *Costs of MS DMTs*

The cost of MS therapies has dramatically risen since the first MS disease-modifying therapy (DMT) was approved in 1993. While not identical, most brand MS DMT's have seen similar pricing trajectories. When the first MS DMT came on the market in 1993, the price range was \$8,000 to \$11,000 for one year of treatment. Since that time, price increases, occurring one or more times per year for almost all DMTs, have become the norm. In 2013, the annual median price for MS DMTs

was less than \$60,000; today, the median price for brand MS DMTs is \$93,672. Five MS DMTs are now priced at more than \$100,000 per year and almost all these treatments must be taken each year. Generics are relatively new to the MS market, but when the costs of those generics are considered, the median price of MS DMTs only falls to \$88,212 a year. Additionally, MS generics have their own unique set of access issues.

#### *Impact of high prices of MS DMTs*

As the prices of MS DMTs increase, health plans and pharmacy benefit managers (PBMs) employ increasingly strict utilization management practices (i.e., prior authorization, step therapy, and formulary restrictions) to minimize their use and cost liability for these therapies. These practices present significant hurdles for prescribers and real barriers for people with MS. Utilization management tools can result in delays or disruptions in treatment as patients wait for their health plan to determine whether they will cover care as prescribed. Any delay or disruption in treatment is particularly problematic for people with MS as delays may result in worse health outcomes, increased healthcare costs over time, and disease progression that cannot be reversed.

#### *Role of financial and copay assistance in providing access to MS DMTs*

Increasingly, people with MS are faced with higher out-of-pocket costs due to high deductibles and co-insurance rather than a flat co-pay for their MS DMT. These insurance plan designs make it more difficult for people to stay on their DMT as they can cost several hundreds of dollars or more each month. In 2019, individuals with MS were surveyed about their use of DMTs and the affordability of those medications. More than half of those surveyed said they were concerned about being able to afford their DMT over the next few years and 40% had altered the use of their DMTs due to cost, with some skipping or delaying treatment<sup>iii</sup>. Additionally, 40% stated that they experience stress or other emotional impacts due to high out-of-pocket costs and are making lifestyle sacrifices to be able to pay for their DMT. More than 70% of people with MS have received financial assistance for their DMT and the vast majority say the financial burden of their DMT would be great without assistance. Further information on the Society's survey is available on the [Society's website](#). This snapshot of real-world experiences shows why 85% of those surveyed said that the federal government should do more to control the high costs of MS DMTs.<sup>iv</sup>

Additionally, many plans are using so-called copay accumulator, or copay maximizer, programs to prohibit the use of financial assistance toward an enrollee's annual deductible or maximum out-of-pocket expense. This practice leads to significantly higher out-of-pocket cost for people with MS, negatively impacts adherence to treatment, can cause delays in patients seeking needed or preventive care and threatens individuals' health and independence. The Society, in coalition with other patient advocacy groups, has worked to oppose these copay accumulator or maximizer programs. In our experience, little to no disclosure of these practices exists at the plan level or for the enrollees' benefit.<sup>v</sup> We do not believe that transparency of these practices will end their practice or lessen their impact on patients, but we believe that transparency is needed around these practices and urge the Departments and OPM to require health plans to report on all practices regarding copay assistance intended for use by enrollees to help offset any/all cost-sharing requirements, including:

- the identification of plan enrollees relying on copay assistance;
- the flow of copay assistance funds from manufacturers or charitable groups to plans, PBMs, enrollees or others;
- marketing materials about their benefit as cost containment strategies to brokers, plan managers and employers;
- disclosure and explanation of them in all plan documents; and
- notice to plan enrollees about the implications of copay accumulators or maximizers for their out-of-pocket costs, including any rights to appeal.

Thank you for this opportunity to comment. For additional information, please contact Kimberly Calder, Senior Director of Health Policy at [Kimberly.Calder@nmss.org](mailto:Kimberly.Calder@nmss.org).

Sincerely,



Bari Talente, Esq.  
Executive Vice President, Advocacy and Healthcare Access  
National Multiple Sclerosis Society

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<sup>i</sup> MS Coalition. The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. [http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT\\_Consensus\\_MS\\_Coalition\\_color](http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color). Accessed December 26, 2018.

<sup>ii</sup> National MS Society. Make MS Medications Accessible: Recommendations. <https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/Recommendations-Make-MS-Meds-Accessible.pdf>. Accessed February 27, 2019.

<sup>iii</sup> National Multiple Sclerosis Society. "Quantifying the Effect of the High Cost of DMTs" Market Research Report. August 2019. <https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/NMSS-Research-Report-Full-Access-to-MS-Medications.pdf>. (Accessed April 27, 2021).

<sup>iv</sup> National Multiple Sclerosis Society. "Quantifying the Effect of the High Cost of DMTs" Market Research Report. August 2019. <https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Advocacy/NMSS-Research-Report-Full-Access-to-MS-Medications.pdf>. (Accessed April 27, 2021).

<sup>v</sup> The AIDS Institute, ['Double Dipping: Insurance Companies Profit at Patients' Expense'](#); viewed online July 21, 2021.