

# Make MS Medications Accessible: Recommendations



## Background

Multiple sclerosis (MS) medications have transformed the treatment of relapsing MS over the last 20 years. Yet, many people living with MS cannot access the medications they need. Continually escalating prices are creating significant barriers to treatment, including higher costs, increased stress, and a greater burden for those who already live with a chronic, life-altering condition.

Studies show that early and ongoing treatment with a disease-modifying therapy is the best way to modify the course of the disease, prevent the accumulation of disability and protect the brain from damage due to MS. So why are these life-changing medications too often out of reach for those who need them?

People with MS report high and rapidly escalating medication prices, increasing out-of-pocket costs, confusing and inconsistent formularies (the lists of medications an insurer will pay for), and complex approval processes that stand in the way of getting the treatments they need. These challenges can cause delays in starting a medication or changing medications when a treatment is no longer working. Delays may trigger new MS activity and cause even more stress and anxiety about the future for people already living with the complex challenges of an unpredictable disease like MS.

It is time for change. People with chronic illnesses need to know that they'll be able to get the life-changing medication they need. The National MS Society is launching our effort to make medications accessible, reflecting the needs of the MS movement and rallying all parties involved — pharmaceutical companies, insurance providers, pharmacy benefit managers, specialty pharmacies, healthcare providers, policy makers, people with MS and others — to work together to focus on getting people with MS the medications they need to live their best lives.

---

**Medications can only change lives if people can access them.**

**Medications and the process for getting them must be:  
affordable, simple and transparent.**

---

The campaign recommendations were developed by the Society’s **Advisory Committee on Access to MS Medications**, a group comprised of people with MS, family members, health policy experts and healthcare providers. They were informed by extensive stakeholder engagement and feedback, including a survey to gain the perspectives of more than 8,500 people with MS. The recommendations are comprehensive, address the challenges across many stakeholders, and provide the basis for conversations to create change. No single stakeholder has all the solutions; we can only find the solutions together.

## Contents

<b>Affordable</b> .....	3
Price.....	3
Insurance Plan Design .....	4
Market and Regulatory Considerations.....	4
Medicare .....	5
<b>Simple</b> .....	5
Get the Right Treatment to the Right Person .....	7
Stay on Treatment that Works .....	7
Simplify and Coordinate Paperwork and Processes.....	8
<b>Transparent</b> .....	8
Clarify how Relevant Information Can Be Shared.....	9
Transparency from Manufacturers .....	9
Transparency from Insurers and Pharmacy Benefit Managers.....	10
Transparency within the System .....	10
<b>Chart: Recommended Stakeholder Action</b> .....	11

## Affordable

The high prices of the MS medications make treatment for many people unaffordable and inaccessible. MS disease modifying therapies first entered the market in the 1990s priced between \$8,000-\$15,000 per year. Newer medications have commonly been introduced to the market costing 25-60% higher than existing therapies.<sup>1</sup>

Today, the average price of the MS treatments has increased nearly 400% since 2004. At the same time, insurance design increasingly moved from co-pays to co-insurance for specialty medications, with co-insurance for MS medications as high as 40%- which could be \$2,600 each month. On the health insurance exchanges created through the Affordable Care Act, more than 10% of silver plans have greater than 40% coinsurance for all the MS medications and nearly a third of plans place all covered MS therapies on a specialty tier. Reducing prices and limiting out-of-pocket costs will allow more people to access life-changing medications

### Price

Innovation in MS has changed the lives of many people living with MS. We need innovation to continue, while finding a better balance between innovation and affordability, so that people with MS can get the treatments they need in a timely and affordable way. Pricing medications and determining price increases is a complicated area that requires greater openness and recognition that price does impact access.

### Recommendations:

- Limit price increases for medications that have been on the market for a considerable time.
- Reduce prices for medications that have drastically increased in price since first entering the market.
- Pricing for new treatments to the MS market should consider research and development costs, the value of the medication from the perspective of people with MS and healthcare providers, how price impacts patient access to medications and other medications on the market.
- Value-based pricing should be explored and must include patient engagement in determining value for a lifelong, chronic disease like MS.

“The medication I am on is administered once every four weeks. It is extremely expensive and causes me to reach my deductible after only 1 dose and my out of pocket maximum after 2 doses. This puts a lot of financial strain on my family. This medication has proven to be very effective for me, but I am strongly considering changing medications due to the financial problems my family is now facing.”

## Insurance Plan Design

Specialty medications to treat a chronic disease like MS are expensive, yet crucial for people to live their best lives. A growing body of evidence suggests that higher cost sharing for specialty medications is associated with reductions in use.<sup>ii</sup>In a recent study of people with MS and health insurance, those who reported a negative insurance change in the previous 12 months had greater odds of not taking their MS medications.<sup>iii</sup> Out-of-pocket costs associated with insurance should not prevent someone from using the medication they and their healthcare provider decide is the best option.

### Recommendations:

- All available medications for a particular disease must not be on a specialty tier with co-insurance.
- Out-of-pocket costs should not be so high that individuals skip doses or abandon their medication entirely. Reduction in use and adherence data should be considered when determining out-of-pocket costs.
- Out-of-pocket costs for those with significant health expenses should be spread more evenly throughout the year so these costs are not a disincentive to receiving needed treatment and care.

## Market and Regulatory Considerations

Specialty medications do not follow a simple supply and demand economic model. Rather, product uptake is dependent on a complex economic supply chain and formulary design. Financial projections should take these factors into consideration and market expectations should be adjusted accordingly. Minor tweaks to existing products should not be afforded lengthy patent protections. Special incentives and possible regulatory intervention should occur when the free market does not appear to be working. When encouraging competition like generics or biosimilars, it should be recognized that multiple generics are required in the market before price is significantly impacted.

**“Without the financial assistance program, I would not still be on my medication. In 15 years, the same has gone from \$585 to \$5200 per month. How can they explain that?”**

### **Recommendations:**

- Incentivize multiple generics or biosimilars for a reference product.
- Increased HHS regulatory oversight of drug classes that do not fit the expectations of a competitive market.
- Eliminate lengthy patent protections for minor tweaks to existing products.

### **Medicare**

People with MS report significant difficulties affordably accessing their medications through Medicare. Cost sharing for brand name medications is increasingly in the form of co-insurance rather than a copayment. In 2016, 31% of Medicare prescription drug plan enrollees have co-insurance for preferred brand medications and 96% have co-insurance for non-preferred brand medications.<sup>iv</sup> In 2012, 96% of those on Medicare taking an MS therapy reached the catastrophic coverage limit, and nearly half did so by February.<sup>v</sup> While the trend in other types of insurance is to limit out-of-pocket costs, people on Medicare currently have no limit on their financial burden.

### **Recommendations:**

- Limit the out-of-pocket costs for prescription medications.
- Allow Medicare to negotiate prices for medications.

**“I have had MS since I was 21 and the financial burden has dominated my life. I have been in remission for much of this time (I am now 40) but the overall cost of medical coverage that would cover the cost of my medication, as well as the cost of it, has been an overwhelming driver of my lifestyle and major financial decisions... As a young person, I dreamed of entering the Peace Corps or travelling but could not pursue those dreams as I could lose my medical insurance and not be able to get my medication. I am glad to have my health but the cost of my medication has gone from \$700/month to over \$5,000.”**

## Simple

Getting your medication shouldn't feel like a full-time job. Living with MS is already difficult for individuals who often experience debilitating fatigue and cognitive challenges. Too often, people with MS report significant delays in getting their treatment and added stress and anxiety from having to navigate a complex web of uncoordinated systems, processes and entities in the healthcare system to get their treatment.

### **Make the Health Care System Work for the Person Who Needs the Medication**

The health care system should be designed for the ease of the person who needs the medication, so they can get their medication without stress or delay. Overwhelmingly, prior authorization requests are approved for MS medications, so simplifying and streamlining these processes just makes sense. Reducing paperwork and end of year burdens on both people with MS and their healthcare providers is a win for individuals and the health system alike. Large health offices report staff spend 20-30 hours per month on prior authorization, step therapy, appeals and other insurance coverage issues for people with MS.

#### **Recommendations:**

- Prior authorization should happen before the person with MS leaves the healthcare provider's office.
- A person with MS should have the option to get their medication from multiple pharmacies; requiring a single specialty pharmacy may not work best for that individual.
- Step therapy should make sense, and not result in detrimental delays in accessing appropriate medications. Individuals should not be required to fail on similar mechanisms of action, similar routes of administration or a medication they have failed previously.
- Prior authorization approval should be good for a lengthy time period, including across multiple years, as long as the person is stable on the medication.
- Allow multi-year approvals for patient assistance programs.

**"I worry the insurance companies or employers will tell the doctors to put me on a less expensive medicine. I do not want to change what is working."**



**National  
Multiple Sclerosis  
Society**

## **Get the Right Treatment to the Right Person**

MS is a heterogeneous disease and medications may work differently for individuals. Insurance and pharmacy benefit manager (PBM) coverage of the MS therapies is currently highly variable and based on rebate negotiations rather than expert advice, making it difficult for people with MS to move between plans. More consistency in coverage of MS medications across plans, with allowances for flexibility in finding the right treatment, would help simplify the system for people with MS and healthcare providers, and promote shared decision-making between a person and their healthcare provider. Today, the decision of which medication to use is often based on what's covered rather than what's best for the individual.

### **Recommendations:**

- Develop consensus prescribing guidelines, led by the MS healthcare provider community.
- Ensure insurance plan design promotes access to treatments, particularly for those with chronic conditions, with decisions based on medical evidence and patient-centered factors.
- Invest in research like precision medicine and biomarkers, to further understanding of which treatment works best for which individuals.

**“It took us over a month from the time my MS medication was prescribed to the time it was shipped to me. We had to personally coordinate between the physician’s office, the insurance company, the specialty mail order pharmacy our plan requires us to use for this drug, another group our insurance uses to complete prior authorizations, the regular mail order pharmacy for our insurance, and the manufacturer’s finance department”**

## **Stay on Treatment that Works**

Once a person with MS finds a medication that works, we should make it simple for that person to stay on their treatment.

### **Recommendation:**

- People should remain on a treatment that works for them regardless of changes in medication coverage and insurance plan changes.



National  
Multiple Sclerosis  
Society

## Simplify and Coordinate Paperwork and Processes

People with MS should not be overburdened by paperwork or be responsible for coordinating different entities to work together just so they can get their medication. We can simplify and integrate processes so there are no delays in getting medication and the person with MS is not overwhelmed.

### Recommendations:

- Develop a uniform patient assistance application for patient assistance/co-pay programs across the manufacturer and non-profit programs.
- Different entities involved in providing medications must work together to coordinate their interactions to increase efficiency and reduce the burden for the person with MS- including the insurer, pharmacy benefit manager, specialty pharmacy and patient assistance program.
- Reduce redundancies and develop integration in processes across stakeholders.

“The medication that I take is roughly \$6000 per month, or \$200 a day. Thanks to copay assistance from the drug company, my medication is more reasonable, but every January I have to reapply for the assistance and hope that I am approved. It is extremely stressful. I don't understand why a drug that helps people with their disease should or would cost so much.”

“The original medication my doctor prescribed was denied by my insurance company. My doctor felt my MS was very aggressive and wanted to start me on a higher end drug. The insurance company said it was a financial decision for them and denied the first and second drug my doctor tried to prescribe. She was then told what drug I was required to try. My treatment was delayed due to the denials resulting in permanent damage to my foot, leg and hand.”



## Transparent

There is increased pressure on all health care consumers to make good choices. Yet, people have very little information about price and cost to make these decisions. Just the term “price” can mean several different things. The prices charged for MS medications, the actual cost paid for them, and the impacting decisions between a manufacturer price and a negotiated contract with an insurer or pharmacy benefit manager, are outside of the public realm. People with MS need more information to make informed choices; and we all need greater information to improve the system.

### Clarify how Relevant Information Can Be Shared

Sharing of relevant information will allow stakeholders and individuals within the health care system to make better decisions. There are ways we can improve the information flow while keeping patient protections at the forefront.

#### Recommendations:

- Clarify regulations to permit greater pre-approval information sharing between manufacturers and payers.
- Clarify regulations to allow greater information sharing regarding post-approval evidence on clinical and economic outcomes.

### Transparency from Manufacturers

Innovation of new and better therapies is crucial and can be costly. People with MS support profitability for pharmaceutical manufacturers, but there must be a better balance between innovation and affordability. People with MS and others want to help find solutions, but to do so they need a greater understanding of research and development and other costs, as well as determining factors in setting price and price increases.

#### Recommendations:

- Greater information and transparency about:
  - How determining factors are used to set prices
  - How price increases are determined, including frequency of increases
  - How prices and price increases support research and development, direct-to-consumer advertising and marketing to healthcare providers
  - Numbers of people assisted and money spent on patient assistance support

“I hesitate to go on disease modifying drugs because of the cost. I work in the insurance industry and even if I have insurance coverage, the cost of these drugs is prohibitive and shifted one way or another. There needs to be much more transparency...”

## Transparency from Insurers and Pharmacy Benefit Managers

For people with MS, the formulary (list of approved medications) is the most important part of their health insurance coverage and a deciding factor in the health insurance plan they choose. Criteria for formulary decisions should be easily available and include factors that are important to people taking these medications.

### Recommendations:

- Formulary coverage, including cost-sharing, must be easily accessible, understandable and searchable (if online) when people with MS are choosing a plan.
- There must be a significant notification period of any changes in coverage in a single year and between plan years.
- Factors used in formulary decision-making should be transparent, and should include patient-centered factors.

## Transparency within the System

The system is driven by rebates, which are negotiations between some parties involved in the supply chain but not all parties. This makes it difficult to understand the true benefit to the person taking a medication.

### Recommendations:

- The public should be allowed greater understanding of the stakeholders engaged in rebate negotiations, of the factors involved in rebates and the benefits to different stakeholders.
- Rebate benefits should be directly passed on to the person taking that particular medication.
- Greater understanding and transparency of the varying prices across the system and internationally is needed.

“Our insurance decides each year what 6 - 8 MS drugs it will cover. So, while there are 14 available, that is not really an option. We must choose between those actually covered. In that list there are some that I would never choose so I am left with a choice of three or four options at best. So, it is not patient driven but cost driven.”

### Chart: Recommended Stakeholder Action

Many of the recommendations above could be implemented by multiple stakeholders. Some require Congressional or regulatory action, others are best achieved through a change in business practices by one or more stakeholders, and other recommendations could be implemented by business practices or public policy change.

Section	Recommendation	Stakeholder with Ability to Change
<b>Price</b>	Limit price increases for medications on market for a considerable time.	<ul style="list-style-type: none"> <li>• Pharmaceutical Manufacturers</li> <li>• Policy Makers</li> </ul>
	Reduce prices for medications which have drastically increased in price since first coming on the market.	<ul style="list-style-type: none"> <li>• Pharmaceutical Manufacturers</li> <li>• Policy makers</li> </ul>
	Pricing for treatments new to the MS market should consider research and development costs, the value of the medication from the perspective of people with MS and healthcare providers, how price impacts patient access to medications, and other medications on market.	<ul style="list-style-type: none"> <li>• Pharmaceutical Manufacturers</li> </ul>
	Value-based pricing should be explored and must include patient engagement in determining value for a lifelong, chronic disease like MS.	<ul style="list-style-type: none"> <li>• Government agencies</li> <li>• People with MS</li> <li>• National MS Society</li> <li>• Pharmaceutical Manufacturers</li> <li>• Insurers</li> <li>• PBMs</li> </ul>
<b>Insurance Plan Design</b>	All available medications for a particular disease must not be on a specialty tier with co-insurance.	<ul style="list-style-type: none"> <li>• Department of Health and Human Services</li> <li>• Policy Makers</li> <li>• Insurers</li> <li>• Employers</li> </ul>
	Out-of-pocket costs should not be so high that individuals skip doses or abandon their medication entirely. Reduction in use and adherence data should be considered when determining out-of-pocket costs.	<ul style="list-style-type: none"> <li>• Insurers</li> </ul>



Section	Recommendation	Stakeholder with Ability to Change
	Out-of-pocket costs for those with significant health expenses should be spread more evenly throughout the year so these costs are not a disincentive to receiving needed treatments and care.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• Employers</li> <li>• Policy Makers</li> </ul>
<b>Market and Regulatory Considerations</b>	Incentivize multiple generics or biosimilars for a reference product.	<ul style="list-style-type: none"> <li>• Government Agency</li> <li>• Policy Makers</li> </ul>
	Increased HHS regulatory oversight of drug classes that do not fit the expectations of a competitive market.	<ul style="list-style-type: none"> <li>• Government Agency</li> <li>• Policy Makers</li> </ul>
	Eliminate lengthy patent protections for minor tweaks to existing products.	<ul style="list-style-type: none"> <li>• Policy Makers</li> </ul>
<b>Medicare</b>	Limit the out-of-pocket costs for prescription medications.	<ul style="list-style-type: none"> <li>• Government Agency</li> <li>• Policy Makers</li> </ul>
	Allow Medicare to negotiate prices for medications.	<ul style="list-style-type: none"> <li>• Policy Makers</li> </ul>
<b>Make the Health Care System Work for the Person Who Needs the Medication</b>	Prior authorization should happen before the person with MS leaves the healthcare provider's office.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• PBMs</li> <li>• Policy Makers</li> </ul>
	A person with MS should have the option to get their medication from multiple pharmacies; requiring a single specialty pharmacy may not work best for that individual.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• PBMs</li> <li>• Policy Makers</li> </ul>
	Step therapy should make sense, and not result in detrimental delays in accessing appropriate medications. Individuals should not be required to fail on similar mechanisms of action, similar routes of administration or a medication they have failed previously.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• PBMs</li> <li>• Policy Makers</li> </ul>



Section	Recommendation	Stakeholder with Ability to Change
	Prior authorization approval should be good for a lengthy time period, including across multiple years, as long as the person is stable on the medication.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• PBMs</li> <li>• Employers</li> <li>• Policy Makers</li> </ul>
	Allow multi-year approvals for patient assistance programs.	<ul style="list-style-type: none"> <li>• Pharmaceutical manufacturers</li> <li>• Non-profit assistance programs</li> </ul>
<b>Get the Right Treatment to the Right Person</b>	Develop consensus prescribing guidelines, led by the MS healthcare provider community.	<ul style="list-style-type: none"> <li>• American Academy of Neurology</li> </ul>
	Ensure insurance plan design promotes access to treatments, particularly for those with chronic conditions, with decisions based on medical evidence and patient-centered factors.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• Policy Makers</li> </ul>
	Invest in research like precision medicine and biomarkers, to further understanding of which treatment works best for which individuals.	<ul style="list-style-type: none"> <li>• Government Agencies</li> <li>• National MS Society</li> <li>• Pharmaceutical Manufacturers</li> <li>• Policy Makers</li> </ul>
<b>Stay on a Treatment that Works</b>	People should remain on a treatment that works for them regardless of changes in medication coverage and insurance plan changes.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• PBMs</li> <li>• Policy Makers</li> </ul>
<b>Simplify and Coordinate Paperwork and Processes</b>	Develop a uniform patient assistance application for patient assistance/co-pay programs across the manufacturer and non-profit programs.	<ul style="list-style-type: none"> <li>• Pharmaceutical Manufacturers</li> <li>• Non-profit Assistance Programs</li> </ul>
	Different entities involved in providing medications must work together to coordinate their interactions to increase efficiency and reduce the burden for the person with MS - including the insurer, pharmacy benefit manager, specialty pharmacy and patient assistance program.	<ul style="list-style-type: none"> <li>• Healthcare Providers</li> <li>• Insurers</li> <li>• PBMs</li> <li>• Specialty Pharmacies</li> <li>• Patient Assistance Programs</li> <li>• People with MS</li> </ul>



Section	Recommendation	Stakeholder with Ability to Change
	Reduce redundancies and develop integration in processes across stakeholders.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• PBMs</li> <li>• Specialty Pharmacies</li> <li>• Patient Assistance Programs</li> </ul>
<b>Clarify how Relevant Information can be Shared</b>	Clarify regulations to permit greater pre-approval information sharing between manufacturers and payers.	<ul style="list-style-type: none"> <li>• Government Agency</li> </ul>
	Clarify regulations to allow greater information sharing regarding post-approval evidence on clinical and economic outcomes.	<ul style="list-style-type: none"> <li>• Government Agency</li> </ul>
<b>Transparency from Manufacturers</b>	Greater information and transparency about: <ul style="list-style-type: none"> <li>○ How determining factors are used to set prices</li> <li>○ How price increases are determined, including frequency of increases</li> <li>○ How prices and price increases support research and development, direct-to-consumer advertising and marketing to healthcare providers</li> <li>○ Numbers of people assisted and money spent on patient assistance support</li> </ul>	<ul style="list-style-type: none"> <li>• Pharmaceutical Manufacturers</li> <li>• Policy Makers</li> </ul>
<b>Transparency from Insurers and Pharmacy Benefit Managers</b>	Formulary coverage, including cost-sharing, must be easily accessible, understandable and searchable (if online) when people with MS are choosing a plan.	<ul style="list-style-type: none"> <li>• Insurers</li> </ul>
	There must be a significant notification period of any changes in coverage in a single year and between plan years.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• Policy Makers</li> </ul>
	Factors used in formulary decision-making should be transparent, and should include patient-centered factors.	<ul style="list-style-type: none"> <li>• Insurers</li> <li>• Policy Makers</li> </ul>



Section	Recommendation	Stakeholder with Ability to Change
<b>Transparency within the System</b>	The public should be allowed greater understanding of the stakeholders engaged in rebate negotiations, of the factors involved in rebates and the benefits to different stakeholders.	<ul style="list-style-type: none"><li>• Pharmaceutical Manufacturers</li><li>• PBMs</li><li>• Insurers</li><li>• Policy Makers</li></ul>
	Rebate benefits should be directly passed on to the person taking that particular medication.	<ul style="list-style-type: none"><li>• PBMs</li><li>• Insurers</li><li>• Employers</li><li>• Policy Makers</li></ul>
	Greater understanding and transparency of the varying prices across the system and internationally is needed.	<ul style="list-style-type: none"><li>• Pharmaceutical Manufacturers</li><li>• Insurers</li></ul>

<sup>i</sup> Hartung DM, Bourdette DN, Ahmed SM, Whitham RH. The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: too big to fail? *Neurology* 2015;84:2185-2192

<sup>ii</sup> Trish E, Xu J, Joyce G. Medicare Beneficiaries Face Growing Out-of-Pocket Burden for Specialty Drugs While in Catastrophic Coverage Phase. *Health Affairs* 2016: 35(9):1564-1571

<sup>iii</sup> Wang G, Marrie RA, Salter A, Fox R, Cofield S, Tyry T, Cutter G. Health insurance affects the use of disease-modifying therapy in multiple sclerosis. *Neurology* 2016;87:1-10

<sup>iv</sup> Hoadley J, Cubanski J, Neuman T. Medicare Part D in 2016 and Trends over Time. Kaiser Family Foundation. September 2016

<sup>v</sup> Trish E, Xu J, Joyce G. Medicare Beneficiaries Face Growing Out-of-Pocket Burden