

# September 2020 Newsletter



## The Rising Cost of MS Treatments

Disease-modifying therapies (DMTs) are treatments that can reduce the activity and progression of MS. They have been shown to reduce the frequency and severity of MS relapses. Unfortunately, continually escalating prices have created a significant barrier to obtaining these important medications for many individuals with MS.

Having an unpredictable progressive disease like MS is stressful on its own. For those living with the disease, the impact of cost on access to treatments only adds to an already taxing situation.



According to [researchers](#) at UCLA, MS is the second most expensive chronic condition (behind congestive heart failure) in terms of medical costs. In 2010, the total lifetime cost per patient with MS was estimated to be \$4.1 million. The high cost of DMTs contribute significantly to the total cost of care and the economic burden of this disease. A [2015 study](#) concluded [first-generation DMTs](#), originally costing \$8,000 to \$11,000, now cost about \$60,000 per year. Prices for these medications have increased annually at rates five to seven times higher than prescription drug inflation. They have also accelerated at rates well beyond inflation and substantially above rates observed for drugs in a similar biologic class. In addition, costs in the United States currently are two to three times higher than in

other comparable countries. Instead of driving down prices, competition has fueled the reverse. Newer DMTs have typically been introduced with a cost 25 to 60 percent higher than existing DMTs and the cost of existing DMTs has risen to meet them. A [recent study](#) suggests the cost of DMTs has increased even with the introduction of [generic drugs](#). For example, when [Glatopa](#) (the generic version of Copaxone) was introduced in 2015 the cost of the name brand drug increased by \$441 per prescription.



Last summer the National MS Society surveyed nearly 600 people with MS currently taking DMTs, then interviewed 15 of them in-depth to gain a more comprehensive understanding of their perspectives. Survey [results](#) shed light on the effects of the exorbitant cost of these drugs on people with MS.

Approximately 45 percent of respondents reported not paying anything out-of-pocket (OOP) for their DMT. The price for those who did pay was up to \$20,000 a year, with an average cost of about \$2,300. This is with 71 percent receiving financial assistance, mostly from pharmaceutical companies. The majority of participants indicated that without financial assistance the OOP cost would be a significant financial burden. One third of survey respondents indicated their OOP cost had increased over the past few years. It's important to note that the expenses associated with DMTs is only one piece of the financial picture for people living with MS. Copays for other medications, treatments and diagnostic tests, high health insurance premiums and deductibles, and lost income can also cause significant financial challenges.

Survey results suggest half of people living with MS are concerned about being able to afford their DMT over the next few years and 40 percent have altered their use of DMT because of rising prices. Only 11 percent said they could afford the medication without financial assistance. Many are going without or altering their treatment. For example, 12 percent of respondents reported stopping their medication for a time due to cost, 9 percent skipped or delayed filling a prescription and 8 percent have taken less than prescribed to stretch their drugs to last longer (to name a few). One third of respondents found the process of obtaining financial assistance to be taxing. They reported having to deal with such problems as excessive amounts of paperwork, countless hours on phone advocating for themselves or administrative delays in getting approval for treatment. Half had to go through the same stressful process to reapply/renew every year. Funding



sources are often exhausted quickly, leaving the very real possibility that these efforts might be in vain.

The NMSS survey suggests paying for DMT also affects quality of life for those living with MS. For instance, participants indicated it impacts their ability to save for college for their children or retirement for themselves and some must resort to paying these costs by using credit cards. When it comes to paying other bills, 9 percent had to put off paying some of them and 11 percent had to cut corners on groceries. A quarter said they spend less on themselves because of the money their medications cost their family, and 21 percent have cut back on entertainment or dining out.



[iConquerMS](#) is a key resource that has been used to understand the perspective of people with MS in this evolving situation. A [recent study](#) surveyed 1,200 network members about their preferences and willingness to pay (WTP) for DMTs. The majority of participants had relapsing-remitting MS. WTP was defined as the maximum amount of money subjects were willing to spend from their OOP money, based on various DMT attributes (relapse rate, disability progression, severe adverse events, route of administration, frequency of administration, and OOP cost). The WTP for DMTs varied widely. There was a strong preference for having DMTs over foregoing therapy. Participants preferred DMTs with lower relapse rate, disability progression, severe adverse event, frequency of administration, and cost. In addition, they preferred oral DMTs. The next preference was intravenous DMTs, followed by subcutaneous and intramuscular DMTs. Data showed participants were willing to pay for the attributes of their DMTs, specifically \$2,768 for every one-time decrease in the number of relapses in two years, \$289 for every one percent decrease in disability progression in two years, \$292 for every one percent decrease in severe adverse events, and \$76 a month for every one-time decrease in the frequency of administration per month. Interestingly, iConquerMS members were willing to pay between \$7,020 and \$134,934 per year for all DMTs, except [interferon beta-1a SC](#) (Rebif). This exception was due to Rebif's relatively high relapse rate and disability progression compared to other DMTs. Respondents also did not like having to administer Rebif three times per week via subcutaneous injection.

Although MS DMTs have been shown to be very effective in slowing the progression of the disease and managing its symptoms, the costs of these agents is problematic. The improved efficacy and safety profiles of newer treatments may provide an invaluable benefit to people with MS, however there is evidence that their high price tag is driving up the cost of older DMTs. The introduction of generics into the market has not offered those living with MS lower priced options. These escalating prices are creating barriers to people with MS getting these important medications and affecting their quality of life.

Change is needed to make these treatments affordable and accessible so people living with MS no longer have to make financial and personal sacrifices in order to obtain their medications. In the meantime, please [read on](#) for more information on financial assistance programs that may help.



### **Financial Help for MS Medications**

The most common ways people with MS pay for their prescription medications in the United States are through commercial or private insurance (which is typically obtained through one's employer), publicly or government-funded insurance (such as Medicare and Medicaid), or patient assistance programs for the uninsured. Even with insurance, many have substantial out of pocket costs for their treatments. A surprising number of plans pay nothing for prescription medications or have extremely high copays or deductibles. It's easy to see how paying for these expensive medications could break the bank for many families. Thankfully, there are numerous resources that can help.



Since the Affordable Care Act went into effect in 2014, people in the United States with pre-existing conditions like MS can no longer be denied health insurance. Many formerly uninsured people now have health insurance as a result of this law and help with the cost of premiums is available to low and middle-income families. The [Health Insurance Marketplace](#) is a service that helps people without coverage shop for and enroll in affordable health insurance. The federal government runs the Marketplace in most states. The federal program can be accessed by visiting [HealthCare.gov](#). Some states don't

participate in the federal program and run their own Marketplaces instead. These states include California, Colorado, Connecticut, District of Columbia, Idaho, Maryland, Massachusetts, Minnesota, Nevada, New York, Rhode Island, Vermont and Washington. Individuals in these states must visit the [state's website](#) in order to apply for and enroll in health coverage. People with MS who cannot work due to MS-related disability may also be entitled to Social Security Disability Insurance (SSDI) and possibly also Supplemental Security Income benefits. Information is available on the [Social Security website](#), or individuals can check with their healthcare provider to see if they qualify based on their level of disability.



For the uninsured or underinsured, most manufacturers of MS medications have patient assistance programs that supply medication to eligible individuals free of charge. These

programs have eligibility requirements that are usually based on income. In general, they are available to those without insurance, individuals with Medicare (who, for example, have extremely high, unaffordable copays), or those whose insurance has denied coverage for a particular treatment. The vast majority of those without health insurance are approved for free drug. Additionally, each drug company also has their own manufacturer support program which offers a variety of services that are available whether an individual has insurance or not. For example, Biogen's program is called [Above MS](#) for those taking Tysabri, Avonex, Plegridy, Tecfidera or Vumerity, Sanofi Genzyme offers [MS One-to-One](#) for those taking Aubagio and Novartis runs the [Gilenya Go Program](#) and the [Alongside Mayzent](#) program. The [National MS Society](#) and the [Multiple Sclerosis Association of America](#) both maintain a comprehensive list of patient assistance programs for many medications. Services these programs offer may include in home or over the phone nurse injection training for injectables, access by phone to nurse educators for questions about the medication or about MS in general. Individuals may also be assigned a patient navigator or coordinator who can answer questions and check on them during treatment.

The process of accessing these resources is relatively straightforward. All MS medications have what is generally referred to as a start form, which needs to be submitted to access the manufacturer support program for the specific medication a person is starting or currently taking. Start forms can be downloaded from the medication's website and are also available in most MS clinics. Each form has a section for the patient to fill out and a section for the provider to complete. Individuals receiving care at smaller community-based clinics (which may not have start forms available) can print it at home, complete the patient section and give it to their doctor to finish and submit.



Drug manufacturers offer [copay cards](#) as a direct way to lower out of pocket costs for prescription medications for individuals with commercial or private health insurance. Copay cards are usually not need-based. They often have monthly caps or maximums for the amount of money they

will contribute toward a copay. They often require a person to re-enroll after a year or at the end of each calendar year. Some health insurance plans require extremely high deductibles that may be unaffordable. To provide assistance with this, manufacturer assistance programs also offer debit cards that can be applied toward one's deductible. Eligible individuals can enroll in these programs by filling out the start form discussed above.



There are a number of private foundations that provide direct financial assistance to those who cannot afford their prescribed medications. They each have their own requirements (typically income-based). Many require applicants to have some form of insurance but there can be restrictions on the type of insurance. Most programs require individuals to receive treatment in the United States and must be renewed each year. They offer a variety of benefits, from copay and coinsurance premium assistance to case

management services and reimbursement for travel expenses. The application process is different for each foundation. In general, it is quick and easy. Individuals can apply online or over the phone, or a pharmacy or provider's office can do it on their behalf (with their permission). Applicants are usually informed of their eligibility instantly, so patient care and access to medications isn't delayed. A foundation will usually grant a certain amount of money and when the grant runs out it can be renewed as long as there are still funds available and individuals still meet the eligibility requirement for assistance.



### **Private Foundations**

[Patient Assistance Network Foundation](#) (PANF) is only available to those with Medicare insurance. They offer financial assistance for all MS disease modifying therapies (except Rituximab), relapse medications, and medications for MS symptoms. Benefits also include case management services and reimbursement for travel expenses. Of note, PANF has a 90-day look back period which covers expenses applicants may have incurred in the 90 days prior to approval.

[HealthWell Foundation](#) is available to patients with either private or publicly funded insurance. They manage a diverse portfolio of [disease funds](#) and provide financial assistance for prescription copays, health insurance premiums, deductibles and coinsurance, pediatric treatment costs and travel expenses.

[Good Days Foundation](#) also offers financial assistance for copays, healthcare premiums, diagnostic testing and travel expenses. They cover a variety of [health conditions](#), including MS. To be eligible, individuals must have Medicare, military or federal medical insurance and 50% of the medication must be covered by insurance.

[Patient Advocate Foundation](#) offers financial assistance, patient education and case management services. Eligible individuals must be currently insured (Medicare, Medicaid or military benefits) and have some coverage for the medications for which they need assistance. In addition, applicants must be either currently on treatment, planning to begin treatment in the next 60 days or have been treated in the past 6 months.

[The Assistance Fund](#) is an open fund, meaning there are no limits on the assistance amount. The Assistance Fund provides financial assistance for copayments, coinsurance, deductibles and travel expenses. They currently manage nearly 70 disease programs, including MS. To be eligible, individuals must have health insurance that covers a portion of their MS treatment.

Foundation assistance is always subject to the availability of funds and there is no guarantee money will be available. These funds open up sporadically throughout the year, sometimes for a very short time because they are depleted quickly. Applying for this type of financial assistance can be hit or miss, success often requires being in the right place at the right time. PANF created a helpful, free resource called [Fund Finder](#) that increases the chance of success. This service pulls information about each disease program's status from the foundation websites and allows anyone interested in obtaining this type of assistance to sign up for a text and/or email notification to let them know when a fund opens up so they can apply right away.



PANF also recently launched the [Disease Fund Waitlist](#), which allows people to get in line for assistance from a closed fund at PANF. This feature gives those on the wait list the first opportunity to apply for assistance when a fund opens (before the general public). Individuals can add themselves to the waitlist, or be added by their healthcare provider, pharmacist or caregiver. Enrollees must provide a valid email address when they sign up. Those on the waitlist are notified by email when funding becomes available for a specific disease state. Once notified, they have two business days to apply and are told within four business days whether or not they will receive a grant. Those not receiving assistance because funding runs out stay on the waitlist and move closer to the top for the next time the funding becomes available.



[NeedyMeds](#) is another free, online resource for people who are unable to afford their medications and health care costs. This is a one stop shop that provides all of the options for assistance for a specific medication (manufacturer assistance programs and private foundations). NeedyMeds also offers a pharmacy discount card that will lower the cost of certain medications. One thing to note, NeedyMeds will provide information on all available resources, regardless of whether or not they are open. The PANF's Fund Finder provides more specific information concerning when foundation funds open.

The process of obtaining financial assistance for MS treatments is not simple and it can be difficult for individuals to know the ins and outs of the process. The National MS Society

has a team of [MS Navigators](#) in place to help with questions or concerns about paying for medications, changes in insurance coverage and other issues. Private insurance companies also may have representatives that can advise clients with chronic conditions, such as MS, on healthcare coverage and costs. Employers can provide the contact information of a representative, or it's also possible to contact the insurance company directly to find out who to talk to. Some MS clinics have someone on staff who's familiar with insurance issues and financial assistance programs. Individuals can also ask their physician or pharmacist who they can call for financial assistance.

Lisa Aquillano is a clinical pharmacist and Multiple Sclerosis Certified Specialist at Emory Healthcare in Atlanta. She works as a liaison in their outpatient MS Clinic to help manage the treatment for MS patients. In her words, "In addition to providing education to my patients about their medication, my favorite part of my job is to help patients gain access to their much-needed MS medications." When asked if she has any suggestions or tips to help make the process of obtaining financial assistance easier, she shares, "Contact the National MS Society and connect with an MS Navigator. These professionals help connect patients to the information, resources and support they need. There are so many resources available to patients with MS, and the MS Navigator Program will point you in the right direction based on your specific situation. In addition, it takes a lot of advocacy on the patient's part. Be your own advocate. Know that there is assistance available and ask your MS Navigator to help you find it. The manufacturer support programs are also extremely helpful. Make sure to fill out the start form, and have your provider fill out their portion, because it is going to start the process of getting you connected with all the resources available for that specific medication like copay cards, patient assistance programs and much more. If a patient applies for a grant with a private foundation or free drug from a manufacturer and gets denied, the patient can often appeal the denial. I've written letters of financial hardship for patients, sent them with the application, and the patient often gets approved. Patients can ask their provider's office for this type of application assistance. Even some specialty pharmacies have financial assistance programs to help patients afford the out of pocket costs of their medications. Again, be your own advocate. If someone tells you no or you get denied for assistance, be persistent and keep asking questions. Sometimes just talking to someone different will give you a whole different answer."



Living with MS and struggling with its symptoms is stressful in and of itself. Dealing with the costs of healthcare and MS treatments can add to that stress for those living with the disease. Fortunately, a number of financial and patient assistance programs are available to help. However, the person with MS, their friend or family member, will likely need to be a strong, persistent advocate to obtain the help they need. Knowing what's out there, understanding the process and taking full advantage of any programs individuals are eligible for may relieve financial strain, help them feel more supported and allow them to focus more on things they enjoy.



## September 2020 Research Spotlight

### **EVENTS**



## A New Podcast Series for People with MS

EMD Serono, in collaboration with Accelerated Cure Project, has released the first three podcasts in a 5-part educational podcast series, hosted by Jon Strum, called "Uncovering Sex in MS: A Dialogue About Sex, Parenthood and Hormones." The topics covered in the

podcast series were developed based on input from the [iConquerMS](#) community – another example of how iConquerMS members are driving and shaping MS research and care!

Women are nearly 3 times more likely to develop MS than men. Because the majority of these women are diagnosed during their childbearing years, clinicians and patients are encouraged to incorporate family-planning discussions into their ongoing MS management conversations. Optimal patient care involves coordination among a woman's neurologist, obstetrician/gynecologist, and primary care provider to ensure alignment on the woman's individual family-planning choices and preferences.

[Episode 1](#) features 3 unique perspectives on preconception planning for women with MS: Dr. Lori Travis, a neurologist who specializes in treating patients with MS; Dr. Erkan Buyuk, a reproductive endocrinologist, and Ms. Shannon Green, a pregnant woman living with MS.

Family planning is not just a concern for women with MS. Men with MS also need to be involved in these discussions. They have different concerns about fertility and pregnancy than women with MS. Thus, optimal MS care involves coordination and communication among a man's neurologist and other care team members, such as reproductive endocrinologists and urologists.

[Episode 2](#) features 3 unique perspectives on preconception planning for men with MS: Dr. Lori Travis, a neurologist who specializes in treating patients with MS; Dr. David Ryley, a reproductive endocrinologist with experience in treating men with MS; and Mr. Josh Evitt, a male patient with MS who has experienced fertility concerns during the family-planning process.

For pregnant women with MS, preparing for the birth of a child can be a time of excitement and anxiety. Each woman should work closely with her neurologist and other care team members to determine how best to manage her MS in the postpartum period. In addition to postpartum disease management, postpartum depression should also be assessed, because although the data are limited, it appears that new mothers with MS may have an increased risk of postpartum depression.

[Episode 3](#) features 3 unique perspectives on postpartum planning for new mothers with MS: Ms. Melanie Huff, a nurse practitioner who specializes in MS; Dr. Adam Kaplin, a

mental health specialist; and Lindsey, a mother with MS who has first-hand experience with the postpartum period.

Stay tuned for future episodes!

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## RESEARCH OPPORTUNITIES



### New Year, New You

**Study Title:** Step for MS (Supervised versus Telerehab Exercise Program for People with Multiple Sclerosis)

**Study Purpose:**

New research shows that exercise is good for people with MS and may decrease symptoms and improve health and walking ability. An exercise study called *STEP for MS* will compare the outcomes of a 16-week exercise program conducted at home to a program conducted in a gym. The researchers conducting the study hope that the findings will make exercise and its benefits more available to people with MS who have problems walking.

**This Study Involves:**

Participants will exercise two times per week for about one hour each session for 16 weeks. A trained “coach” will help participants learn how to exercise and will provide encouragement throughout the program. Participants will take assessments before starting the program, two months into the program, at 16-weeks when the program ends, and at 6 and 12 months after starting the program.

## Eligibility:

If you are between the ages of 18 and 65 years and you have Multiple Sclerosis you may qualify if you:

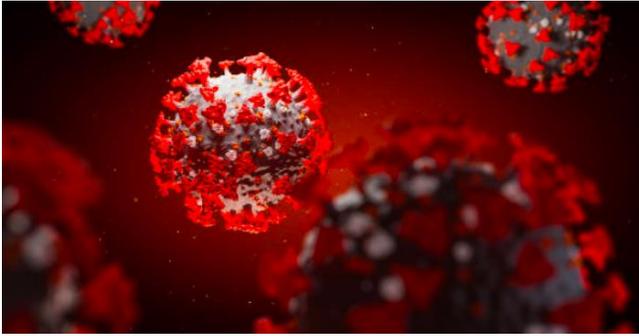
- Can **walk** but you have **some difficulty**, with or without a device
- **Do not exercise** regularly
- Have not had a **relapse** in the past month
- Can commit to **train 2 times a week for 16 weeks**
- Can **drive to study site** for assessments and potentially for exercise training
- Have reliable **internet access**

## Participating Locations:

- Massachusetts General Hospital, Boston, MA (**new site now open!**)  
**Contact:** Dr. Plumer 617-724-3103 / [PPlummer@MGHIHP.EDU](mailto:PPlummer@MGHIHP.EDU)
- Shepherd Center, Atlanta, GA  
**Contact:** Erica Sutton at 404-367-1305
- Cleveland Clinic, Mellen Center, Cleveland, OH  
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- University of North Carolina, Chapel Hill  
**Contact:** Rachel Keen at 704-877-5636 / [rayray@live.unc.edu](mailto:rayray@live.unc.edu)

For more information, please visit our

website: <https://www.iconquerms.org/welcome-step-ms>



## **Share your experience with COVID-19**

As a supporter of Accelerated Cure Project, you know one way to deal with the uncertainty of MS is to **act** – to be proactively involved in research and to contribute your insights, expertise, and information so that key questions about MS may be answered.

The COVID-19 crisis has added an additional level of complexity and urgency for those affected by MS.

**In response, we have launched a survey on iConquerMS to learn more about how people affected by MS are dealing with the COVID-19 pandemic and what their personal experience has been with COVID-19.**

**We are interested in responses from all – those with and without MS, whether or not you have been diagnosed with COVID-19 – and hope the information gathered through this survey will help people affected by MS and their doctors during the current pandemic and in the case of future viral outbreaks.**

Participating in the COVID-19 in MS study is easy. If you are not already a member, please consider [joining iConquerMS](#). Your voice matters! Already a member? Please [login](#) to your account and complete your COVID-19 survey. Thank you for your participation!

## NEW RESEARCH RESULTS



The US Food and Drug Administration (FDA) recently approved [Kesimpta®](#) (ofatumumab) for the treatment of relapsing forms of MS in adults, including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. Kesimpta is the first B-cell therapy that can be self-administered subcutaneously once monthly at home. Approval is based on results from the [ASCLEPIOS I and II studies](#) in which Kesimpta was shown to be more effective than teriflunomide in reducing relapse rate, disability progression, and the number of lesions on MRI. Kesimpta is now available in the United States.