National
Multiple Sclerosis
Society

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Re: Rulemaking – PBM/Insurer Reporting SB 192, OAR 836-200-04?? & 836-053-????

Numi Rehfield-Griffith,

The National Multiple Sclerosis Society (Society) appreciates the opportunity to provide public comments on the Department of Financial Regulations' (DFR) proposed rulemaking regulations referenced above. We appreciate the DFR's leadership and investigation into pharmacy benefit managers (PBMs) and their role in the pharmaceutical drug supply chain that impacts the price patients pay at the pharmacy. We encourage the DFR to investigate all anticompetitive practices that, as part of the U.S. prescription drug supply chain, both limit access to needed life-changing therapies and increase the price that patients pay for those therapies. The Society also urges the DFR to investigate practices that limit access to health care services, anti-competitive tactics that inhibit generic competition, and PBMs' integration into the U.S. healthcare system In ways that impact access for those who need it.

Multiple sclerosis (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 the body. Symptoms range from numbness and tingling to blindness and paralysis. The progression, 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 works to cure MS while empowering people affected by MS to live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

MS is a highly expensive disease. The average total cost of living with MS is $88,487 per year[i]. **The total estimated cost to the U.S. economy is $85.4 billion per year and the direct medical cost to live with MS is an average of $65,612 more than a person who does not live with MS[ii].** Today, evidence demonstrates that early and ongoing treatment with a MS disease-modifying therapy (DMT) is the best way to manage disease course, prevent accumulation of disability, and protect the brain from damage due to MS[iii]. There are now more than twenty DMTs on the market, including generic options and one biosimilar, and these medications have transformed the treatment of MS over the last 30 years. Unfortunately, these DMTs significantly increase the cost of living with this disease. The annual cost for individuals on an MS DMT ranges from $57,202 to $92,719, depending on an individual's age and gender[iv] and people with MS stay on these medications for 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[v] and, as MS presents differently in each person, every person's response to a DMT will vary. It is common for people with MS to move through several different DMTs throughout their life as they may "break-through" on a medication, or have disease activity, and need to try a different DMT.

PBMs' role in formulary development and restrictions to access

As you are aware, PBMs have played an increasingly important - but often hidden - role in the U.S healthcare system. PBMs manage prescription drug benefits on behalf of health insurers, Medicaid drug plans, large employers, and other payors. While initially created in the 1960s to help control the cost of prescription drugs, their role has evolved and today they are a core part of the American healthcare system and play a fundamental role in determining the cost of prescription drugs for payors, influencing the access to medication that people with MS and other patients need, and determining how much pharmacies are paid for these medications.

When the first MS DMT came to market in 1993, the price range was approximately $11,500 for one year of treatment. The price of MS therapies has dramatically risen since that time. The annual median price for MS DMTs has increased nearly $34,000 in less than 10 years. As of January 2023 (see appendix), the median annual price of brand MS DMTs is close to $98,000. Six of the MS DMTs have increased in price more than 200% since they came on market, with eleven now priced at over $100,000. While not identical, most brand MS DMTs have seen similar pricing trajectories which is not sustainable for people with MS or the U.S. healthcare system. Cost increases have also impacted MS symptom management medications. For example, H.P. ActharGel (Acthar), approved in 1952, is used as a short-term treatment for acute exacerbations of MS. For years, this medication was priced at less than $40 per vial. However, today, a vial of Acthar is priced at $39,864-—approximately 140,000% more expensive than when it was approved 68 years ago. The price increases and additional out-of-pocket costs associated with these medications present real hurdles and barriers to people affected by MS.

PBMs play a significant role in the access that people with MS have to their DMTs and symptom management treatments which this population relies on to live their best life. As costs have increased, health plans and PBMs employ increasingly strict utilization management practices to minimize the use and cost liability for these therapies. These practices present significant hurdles for prescribers and real barriers for people with MS. While PBMs often cite part of their role as keeping pharmaceutical and health costs down, there are documented examples that PBM practices can add costs to the healthcare system overall and inhibit patient care. For example, physicians in the United States complete an average of 33 prior authorization requests every week, taking an average of 14.4 hours to process.[vi]

Additionally, too often, formularies designed by PBMs and health insurers are driven not by medical advice, but by rebates in the system. For example, according to a 2020 staff report from the congressional House Committee on Oversight and Reform Committee, Teva Pharmaceuticals exerted pressure on PBMs by tying contractual rebates on Copaxone 20 mg/ml to adding Copaxone 40 mg/ml to their formularies[vii].

There is often little transparency into how formularies or step therapy protocols are developed, especially in MS, where there are no algorithms describing how to move through the different MS medications. Through the years, people with MS and their healthcare providers have described some

egregious step therapy practices and prior authorization delays that have likely resulted in MS exacerbations, worsening health, and increased costs to the healthcare system. Examples of these practices include requiring a person with MS to fail on three to five DMTs prior to accessing their provider-prescribed medication, requiring someone to use a DMT they already know does not work for them, and requiring people with needle phobia to use self-injectable medications even though oral medications are available. Rather than "getting the right medication to the right person" as the industry describes, these practices result in nonadherence and dangerous delays to people getting on the DMTs that will work for them. With every delay, people with MS risk disease activity and underlying progression from which they may not recover.

Additionally, increasing vertical integration of PBMs and payors, rebating, and other business-related practices often result in formulary placement of medications that steer individuals towards more expensive medications, while generics and biosimilars are available. For example, PBMs often place generic drugs and biosimilars in higher formulary tiers alongside brand medications, thus negating the cost savings to the health system and the patient. We have seen this practice in the MS space as MS generics are often covered as specialty medications and as a result sit on a higher cost-sharing tier than most regular generic medications; this results in higher out of pocket costs for people with MS. Likewise, a PBM may prefer a higher cost drug because it will increase their revenue so, despite lower cost alternatives being available, a higher cost product receives favorable formulary placement. We believe that the choice of therapy for people with MS should be between the patient and their healthcare provider, with the enrollee's health being the top priority.

Any delay or disruption in treatment is particularly problematic for people with MS as delays may result in irreversible disease progression. People with chronic illnesses need to have confidence that they will be able to get the life-changing medication they need. The Society is increasingly concerned about the role PBMs play in the current system practices, particularly those related to cost-sharing, step therapy, prior authorization, and copay accumulator programs.

Policy Changes To Promote Transparency and Accountability are Needed

There is increased pressure on people with MS and other chronic health conditions to make good choices about the cost of their care and prescription drug medications, yet there is very little true transparency throughout the healthcare system, and people often have very little information about price and cost to guide these decisions. We believe that these regulations will be a good first step to increase transparency to help people affected by MS understand why formularies are designed the way they are, prohibit unfair PBM business practices, incentivize those practices that are fair and promote transparency, protect patients, and have an enforcement mechanism that will bring about change.

The Society's full set of policy recommendations for PBM reform is outlined below.

- **Ensure transparency by requiring disclosure of specific costs, prices, reimbursements, fees, mark ups, discounts and aggregate payments received with respect to their PBM service.**
- Prohibit unfair and deceptive pricing models including spread-pricing and arbitrary claw backs of payments.
- Require pass-through pricing models.
- Require oversight and reporting on PBM behavior and allows state authorities to take legal action when a PBM is found in violation of the law.

- Ban PBMs from using discriminatory formularies.
- Allows for patients to have a choice of the pharmacy where they receive their medications.
- Allows patients to receive the benefits from rebated savings and pay the lesser amount of copay/co-insurance, the amount charged by the PBM to the pharmacy, or the cost of the drug.
- Include a substantial monetary penalty for those PBMs who act in violation of the law.

Thank you again for taking such leadership on this issue and accepting comments from patient and consumer stakeholders. If you have any questions about our comments or recommendations, please contact Seth Greiner, Senior Manager, Advocacy at seth.greiner@nmss.org

Regards,

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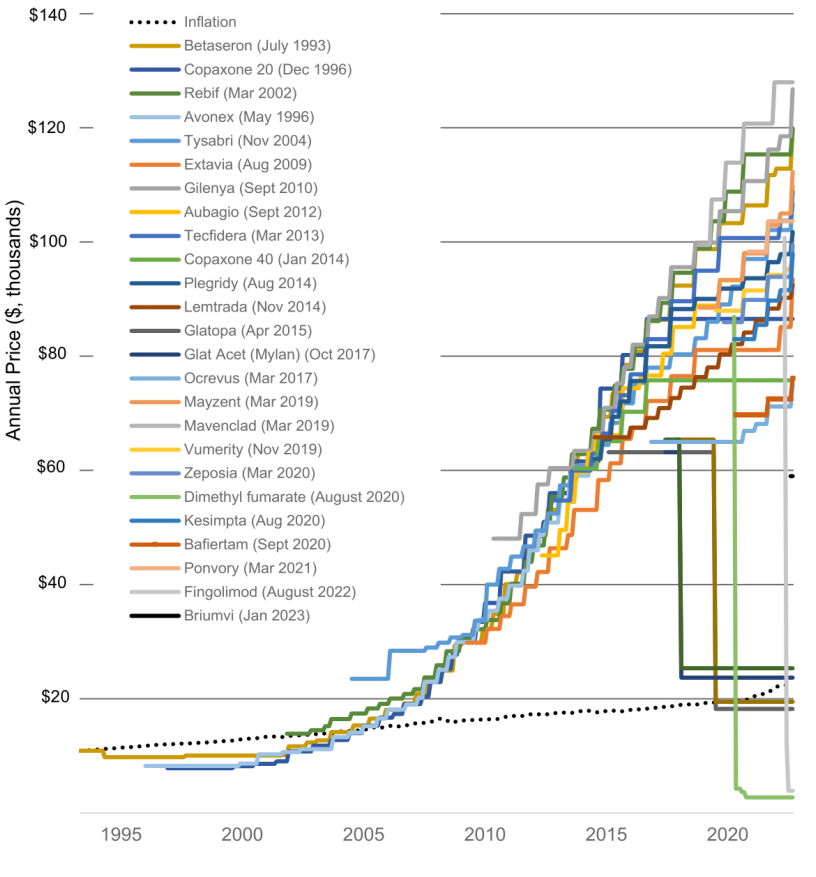
Appendix

Trends in annual price for disease-modifying therapies for multiple sclerosis; 1993 to 2023



Notes: Annual price estimated from wholesale acquisition costs (First Databank)
Market entrance date in parenthesis
Dashed line is projected annual price of Betaseron assuming only inflationary increases in price (CPI)
Lemtrada is based on four 12 mg vials (Package insert dosing: 12 mg/day (5 vials) for five consecutive days in first year; 12 mg/day (3 vials) for three days in year 2);
Briumvi is based on maintenance dose of 450 mg (3 vials) twice a year;
*2021 to 2022 (January); **Generic, lowest WAC reported

Drug (manufacturer)	1 Year Change*	Annual Price 2023
Self-administered Injections		
Betaseron (Bayer)	7.1%	$119,610
Avonex (Biogen)	5.5%	$101,796
Rebif (EMD Serono)	4.0%	$119,973
Extavia (Novartis)	15.4%	$93,566
Plegridy (Biogen)	5.5%	$101,796
Kesimpta (Novartis)	9.1%	$97,969
Glatiramer Acetate		
Copaxone 20 (Teva)	0.0%	$86,554
Copaxone 40 (Teva)	0.0%	$75,816
Glatopa (Sandoz)	0.0%	$18,250
Glatopa 40 (Sandoz)	0.0%	$19,500
Glat Acet (Mylan)	0.0%	$23,725
Glat Acet 40 (Mylan)	0.0%	$25,350
S1P Receptor Modulators		
Gilenya (Novartis)	9.1%	$126,812
Mayzent (Novartis)	9.1%	$112,346
Zeposia (Celgene)	6.0%	$99,549
Ponvory (Janssen)	0.0%	$103,660
*Fingolimod (generic)***	NA	$3,893
Fumarates		
Tecfidera (Biogen)	8.1%	$108,896
Vumerity (Biogen)	4.0%	$98,064
Bafiertam (Banner)	5.0%	$76,192
*Dimethyl fumarate (generic)***	0.0%	$2,738
Other Oral DMTs		
Aubagio (Genzyme)	6.0%	$109,862
Mavenclad (EMD Serono)	6.0%	$127,986
Infusions		
Tysabri (Biogen)	4.5%	$106,722
Lemtrada (Genzyme)	4.7%	$92,496
Ocrevus (Genentech)	5.5%	$75,102
Briumvi (TG Therapeutics)	NA	$59,000

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[i] Bebo, Bruce et. al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810-e1817; DOI: 10.1212/WNL.0000000000200150. https://n.neurology.org/content/98/18/e1810 (accessed May 4, 2022).

[ii] Bebo, Bruce et. al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810-e1817; DOI: 10.1212/WNL.0000000000200150. https://n.neurology.org/content/98/18/e1810 (accessed May 4, 2022).

[iii] Costello, K. et al. MS Coalition. "The Use of Disease Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence. September 2019. https://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/DMT_Consensus_MS_Coalition.pdf (accessed May 20, 2022)

[iv] Bebo, Bruce et. al. The Economic Burden of Multiple Sclerosis in the United States: Estimate of Direct and Indirect Costs. Neurology May 2022, 98 (18) e1810-e1817; DOI: 10.1212/WNL.0000000000200150. https://n.neurology.org/content/98/18/e1810 (accessed May 4, 2022).

[v] 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. Accessed December 26, 2018.

[vi] 2019 AMA Prior Authorization (PA) Survey. American Medical Association. June 2020. www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf

[vii] Drug Pricing Investigation Teva-Copaxone. Staff Report Committee on Oversight and Reform. U.S. House of Representatives. September 2020. https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf (Accessed May 3, 2020).