Disease-Modifying THERAPIES FOR MS

SUSAN, DIAGNOSED IN 1988

National
Multiple Sclerosis
Society

Most people recently diagnosed with MS are interested in learning as much as possible about available treatments. The chapter on **Treating Yourself Well** covers ways to manage symptoms and support your overall health. Your physician may already have recommended some of these strategies to you. This chapter includes information about the disease-modifying therapies (DMTs) for MS — those treatments that have been shown to alter the rate and/or extent of disease activity and progression.

Changing the course of MS

Since 1993, the U.S. Food and Drug Administration (FDA) has approved many medications for use in multiple sclerosis. These medications do not cure MS, and they're not designed to provide relief from current symptoms — in fact, the effects on the disease may not be immediately apparent. However, each of these medications has been shown in large-scale, placebo-controlled, double-blind clinical trials to provide significant benefit for people with relapsing forms of MS.

Because the number of treatment options for MS change so rapidly, this chapter does not include specifics about each DMT, but will answer many of the most common questions people have. Stay in close contact with your doctor for the most up-to-date information. The Society is also a source of information on new developments.

The Society's **Disease-Modifying Therapies for MS** publication is updated regularly with the most current list of approved therapies, including their method of administration, common side effects and risks, and financial assistance resources. The brochure is available at **nationalMSsociety.org/DMT**.

Common questions about disease-modifying therapies

What is the goal of treatment with a DMT?

There are several goals of disease-modifying therapies, including:

- reducing the number of relapses
- limiting new inflammatory activity in the central nervous system (CNS), as seen on magnetic resonance imaging (MRI)
- delaying progression of disability

Who should take a DMT?

The available DMTs are approved for people with relapsing forms of MS, which include relapsing-remitting MS as well as progressive forms of MS if the person is experiencing relapses. None of the medications are approved for use in people with primary progressive MS who have experienced no relapses. The medications are approved for relapsing forms of MS because they primarily target inflammation, which is more common in relapsing forms of MS.

How are the DMTs administered?

The DMTs are administered in a few different ways — some are taken by injection, others are taken by mouth in pill form, and still others are infused directly into the vein. The frequency varies as well, from once or twice a day to monthly or even less frequently.

How do these medications work?

The inflammatory process that causes damage within the CNS occurs in multiple steps that involve many different immune cells, processes and chemical messengers. The DMTs aim to modify, block or suppress this inflammatory process with the goal of reducing relapses and delaying disability progression. While all of the medications work to reduce inflammation, they do so through different mechanisms of action — which means that if a medication is not providing adequate control of a person's disease activity, another medication with a different mechanism of action can be tried.

Why should one start treatment early?

Substantial evidence from clinical research has demonstrated that early and ongoing treatment with a disease-modifying therapy is the best available strategy for limiting new disease activity and progression of disability in relapsing forms of MS. These medications have been shown to have greatest benefit early in the disease when the inflammatory process tends to be most active. Read more from the MS Coalition at **ntl.ms/coalitionDMTsummary**.

Which is the best therapy?

The "best" therapy is the one that effectively limits disease activity and accumulation of disability for an individual with the fewest side effects. A person must be able to tolerate the medication well and adhere to the administration schedule in order for the treatment to be effective. The best medication for a person at one point in time may not be the best for that person at a different point in time. Work with your healthcare provider to choose a treatment that will best meet your current needs, and then change to another option if the goals of treatment are not being met.

What are the side effects of DMTs, and how will they impact my daily life?

The side effects of the DMTs vary in type and severity — and individual tolerance for them will vary as well. Most people are able to take the medications comfortably with minimal or no negative impact on daily life. If side effects persist in spite of efforts to limit their impact, and interfere with personal comfort and quality of life, you may want to consider switching to another DMT. The goal is to find a treatment that provides optimal benefit and that you can comfortably take on a consistent, long-term basis.

What are the risks associated with these medications?

Like side effects, risks vary among the DMTs. Since DMTs target the immune system, some of them can increase the risk for certain types of infections and possibly other immune system problems — which can range from relatively mild to quite serious. Some DMTs can also impact other body systems such as the cardiac or respiratory systems, so they may not be appropriate options for people who have certain other health conditions. Your healthcare provider will carefully review your health history in order to determine which of the DMTs might be the best options to consider. Most of the DMTs require periodic blood tests to monitor for risks. Discuss the potential benefits and risks of a therapy, as well as any periodic monitoring that may be necessary, before beginning treatment.

When evaluating the potential risks of treatment, it is also important to consider the risk of the disease itself. Not treating the disease, or treating it with a medication that is not optimally effective, puts a person at significant risk of uncontrolled disease activity (more relapses and lesions on MRI), disease progression and the accumulation of disability.

None of these medications are approved for use during pregnancy or breastfeeding. Discuss with your healthcare provider when to stop each of these medications before trying to conceive. Men should also discuss treatment options before trying to conceive.

How can my doctor and I evaluate the potential benefits of these medications for me versus their risks?

After initiating treatment with a DMT, your healthcare providers will want to see you regularly to evaluate your neurological function and to hear how you have been doing since your previous visit. He or she is specifically looking for evidence of new clinical activity (new symptoms, or worsening symptoms) that would suggest a sub-optimal response to the DMT. Periodically your neurologist will also order an MRI of the brain (and sometimes the neck or back). Should there be new or enlarging lesions, and/or new clinical activity, you and your healthcare provider may want to consider switching to a different DMT.

Will the treatment make my symptoms go away?

The role of DMTs is more preventive — to reduce relapses and inflammation in the CNS, and delay disability. They do not treat symptoms and are unlikely to change any symptoms you are experiencing. It is best to think of these medications as an investment in the future — reducing disease activity now in order to limit progression and disability in the future.

How will I know if the DMT is working?

While the DMTs are not a cure for MS, an optimal outcome would be disease stabilization — meaning few or no relapses, no worsening of disability and no new MRI activity.

Will I have to have blood tests or other monitoring done?

Nearly all of the DMTs require periodic blood tests to monitor blood cell counts and liver function. In addition, periodic MRIs will be used to monitor for new MS activity. Several of the DMTs will require other types of testing as part of ongoing safety monitoring. Discuss this monitoring with your healthcare provider to ensure that you adhere to all recommended and required testing.

How often do I need to have an MRI while I'm on treatment?

It is likely that you will have regularly scheduled MRIs while you are taking a DMT. The MRI allows your doctor to "see" inside of your brain and identify any new areas of MS activity — even if you have not had any new or worsening symptoms. This activity without symptoms is called "sub-clinical" activity and is important to watch for as it contributes to the overall MS disease process and may signal that the DMT is not adequately controlling disease activity.

How often do I need to be seen by someone while I'm on treatment?

You should be seen on a regular schedule so that your healthcare provider can assess your response to the treatment as well as your ability to tolerate any side effects you may be experiencing. For many neurology providers, the frequency of follow-up appointments is every 3–6 months. However, there are no set rules or standards for the frequency of follow-up visits with your provider.

My friend is taking a different medication than I am and is doing really well; why aren't I on that medication?

It is tempting to compare treatments and response to treatment with other people living with MS. However, MS affects every person differently, and individual response to treatment varies widely. Therefore a treatment that may be optimal for your friend may not be right for you, and your tolerance for various side effects may differ as well.

Why are these therapies so expensive?

The DMTs are highly specialized medications that generally require complex and costly manufacturing processes. For each medication that comes to market, there are many that did not make it through the lengthy, multi-step clinical trial process, which means that the medications that come to market must help to pay for those that do not. In addition, reinvestment into the company's research pipeline requires significant financial resources. The manufacturers provide assistance programs to help ensure that people who need the DMTs have affordable access to them. **nationalMSsociety.org/DMTassistance**

Will I be able to afford my DMT?

Insurance benefits vary considerably, which means that people often pay very different amounts for the same medication or have access to only some of the medications. Most insurers provide coverage for DMTs, although most limit the number of therapies they cover or require that a person try certain therapies before they can get coverage for others. Medicare, in particular, changes frequently. It is important to find out what your insurance company will cover now,

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and what the co-pay or co-insurance is for a particular DMT. A Society MS Navigator® (1-800-344-4867) can provide information about how to access financial assistance for your DMT.

Are there any natural or alternative therapies that can be used to treat MS?

At the present time, there are no natural or alternative therapies that have been shown in large-scale controlled clinical trials to be effective in treating MS. Only the medications listed here: **nationalMSsociety.org/DMT** have demonstrated ability to reduce MS relapses and slow disease progression.

The world of complementary and alternative medications (CAM) and treatments is enormous and little is known about the effect of these interventions on the MS disease process or on MS symptoms. Treatments are referred to as "alternative" when they are used **in place of** any conventional medication or treatment, and "complementary" when they are used **along with** conventional treatments or medications. Although many people and websites champion various treatments, evidence for their effectiveness and safety is often limited.

The Society's brochure, **Clear Thinking about Alternative Therapies** discusses some common CAM. It is important to evaluate complementary or alternative treatments by learning about them from reputable sources, and discussing with your healthcare provider.

What other strategies are available to help people manage their overall health and wellness?

Taking care of your overall health and well-being is important for living your best life with MS. In the areas of diet, exercise and emotional health, there are ample data to help guide choices and strategies. A Wellness Discussion Guide (**nationalMSsociety.org/wellnessguide**) is available to help people with MS and their healthcare providers discuss options for integrating wellness strategies in the MS treatment plan, and additional resources are available at **nationalMSsociety.org/Living-Well-With-MS**.

The importance of early treatment

Decades of research and clinical experience have demonstrated that early and ongoing treatment with a disease-modifying therapy can help reduce disease activity, prevent progression of disability and protect quality of life, thus prolonging a person's ability to remain active, productive and engaged. Any person who is having relapses or whose MRI scans show areas of inflammation should be considered a candidate for treatment with one of these medications.

The importance of early treatment has been reinforced by a growing understanding of the disease process in MS: inflammation causes damage not only to the myelin, but also to the nerve fibers themselves. This damage is visible on MRI scans as lesions and as damaged areas referred to as "black holes." Since the damage to myelin and nerve fibers can be permanent, a primary goal of early treatment is to reduce the frequency and severity of exacerbations during which inflammation and demyelination can occur.

Several of the DMTs have also been shown to delay the development of MS in people who have experienced their first clinical episode (clinically isolated syndrome) and have MRI-detected brain lesions consistent with MS. More information about the importance of ongoing treatment is available at **nationalMSsociety.org/adherence**.

Decisions concerning whether or when to begin treatment with one of the disease-modifying therapies will best be made by you and your physician together. The factors to be taken into account in making these decisions include the disease course you are experiencing, each medication's potential benefits and side effects, the route of delivery and frequency of dosing, and your personal priorities and lifestyle. As you think through the various options, focus on finding a treatment you can use comfortably and consistently until an even better treatment is identified.

Summary

The care and treatment of MS is in an exciting phase, and with treatment options comes the opportunity to learn and participate with your physician in the decision-making process. Your best sources of additional information about these medications are your healthcare providers, the National MS Society and the pharmaceutical companies who distribute them. Most of these companies offer their customers information, training and support, and financial assistance for qualifying individuals. Visit **nationalMSsociety.org/assistanceprograms** to learn more about patient information and financial support programs for each medication.

Things to think about

- Initiation of treatment is advised for any person with a confirmed diagnosis of MS who has active symptoms or evidence of disease activity on his or her MRI scans. Treatment may also be considered for people who have experienced their first clinical episode and have MRI-detected brain lesions consistent with MS (clinically isolated syndrome or CIS).
- By learning about the route of delivery, possible benefits and potential side effects of each of these medications, you become an informed partner in making treatment decisions.
- Your best sources of additional information about these medications are your healthcare providers, the National MS Society and the pharmaceutical companies who distribute the medications.
- As with all medications, women who are pregnant or wish to become pregnant should consult with their physicians about use of any of these medications. Men should also discuss treatment options before trying to conceive.

Resources

Thousands of resources, pieces of information and shared experiences about MS are available in print and on the internet. Some of the information you come across may be strictly experiential, anecdotal, unsupported or even inaccurate. Always consider the source; ask your healthcare provider or the National MS Society to help you identify credible resources.

From the National MS Society

For answers to questions about MS and its management, contact the National MS Society at 1-800-344-4867 or visit the Society's website at **nationalMSsociety.org** or the following topic-specific pages:

- **nationalMSsociety.org/DMT**
- **nationalMSsociety.org/newlydiagnosed**
- **nationalMSsociety.org/aboutMS**
- **nationalMSsociety.org/treatments**
- **nationalMSsociety.org/clinicaltrials**
- **nationalMSsociety.org/meds**
- **nationalMSsociety.org/KIPtreatments**

The Society produces many other resources about various aspects of MS. These resources are available online or call 1-800-344-4867 to request.

- **nationalMSsociety.org/educationalvideos** (also at youtube.com/nationalMSsociety)
- **nationalMSsociety.org/brochures** (also in the Catalog of Informational Resources mailed with this book)

Books

Books may be available from bookstores and/or online booksellers.

- Kalb R (ed.). **Multiple Sclerosis: The Questions You Have; The Answers You Need** (5th ed.) (2012). (NY:DemosHealth)

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The National MS Society's mission is for people affected by MS to live their best lives as we stop MS in its tracks, restore what has been lost and end MS forever. To fulfill this mission, the Society funds cutting-edge research, drives change through advocacy, facilitates professional education, collaborates with MS organizations around the world, and provides services designed to help people with MS and their families move their lives forward.

The National Multiple Sclerosis Society ("Society") is proud to be a source of information on multiple sclerosis related topics. The information provided is based on professional advice, published experience, and expert opinion, but does not constitute medical or legal advice. For specific medical advice, consult a qualified physician. For specific legal advice, consult a qualified attorney.

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Early and ongoing treatment with an FDA-approved therapy can make a difference for people with multiple sclerosis. Learn about your options by talking to your healthcare professional and contacting the National MS Society at **nationalMSsociety.org** or 1-800-344-4867.

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