National
Multiple Sclerosis
Society

May 21, 2019

The Honorable Jan Schakowsky
United States House of Representative
2367 Rayburn House Office Building
Washington, DC 20515

Dear Representative Schakowsky,

On behalf of the National Multiple Sclerosis Society (Society), we write to share our experience and recommendations relating to high prescription drug costs and the real-life impact these prices have on people living with multiple sclerosis (MS). We hope these recommendations will be useful to you as you consider advancing legislation to tackle high prescription drug costs in the United States.

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. A new study funded by the National MS Society has confirmed that nearly one million people are living with MS in the United States, more than twice the original estimate from a previous study[i]. The progress, severity and specific symptoms of MS in any one person cannot yet be predicted but advances in research and treatment are leading to better understanding and moving us closer to a world free of MS.

The MS experience with high prescription drug and out- of-pocket costs:

The Society believes that the MS drug class clearly demonstrates areas where the reliance on simple forces of supply and demand, or the purported efficacy of a competitive market, is failing people with MS and other high cost chronic diseases and conditions.

A growing body of evidence indicates that early and ongoing treatment with a Food and Drug Administration (FDA) approved disease-modifying therapy (DMT) is the best way to manage the MS disease course, prevent accumulation of disability and protect the brain from damage due to MS, and these medications have transformed the treatment of MS over the last 25 years. Fortunately, there are now over a dozen FDA-approved DMTs for different forms of MS. 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[ii]. As MS presents differently in each individual, every person's response to a DMT will vary. In fact, it is critically important that payers, payment models and delivery systems recognize that despite similarities in their indications and usage, these medications are not

therapeutically interchangeable.

Unfortunately for people affected by MS, the cost of MS therapies has dramatically risen since the first DMT was approved in 1993. Today, people with MS report high and rapidly escalating medication prices, increasing out-of-pocket costs, confusing and inconsistent formularies and complex payer approval processes that stand in the way of getting the treatments they need. When MS DMTs first 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 was less than $60,000. In 2019, the median price for brand MS DMTs is $88,853[iii] and several pharmaceutical companies have already raised prices this year (see Appendix 1 and 2). Recent analysis shows that price increases of brand name drugs are largely driven by year-over-year price increases of drugs that already in the market vs. new products. [iv]

While we have seen prices of most MS DMTs rise in a similar trajectory, there has been, generally, no lowering of prices due to increased competition in the market as more therapies have come on market. This is true even with the generics now available as alternatives to one of the brand disease-modifying therapies. These generics are also very expensive- having entered the market with a list price of more than $60,000 per year. One MS generic recently dropped its list price in half, yet this has had little impact on both overall costs within the class or on patients‘ out-of-pocket costs.

High costs create access challenges for people with MS

As the prices of MS DMTs increase, health plans and pharmacy benefit managers (PBMs) employ increasingly strict utilization management practices (prior authorization, step therapy and formulary restrictions) to minimize their use and cost liability for these therapies. This practice presents 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 disease progression that cannot be reversed. Many proposals offered to lower drug prices do so by restricting access or employing utilization management practices and we would urge Congress to evaluate the impact of any legislative proposals on patient access to therapies. We believe that any delivery system reform that aims to provide true patient-centered care for persons with MS must allow for timely access to the DMT most likely to produce optimal treatment outcomes for each person. Further, persons with MS who are stable on a DMT should be allowed to stay on that DMT without interruption until, or unless, changes in the patient’s clinical status warrants a new treatment plan.

The Society has supported legislation in previous Congresses that would require health plans to provide a clear, easily-accessible, expedited process to seek an exception to step therapy protocols. In Rep. Wenstrup’s Safe Step Act (H.R. 2279), a patient or provider could request an exception based on certain criteria outlined in the bill—for example, if the insurer’s preferred treatment is likely to cause an adverse reaction, or likely to be ineffective. If those

criteria are met, the request would be granted in a timely manner. We would suggest that Congress look to policies like these as they are looking to advance legislation that lowers drug price so that patient's access to needed therapies are not negatively impacted.

Recommendations for drug pricing legislation

In 2016, the Society released comprehensive recommendations to Make MS Medications Accessible (Recommendations), **which 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**[v]. We believe 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. All stakeholders must engage in conversations to drive solutions. The Society's Recommendations call for increased transparency in all areas of the pharmaceutical supply chain, so that all stakeholders are operating from the same level of information. This includes transparency from the manufacturer on what factors are used to set prices, how price increases are determined (including frequency of increases), how prices and price increases both support the research and development of new therapies and the marketing of these to both physicians and the public, and money spent on patient assistance programs and the numbers of patients assisted with those programs.

Our recommendations also call for increased transparency from insurers and pharmacy benefit managers by encouraging them to provide easily accessible, understandable, and searchable information on formulary coverage determinations, including information about cost-sharing. Further, our recommendations call on Congress to limit price increases for medications on the market for a considerable time and to act so that prices can be reduced for medications which have drastically increased in price since first coming on the market. Many of the MS DMTs have been on the market since the early-mid 1990's and should be long past patent and market exclusivity protections, yet they are still increasing in price. We believe that Congress should increase HHS regulatory oversight of drug classes that do not fit the expectations of a competitive market, like the MS DMT class, and authorize HHS to act to help lower prices for products whose prices do not reflect normal economic forces of supply and demand.

As the Society supports transparency in all areas across the pharmaceutical supply chain, we acknowledge that we have financial and collaborative relationships with the manufacturers of MS therapies. The Society works with all ethical companies, organizations and individuals that share our mission to end MS forever. However, we do not accept pharmaceutical support for our advocacy work. In 2017, the National Multiple Sclerosis Society received, $8 million USD in support our work. This represented less than 4% of the organization's revenue in 2017. Additional detailed information on our financial relationships with the pharmaceutical sector can be found on the Society's website at - https://www.nationalmssociety.org/About-the-Society/Financials/Sources-of-Support/Pharmaceutical-Support.

Recently, the Society's activists brought a full slate of drug pricing legislation to the Hill as a part of our Public Policy Conference Hill Day. This slate of legislation would improve access to MS medications by removing barriers to generics, reining in price increases and capping out-of-

pocket costs in Medicare Part D. We urge Congress to closely examine these proposals as you engage in conversations around advancing a larger drug pricing package.

Reining in Price Increases

The CURE High Drug Prices Act (S.637), introduced by Sen. Richard Blumenthal, would require pharmaceutical manufacturers to justify to the Department of Health and Human Services price increases of 10% or more within the previous year; 20% or more over 3 years; and 30% or more over the preceding 5 years. If the increases are found unreasonable, HHS could require the company to reimburse consumers and payors (including Medicare & Medicaid); provide the product for the price before the increase for up to one year; and pay civil penalties if the price gouging was done knowingly.

The Society has endorsed the Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, sponsored by Representatives Jan Schakowsky (D-IL) and Francis Rooney (R-FL), and U.S. Senators Tammy Baldwin (D-WI) and Mike Braun (R-IN). The bipartisan, bicameral legislation would require transparency from pharmaceutical manufacturers who increase drug prices by more than 10% per year or more than 25% over a three year look-back period and justification for each price increase, including manufacturing, research and development costs for the qualifying drug and other information that is deemed appropriate.

The Society also supports the Prescription Drug Sunshine, Transparency, Accountability and Reporting (STAR) Act, which includes the Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2019. The SPIKE Act requires manufacturers to report detailed information to the Secretary of the Department of Health and Human Services (HHS) for certain drugs if their prices exceed certain thresholds. Beginning in 2021, if a drug price increases by more than 10 percent or $10,000 over one year, 25 percent or $25,000 over three years, or has a launch price higher than $26,000, pharmaceutical manufacturers would be required to submit a justification for the price or price increase to the HHS Secretary. This justification would have to explain the causes of a price increase or high launch price, which could include information on expenses pertaining to developing, manufacturing, licensing, and marketing the drug. The STAR Act also includes language that would make information on PBM rebates public on the Department of Health and Human Service's website.

While these pieces of legislation have similar intent, the Society believes that the language in the FAIR Drug Pricing Act will go further to level the playing field in regard to information that people with MS need to make more informed choices. While the SPIKE Act requires the manufacturer (once a SPIKE is triggered) to submit information on individual factors that have contributed to the increase in the cost of the drug, the manufacturer would be able to make the determination on what factors have contributed to the price increase of the drug and submit information only on those factors. The Society's recommendations call for increased transparency in all levels of the prescription drug supply chain, so that all stakeholders are operating with the same information and we believe that the requirements outlined in the FAIR Drug Pricing Act move us closer to that goal.

Incentivizing generics in the MS market

The Society is concerned with anticompetitive practices that may be delaying the entry of lower

cost generics into the market and urges Congress to put an end to these practices. We support the Creating and Restoring Equal Access To Equivalent Samples Act (CREATES) Act, (S.340/H.R.965), which allows the FDA more discretion to approve alternative safety protocols, rather than requiring parties to develop shared safety protocols. It also creates a mechanism by which the generic manufacturers can seek a civil action against the brand company if that company refuses to provide samples within commercially reasonable, market-based terms. This legislation has bi-partisan, bi-cameral support, and we have urged Congress to swiftly pass it to ensure that bad actors cannot further delay needed therapies to the market.

Additionally, the Society believes that Congress should pass legislation that prohibits "pay-for-delay" settlements and other anticompetitive tactics that prevent lower-cost generic medications from coming to market. We support the Preserve Access to Affordable Generics and Biosimilars Act (S.64) from Senators Chuck Grassley and Amy Klobuchar. This bill would prohibit brand name drug companies and biologic manufacturers from compensating generic companies or biosimilar manufacturers to delay the entry of a generic drug or biosimilar into the market. According to a recent Kaiser Health News data analysis the FDA has approved over 1,600 generic drug applications since January 2017, yet more than 700 (43%) were not on the market as of January 2019.[vi] According to that same analysis, 36% of generics that would be the first to compete in the marketplace against the branded drug are not yet for sale. FDA approval is one important step to improving access to lower cost medications, but these products need to be available for patients and the healthcare system to benefit and we urge you to consider this legislation for inclusion in your larger drug pricing package.

The Society also supports the Biologic Patent Transparency Act (S. 659), sponsored by Senators Collins and Kaine. This bill aims to provide transparency around patents, promote competition in the biosimilar space in order to expedite lower cost biosimilar treatments. The Society believes that issues surrounding patents need to be examined more broadly, and we urge Congress to thoroughly examine patent issues and the role they play in high prescription drug costs. The Society believes that novel innovation and intellectual property must be protected in order to foster better therapies, but that protection needs to be balanced with the goals of the Hatch-Waxman act to ensure that after the protection period, that both biosimilar and generic therapies have an uninterrupted pathway to market.

Cap Out-of-Pocket Costs in Medicare Part D

The Society supports the RxCAP Act (S.475) from Senator Ron Wyden, which would cap out-of-pocket costs in Medicare Part D by eliminating cost-sharing for beneficiaries once they reach catastrophic coverage. The price of MS DMTs has skyrocketed in the 16 years since passage of the Medicare Modernization Act of 2003, which created the Part D drug benefit. As a result, so has the out-of-pocket costs for beneficiaries living with MS because co-insurance is tied to the price of the prescription drug. Given the current market for MS DMTs and prescription drug prices overall, Congress should update Medicare policy to reflect the growing out-of-pocket costs for Medicare beneficiaries and pass the RxCAP Act.

As we noted above in the MS experience, one generic manufacturer cut its list price in half, but due to other incentives in the system, this move had little to no impact on the costs to the system or, importantly, on patients' out-pocket-costs. One beneficiary with MS shared that

while researching a Medicare Part D plan for 2019, he found that his annual out-of-pocket burden varied only by $80 whether he chose the generic or brand- despite a more than $50,000 difference in the drugs' respective list prices. Therefore, we urge Congress to discourage mixing generics on brand tiers to better incentivize the use of these therapies.

According to a recent report, the average coinsurance for the MS DMTs in Medicare Part D is 30 to 33%[vii]. This could mean a monthly out-of-pocket cost burden of thousands of dollars for this treatment alone. Even the MS generic DMTs are often found on specialty tiers in Medicare, coming with co-insurance that offers no relief from overwhelming cost-share burdens. People with MS are frequently in the Part D catastrophic coverage phase in the first quarter of the year and their average annual out-of-pocket for their DMT alone is $6,000[viii] (See Appendix 3). Additional prescriptions to manage the symptoms of MS, rehabilitation and neurology services, periodic magnetic resonance imaging (MRI), laboratory tests, durable medical equipment needs, and other associated costs add to the ongoing financial burden of living with MS. The average one year direct medical costs per person with MS has been estimated as more than four times the amount compared to the general population.[ix] We also urge you to explore policies that would allow out-of-pocket costs for those with significant health expenses to be spread more evenly throughout the year so that they are not a disincentive to receiving treatment. This includes deductibles, co-pays, and co-insurance amounts, which often are a barrier to people getting the treatment they need.

Recommendations for a legislative package targeting increasing drug prices.
Drawing from the Society's recommendations, we urge Congress to put together a legislative package that makes medications affordable for those who need them. Any legislative effort must ensure that medications, and the process for getting them, is simple, affordable, and transparent.

We urge Congressional leaders to advance proposals that:

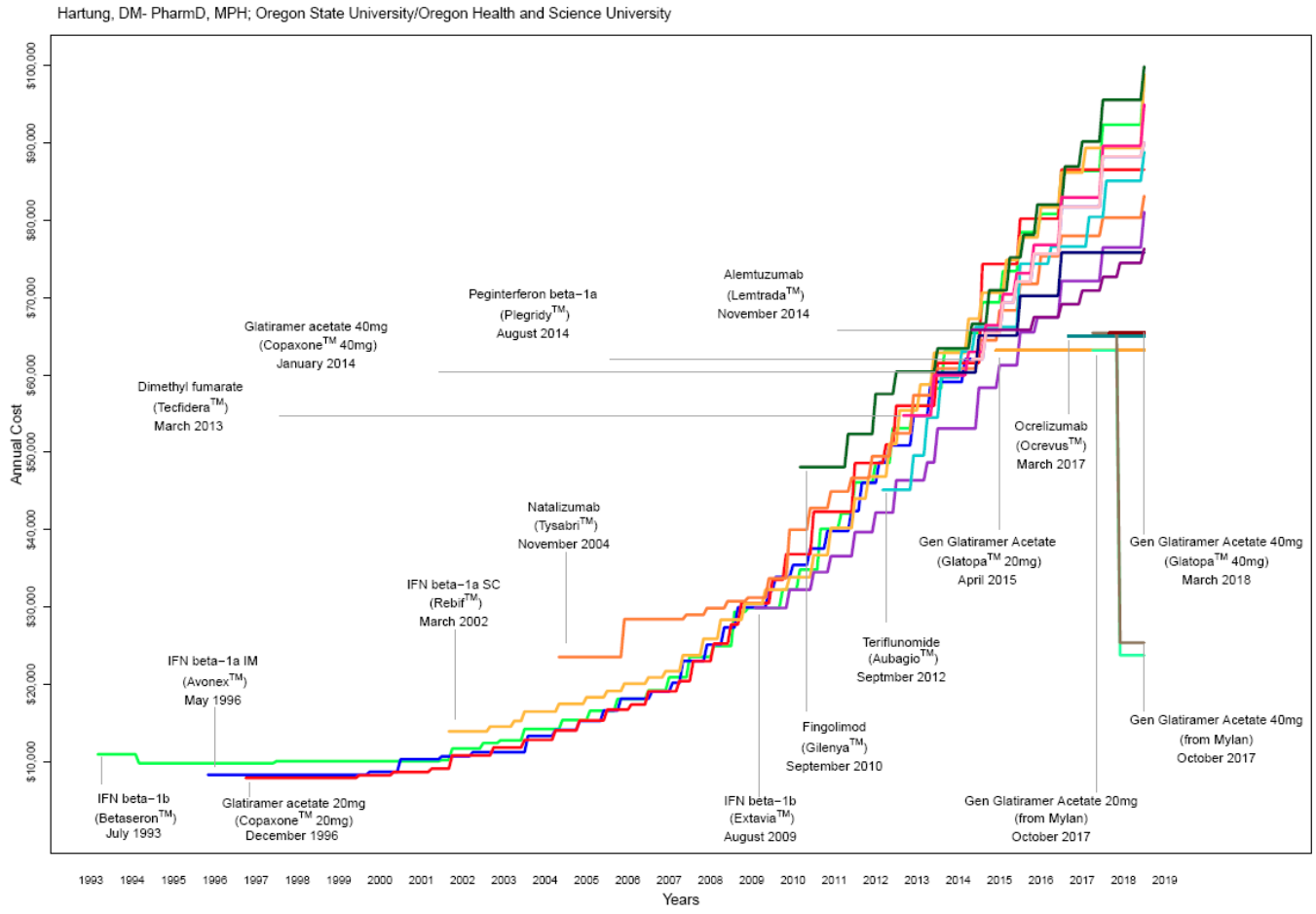
- Increase transparency from manufacturers, insurers and pharmacy benefit managers and require justification from manufacturers on price increases.
- Advance proposals that allow the federal government to act if price increases are found to be excessive or unjust.
- Require health plans to provide processes for both approvals and exceptions to utilization management protocols.
- Ensure any reform of the rebate system makes certain that the rebate is passed directly on to the consumer, regardless of whether that rebate occurs in person at a pharmacy counter or via a specialty pharmacy.
- Examine issues surrounding patent and market exclusivity that may be helping to keep prescription drug costs high.
- Cap out-of-pocket costs in Medicare Part D by eliminating cost-sharing for beneficiaries once they reach catastrophic coverage.
- Address anticompetitive practices that may be delaying the entry of lower cost generics and biosimilars into the market.

Thank you for the opportunity to provide the Society's perspective to inform your discussions around a larger drug pricing package. If you have any questions on our comments or need additional information, please contact Leslie Ritter at Leslie.Ritter@nmss.org or 202-408-1500.

Sincerely,

Bari Talente, Esq.
Executive Vice President of Advocacy
National MS Society

Appendix 1


Hartung, DM- PharmD, MPH; Oregon State University/Oregon Health and Science University
Annual Cost
$10,000
$20,000
$30,000
$40,000
$50,000
$60,000
$70,000
$80,000
$90,000
$100,000
1993
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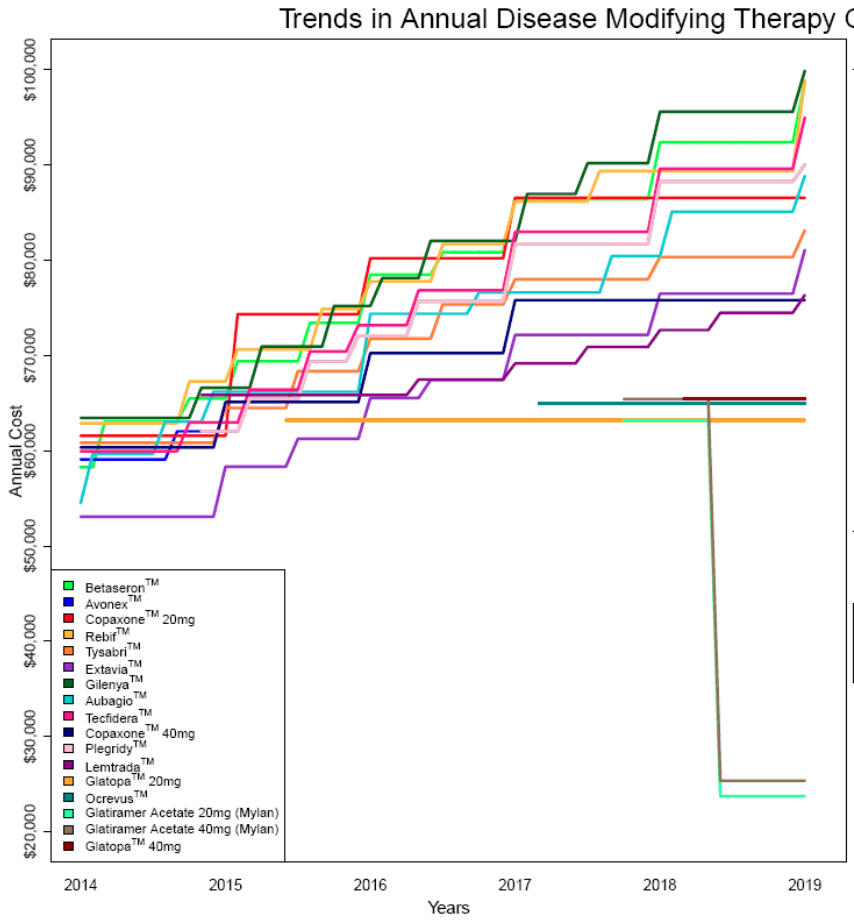
Years
IFN beta−1b (Betaseron™) July 1993
IFN beta−1a IM (Avonex™) May 1996
Glatiramer acetate 20mg (Copaxone™ 20mg) December 1996
Dimethyl fumarate (Tecfidera™) March 2013
Glatiramer acetate 40mg (Copaxone™ 40mg) January 2014
Peginterferon beta−1a (Plegridy™) August 2014
IFN beta−1a SC (Rebif™) March 2002
Natalizumab (Tysabri™) November 2004
Alemtuzumab (Lemtrada™) November 2014
IFN beta−1b (Extavia™) August 2009
Fingolimod (Gilenya™) September 2010
Teriflunomide (Aubagio™) Septmber 2012
Ocrelizumab (Ocrevus™) March 2017
Gen Glatiramer Acetate (Glatopa™ 20mg) April 2015
Gen Glatiramer Acetate 20mg (from Mylan) October 2017
Gen Glatiramer Acetate 40mg (Glatopa™ 40mg) March 2018
Gen Glatiramer Acetate 40mg (from Mylan) October 2017

Appendix 2



Drug	2019 Cost*	2014 Cost**
Betaseron™	$98,759	$58,265
Avonex™	$90,035	$59,085
Copaxone™ 20mg	$86,554	$61,567
Rebif™	$98,899	$62,873
Tysabri™	$83,152	$60,827
Extavia™	$81,079	$53,080
Gilenya™	$99,896	$63,444
Aubagio™	$88,853	$54,500
Tecfidera™	$94,991	$59,957
Copaxone™ 40mg	$75,816	$60,336
Plegridy™	$90,035	$62,036†
Lemtrada™	$76,346	$65,833†
Glatopa™ 20mg	$63,193	$63,193†
Ocrevus™	$65,000	$65,000†
Glatiramer Acetate 20mg (Mylan)	$23,725	$63,193†
Glatiramer Acetate 40mg (Mylan)	$25,350	$65,432†
Glatopa™ 40mg	$65,433	$65,433†

*January 2019
**January 2014
†Market entry cost if approved after January 2014

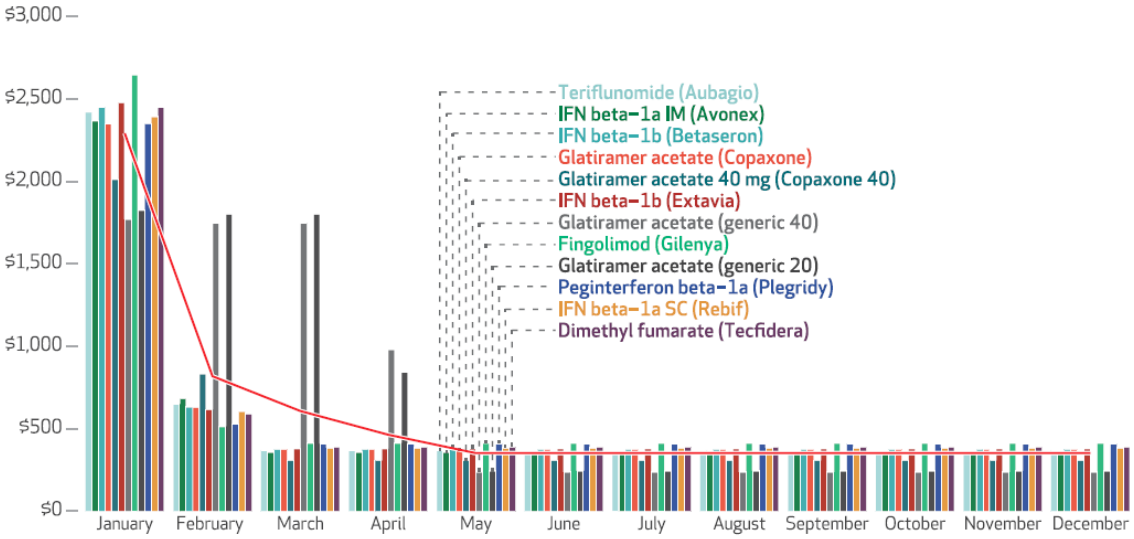
We estimated annual costs using wholesale acquisition cost. Package insert for Lemtrada™ states initial dose is five consecutive daily infusions with three consecutive daily infusions in subsequent year. We estimated the annual cost for Lemtrada™ based on the use of four vials.

Hartung, DM- PharmD, MPH; Oregon State University/Oregon Health and Science University

Appendix 3

EXHIBIT 4

Projected out-of-pocket spending for beneficiaries without a low-income subsidy for multiple sclerosis disease-modifying therapies, by month, 2019



SOURCE Authors' analysis of data from the Prescription Drug Plan Formulary files of the Centers for Medicare and Medicaid Services (CMS), and CMS enrollment data in 2016 (the most recent data available); and 2019 basic Part D benefit plan parameters. Drug prices are derived from the Medicare Plan Finder, using the nationwide plan that reported the lowest retail costs in the Portland, Oregon, metropolitan area. **NOTES** The solid line is average projected out-of-pocket spending across drugs. Appendix exhibit A6 shows details by drug (see note 20 in text). IFN is interferon. SC is subcutaneous. IM is intramuscular.

Hartung DM. Trends In Coverage For Disease-Modifying Therapies For Multiple Sclerosis in Medicare Part D. Health Affairs. February 2019. doi:10.1377/hlthaff.2018.05357

[i] Mitchell T. Wallin, William J. Culpepper, Jonathan D. Campbell, Lorene M. Nelson, Annette Langer-Gould, Ruth Ann Marrie, Gary R. Cutter, Wendy E. Kaye, Laurie Wagner, Helen Tremlett, Stephen L. Buka, Piyameth Dilokthornsakul, Barbara Topol, Lie H. Chen, Nicholas G. LaRocca. Neurology Mar 2019, 92 (10) e1029-e1040; DOI: 10.1212/WNL.0000000000007035

[ii] 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.

[iii] Hartung DM. Economics and Cost-Effectiveness of Multiple Sclerosis Therapies in the USA. Neurotherapeutics. 2017 Oct;14(4):1018-1026. doi: 10.1007/s13311-017-0566-3. **https://www.ncbi.nlm.nih.gov/pubmed/28812229**

[iv] Hernandez, Inmaculada et all. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." Health Affairs. Vol.38, No. 1. https://doi.org/10.1377/hlthaff.2018.05147

[v] 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.

[vi] Lupkin, Sydney and HJancock, Jay. Trump Administration Salutes Parade of Generic Approvals, But Hundreds Aren't For Sale. https://khn.org/news/trump-administration-salutes-parade-of-generic-drug-approvals-but-hundreds-arent-for-sale/. February 7, 2019. (Accessed February 28).

[vii] Hartung DM. Trends In Coverage For Disease-Modifying Therapies For Multiple Sclerosis in Medicare Part D. Health Affairs. February 2019. doi:10.1377/hlthaff.2018.05357 .

[viii] Hartung DM. Trends In Coverage For Disease-Modifying Therapies For Multiple Sclerosis in Medicare Part D. Health Affairs. February 2019. doi:10.1377/hlthaff.2018.05357

[ix]Campbell JD et.al, '*Burden of MS on direct, indirect costs and quality of life: National US Estimates'*, Multiple Sclerosis and Related Disorders (2013), March 2014 Volume 3, Issue 2, Pages 227–236