

TALKING WITH YOUR PATIENTS ABOUT
**INITIATING & ADHERING TO
TREATMENT WITH A DISEASE
MODIFYING THERAPY**

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**National
Multiple Sclerosis
Society**

The National MS Society's Professional Resource Center provides:

- Easy access to comprehensive information about MS management in a variety of formats;
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Introduction

Use this resource to help to facilitate conversations with your patients about starting and adhering to treatment with a disease modifying therapy (DMT). Discussions about initiating a DMT, switching DMTs, and adherence to treatment will occur over many years and will present several challenges. Your patients may be reluctant to discuss initiating a DMT at the time of diagnosis – when they don't feel “sick enough” – despite evidence that these medications are most effective early in the disease course. It may also be difficult for people to accept that significant, irreversible damage can occur very early in the disease, even before they are experiencing any major symptoms (figure 1). Each of the DMTs has potential side effects and risks that may raise anxiety in some people. Since these medications do not immediately alter the disease course or symptoms, and the potential benefit is uncertain for any given individual, encouraging adherence to the treatment regimen may also prove difficult.

The following recommended strategies for discussing DMT initiation and adherence with your patients may help to foster realistic expectations, active participation, and hope. (figure 2)

Figure 1. The Topographical Model of MS

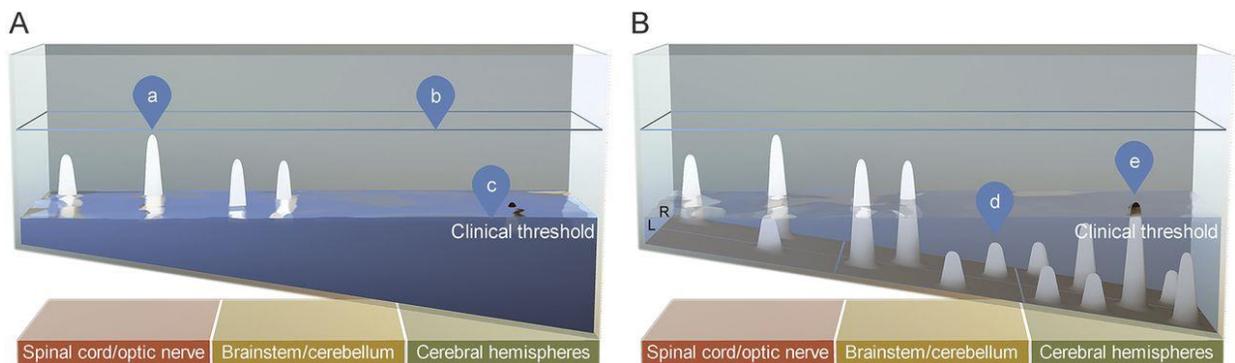
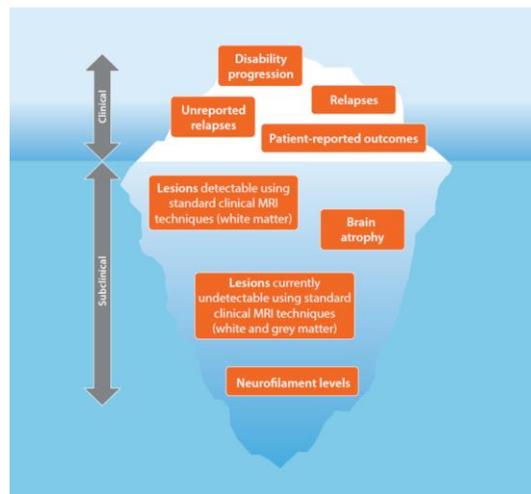


Figure 1. The topographical model of multiple sclerosis, clinical (A) and subclinical (B) views

(A) Clinical view: water is opaque, only above-threshold peaks are visible. (a) Above-threshold topographical peaks depict relapses and quantified Expanded Disability Status Scale/functional system disability measures. Each peak yields localizable clinical findings; the topographical distribution defines the clinical picture for an individual patient. (b) Water level at outset reflects baseline functional capacity and may be estimated by baseline brain volume. (c) Water level decline reflects loss of functional reserve and may be estimated by metrics of annualized brain atrophy.

(B) Subclinical view: water is translucent, both clinical signs and subthreshold lesions are visible. (d) Subthreshold topographical peaks depict T2 lesion number and volume. (e) The tallest peaks (i.e., the most destructive) in the cerebral hemispheres are shown capped in black as T1 black holes. (Krieger S et al. *Neurol Neuroimmunol Neuroinflamm* 2016;3: e279).

Figure 2. The clinical and subclinical features of MS



MS as a Silent Disease

Clinical visibility

- Disability
- Relapses
- Patients' Outcomes

Subclinical

- Brain Atrophy
- Lesion Burden
- Neurofilament levels

Giovannoni et al. (2016). Multiple Sclerosis and Related Disorders, 9, S5-S48

How and when should I address the topic of initiating a DMT?

- Engage in a discussion about the available treatments for multiple sclerosis as soon as a diagnosis of multiple sclerosis has been made, or when you have determined that a patient with clinically isolated syndrome (CIS) may be a suitable candidate for treatment. Know that this is a very difficult time and multiple conversations may be needed to ensure adequate understanding of information.
- Ask your patient what she or he understands about MS and MS treatments. Provide information about the disease and the overall goals of treatment.
- Discuss the available DMTs and explain the purpose and benefits of early treatment. Ask your patient about her or his goals for treating MS.

- Discuss the side effects and risks of the DMTs – as well as the risk of MS worsening and progression. Discuss risk in general to understand your patient’s risk tolerance.
- Explain that:
 - These medications are indicated for relapsing forms of the disease, including secondary progressive MS (SPMS) in which there is evidence of inflammation.
 - One DMT that demonstrated modest efficacy in reducing the risk of progression in pivotal trials is approved for primary progressive MS (PPMS).
- Explain what the DMTs can and cannot do. People are more likely to adhere to treatment when their expectations of treatment are realistic. Describing the experience of other patients who have successfully initiated and managed DMTs may be helpful in relieving a person’s anxiety
 - If possible, offer your patients an opportunity to speak with other patients who have initiated a DMT and have been on a DMT for some time.
- Note the availability of manual and electronic devices that assist with the injectable medications for those who may be concerned about self-injecting or have injection anxiety.
- At the same time that you are discussing the importance of disease-modifying therapy with your patients, assure them that you will also be working with them to manage their symptoms and promote their overall wellness.
- Discuss family planning with patients in that stage of life since their plans for pregnancy will influence your treatment recommendations.

How can shared decision-making be used most effectively in these conversation about DMTs?

- Evidence indicates that a shared decision-making process is optimal for conversation about treatment initiation or persistence with a treatment plan.
- Shared decision making requires the individual to have adequate knowledge and information to be an active participant in the decision-making process. In addition, it is important for the provider to understand and respect the individual’s needs, values and goals.
- Some patients may choose not to start a DMT initially or may be reluctant to change to a more aggressive treatment when their disease is not being adequately controlled. While these choices may not be the provider’s preference, an informed patient decision needs to be respected. Treatment discussions can and should be revisited in subsequent visits.

What are the most important points to discuss when initiating a DMT?

- Early and consistent treatment with a DMT is the best way to reduce relapses, delay disability and limit new areas of MS damage in the central nervous system.
- Safety monitoring and regular follow-up with you are essential for successful and optimal MS management.
- You will work together with your patient to identify which of the available options might be most appropriate.
- Most patients generally tolerate the medications well, with some side effects that can usually be managed effectively.
- Adherence to the treatment plan can be challenging but is an essential investment in their future.
- Although there is no specific way to measure the effectiveness of a DMT, an individual's response to a therapy as indicated by relapses, new symptoms or lesions on MRI will help to assess overall disease state and response to therapy.
- The DMTs differ in mechanism of action and in side effect profile. Tolerance of the DMTs and their impact on the disease are variable among patients. It is important for people to know that the need to switch from one therapy to another is not a treatment “failure,” but rather a suboptimal response due to lack of efficacy or tolerability. If a treatment change is needed, a decision will be made through shared decision-making.
- Learning to self-inject can contribute to feelings of control and independence. Those who do not have the dexterity to do so can maintain an active role in other ways—e.g., by learning the proper procedures and assisting the person who gives the injection, or by initiating treatment with an oral DMT or an infusion.

How and when should the information about the DMTs be shared with family members?

- While it is preferable to engage family members from the outset, patients should decide when and with whom the information about the DMTs should be shared.
- In cases where the patient is a minor, severely cognitively or physically impaired, has a significant mood disorder and/or is unable to self-inject, family participation in the decision and the administration of the DMT is necessary.
- Patients often find that having a family member or friend with them during the discussion is helpful—both for remembering the facts presented and for making an informed decision.
- Encourage a patient who is initiating an injectable therapy to bring a family member to the initial injection training session.
- You or your staff must be available. Assure patients that they can call their MS team (or in some cases use an EMR patient portal) with any questions about the DMTs or their disease. And with a patient's permission, a family member can call with questions as well. When family members are needed to communicate with the healthcare provider, it is important to explain the need for a single point person.

What is the best format for providing information about the DMTs to my patients?

- Patients benefit from face-to-face time with their MS clinician (doctor, nurse or nurse practitioner, physician's assistant or other MS professionals). Do not initiate discussion of DMTs over the telephone (although patients should be encouraged to discuss ongoing issues on the phone between office visits). You may choose to offer patients an educational follow-up visit just to discuss the DMTs, including any questions or concerns they may have.
- Evaluate patients' readiness for getting information and education about the DMTs and MS; some patients may take more time than others to decide about starting treatment.
- Where circumstances allow, patients benefit from meeting with a social worker, psychologist or counselor upon initial discussion of the DMTs or during the initiation of the DMT. This kind of contact allows more time for addressing questions and concerns.
- Refer patients who are having significant anxiety about using the DMT to a social worker, psychologist or other support person or group to facilitate adjustment to the disease and the treatment. The Self-Injection Anxiety Counseling protocol (SIAC), available at nationalMSSociety.org/siac, is a useful tool for patients to use with an experienced nurse or counselor.
- Emphasize to patients that not all MS-related resources and websites contain accurate and reliable information. In general, the most fair-balanced and evidence-based web resources are provided by academic (.edu) or advocacy (.org) organizations.
- Each of the pharmaceutical companies offers a telephone help line staffed by nurses, web-based information, reimbursement assistance and written materials about its product(s) (see Additional Resources).
- The National MS Society's website (nationalMSSociety.org) offers accurate, up-to-date information about treatment, including booklets and online programs that can enhance understanding and provide support.
- [The Use of Disease-Modifying Therapies in Multiple Sclerosis](#) – a consensus paper from the Multiple Sclerosis Coalition -- provides accurate and peer-reviewed data about the DMTs. A [lay summary](#) of the paper is also available.

What kinds of emotional responses might I expect from my patients?

- The DMTs are generally introduced close to the time of diagnosis when the patient and family are grappling with the sudden change in their lives. Introducing the prospect of lifelong treatment is likely to be overwhelming for many patients and family members.

- Patients may express a wide range of feelings in reaction to the discussion about the DMTs, upon initiation, and over time while on the medication. Common emotional reactions include:
 - Anger about the disease and the need for ongoing treatment
 - Belief that there has been a mis-diagnosis and therefore treatment is not needed
 - Belief that the course of the MS will be benign and therefore a DMT is not needed
 - Anxiety about choosing the “right” DMT
 - Doubt that they will be able to self-inject or adhere to a treatment regimen or oral or infused medication
 - Fear of needles and concern about injection-site reactions
 - Anxiety about potential side effects and long-term risks, including infections, progressive multifocal leukoencephalopathy (PML), malignancies, liver damage, cardiac issues
 - Apprehension and doubt about the effectiveness of the treatment and the impact of the DMT on their quality of life
 - Guilt about the burden of the disease on family members and the need to rely on others for assistance
- Common practical concerns include:
 - Assessing the risks associated with stopping the medication during pregnancy (and breastfeeding if the woman chooses to do so)
 - Managing the cost of therapy and coverage by insurance
- Refer patients and families with significant adjustment problems for supportive counseling and suggest participation in support groups directed by MS Centers or the National MS Society.

What can I do to promote adherence to the DMTs?

- Respect the patient’s values and goals.
- Listen to patients’ comments/problems related to the DMTs and encourage them to call with any questions or concerns.
- Manage side effects aggressively.
- Recognize the factors that promote adherence among patients with relapsing and progressive forms of MS, including: hope, self-efficacy, and perceived support from their doctor, other clinicians and family members.
- Reinforce and actively participate in shared decision-making.
- Explain the efficacy and safety data of the DMTs and the importance of adherence.
- Suggest ways to incorporate the DMT into their routine.
- Assist with management of the high cost of the DMTs by referring patients to the available co-pay assistance programs, a social worker, if available, and the National MS Society for help with insurance-related questions or concerns.
- Involve family members with patient’s permission.

- Recommend an alternate treatment option if the patient is unable to tolerate a specific medication.
- Employ a hopeful approach when discussing future therapy options and ongoing research.
- Congratulate patients and their partners for being adherent to the DMT and monitoring requirements.

How often should I see my patients once they have initiated a DMT?

- Patients should be seen relatively soon after starting a DMT, and while a standard does not exist, many providers reevaluate their patients within 1-2 months of treatment initiation.
- Stable patients who are comfortable with their medication and tolerating it well are typically seen every 3–6 months.
- Monitoring includes the patient’s response to treatment, including symptom changes reported to you, clinical findings on the neurologic exam and radiological activity detected on MRI. Discuss and explain any MRI changes that occur, their clinical and future implications, and their relevance for the ongoing treatment decisions you and the patient will be making together.

What are the important issues to address related to side effect management?

- With the frequently administered interferons and dimethyl fumarate (Tecfidera), the dose will initially be titrated to reduce the severity of any side effects.
- It is important to take the medication as prescribed.
- Safety monitoring is as important as taking the DMT regularly – and must be adhered to so that serious side effects and risks can be minimized.
- Side effects can usually be managed effectively with strategies that are used consistently – for example, taking a medication with meals, pre-medicating prior to taking an interferon medication, rotating injection sites.
- Support programs are offered by the pharmaceutical companies that manufacture the medications.
- Self-help groups, available from the National MS Society, offer opportunities to share strategies with others taking a DMT.
- Switching to another medication is an option if strategies to manage the side effects have not been successful or the medication has not provided adequate control of the disease.

What is the most important information to convey regarding injectable DMTs?

- Mode of action, efficacy and the long-term safety of the available injectable DMTs
- The need for follow-up visits and follow-up MRIs
- Use of birth control while on these medications, which are not approved for use during pregnancy or breastfeeding
- Use of correct self-injection procedures and a clean technique
- Adherence to the injection schedule and rotating injection sites
- Realistic expectations
- Availability of:
 - Manual auto-injectors or electronic devices to ease the self-injection procedure.
 - Injection reminder options (e.g., use of an app or other tools from the pharmaceutical companies)
 - Resources from the pharmaceutical companies (e.g., information, support, home visit(s) by a nurse for injection training)
 - Strategies to address needle phobia
- Potential for injection fatigue. Encourage patients to tell you if they are feeling that they cannot continue with the injections so that you can discuss strategies to improve motivation or identify a different treatment option.
- With glatiramer acetate:
 - No need for follow-up lab tests
 - Description of the post-injection reaction that can occur
- With interferon medications:
 - Importance of baseline and follow-up lab tests (CBC and hepatic function)

What is the most important information to convey regarding oral DMTs?

- Mode of action, efficacy and the long-term safety of the available oral DMTs
- The need for baseline and follow-up imaging to assess for sub-clinical activity
 - Explain retention of gadolinium and the unknown risk of toxicity (see CMSC MRI guidelines)
- Baseline tests such as a skin exam, baseline lab tests including:
 - CBC w/ diff (all oral therapies)
 - Hepatic enzymes (all oral therapies)
 - TB test (teriflunomide)
 - VZV IgG (fingolimod)
 - EKG (fingolimod)
 - Vision exam to assess for macular edema (fingolimod)
- Ongoing monitoring, including follow-up visits, a neurological examination at regular intervals, blood tests and magnetic resonance imaging (MRI) to monitor disease stability versus progression and identify any potential complications

- Taking the DMTs as prescribed and reporting missed doses
- Using birth control while on these medications, which are not approved for use during pregnancy or breastfeeding
- Reporting any change in neurological function that lasts >24 hours
- Reporting any infections
- Maintaining realistic expectations
- Recognizing the potential for serious infections (e.g., herpetic infections, progressive multifocal leukoencephalopathy (PML), and malignancies)

What is the most important information to convey regarding intravenous DMTs?

- Mode of action, efficacy and long-term safety of the available infusion therapies
- Importance of:
 - Use of birth control while on these medications, none of which are approved during pregnancy or breastfeeding
 - Thorough work-up before initiating therapy
 - Assess JC virus antibody status every 3-6 months for patients taking natalizumab and discuss risk of PML if testing is positive
 - Regular follow-up and repeat blood work (CBC with diff (including ALC), hepatic
 - Repeat MRI at regular intervals to assess for sub-clinical activity
 - Reporting any side effects Report any change in neurological symptoms or function that lasts > 24 hours
 - Realistic expectations
- Potential for serious infusion reactions and/or serious complications (e.g., infection, autoimmune conditions, malignancies)

What are the indications for switching DMTs?

- Intolerable side effects
- Contraindications – hypersensitivities, other medications, JC+ antibody status, severe hepatic impairment, life-threatening infusion reactions, etc.
- Inability to adhere to treatment despite reasonable effort
- Breakthrough disease
 - Relapses
 - Progression
 - New MRI activity (new or enhancing lesions)
 - Consideration of cognitive function when assessing response to therapy
- Positive JC virus antibody status for patients on natalizumab – particularly high index and in those patients on treatment for > 2 years. And particularly if previous use of chemotherapy
- Change in lab tests – for example, persistent lymphopenia and/or transaminitis

What other resources are available on this topic?

- MS Navigators (1-800-344-4867; ContactUsNMSS.org) provide information, referrals to healthcare providers in the community, emotional support
 - Educational programs and self-help groups
 - Print materials on a range of topics, available free of charge and also on the National MS Society's website (nationalMSSociety.org/Brochures)
- Pharmaceutical Company Support Programs
 - Aubagio: MS One to One: MSOnetoOne.com or 1-855-676-6326
 - Avonex: Above MS: abovems.com or 1-800-456-2255
 - Betaseron: Betaseron Patient Assistance Program: betaseron.com/betaplus/affordability or 1-800-788-1467
 - Copaxone: Shared Solutions: 1-800-887-8100 or sharedsolutions.com
 - Extavia: Extavia Go Program: extavia.com or 1-866-925-2333
 - Gilenya: Gilenya Go Program: gilenya.com/c/ms-pill/go-program or 1-800-445-3692
 - Glatopa: glatopa.com/glatopa_care/financial_support.shtml
 - Lemtrada: MS One to One; msonetoone.com or 1-855-676-6326
 - Novantrone: none available at this time
 - Ocrevus: Genentech Access Solutions: genentech-access.com or 1-844-627-3887 or 1-866-422-2377
 - Plegriby: Above MS: abovems.com or 1-800-456-2255
 - Rebif: MS Lifelines: mslifelines.com or 1-877-447-3243
 - Tecfidera: Above MS abovems.com or 1-800-456-2255
 - Tysabri: Above MS abovems.com or 1-800-456-2255
 - Zinbryta: Above MS: abovems.com or 1-800-456-2255
- Clinical Trials listing: National Institutes of Health – ClinicalTrials.gov

Recommended Reading

[The Use of Disease-Modifying Therapies in Multiple Sclerosis: Principles and Current Evidence.](#) (2017). A consensus paper by the Multiple Sclerosis Coalition. [Patient summary](#) also available.

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Aliza Ben-Zacharia, DNP, ANP-BC, a nurse practitioner at the Corinne Goldsmith Dickinson Center for Multiple Sclerosis at the Icahn School of Medicine at Mount Sinai, performs specialized work focused on MS and rehabilitation. Dr. Ben-Zacharia is board-certified in adult primary care by the Academy of Nurse Practitioners and in acute care by the American Nurses Credentialing Center. She earned her BSN degree from the Hebrew University in Jerusalem, Israel, her MSN from Hunter College Bellevue School of Nursing, and her NP certificate from Columbia University. She earned a master degree in nutrition from Columbia university and a doctorate degree from Case Western Reserve University, Payne Bolton School of Nursing.

Prior to joining the Center, Dr. Aliza Ben-Zacharia worked as an acute nurse practitioner in rehabilitation medicine, caring for inpatients with diverse acute medical and neurological problems, with an emphasis on rehabilitation. She has published articles and book chapters on Palliative Care in MS, the disease modifying agents, and MS symptomatology. She was among the first group of nurses to be certified in Multiple Sclerosis Nursing. Dr. Ben-Zacharia has won several educational awards from Mount Sinai Hospital, the International Organization of MS Nurses (IOMSN) and the National MS Society recognizing her outstanding work as a clinician and an educator. She is the president elect of the IOMSN and a former board member of the Consortium of MS Centers (CMSC).

Fred D. Lublin, MD is the Saunders Family Professor of Neurology at the Icahn School of Medicine at Mount Sinai and Director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis at that institution. Dr. Lublin received his medical degree in 1972 from Jefferson Medical College, Philadelphia, PA. He completed his internship in Internal Medicine at the Bronx Municipal Hospital, Albert Einstein Medical Center, and his residency at the New York Hospital, Cornell Medical Center.

As a neuroimmunologist, Dr. Lublin has a special interest in immune functions and abnormalities affecting the nervous system. He has been involved in both basic science and clinical research. He and his colleagues were among the first in the country involved with studies of Interferon beta-1b, which was approved by the Food & Drug Administration in 1993 to treat the relapsing-remitting form of Multiple Sclerosis. He is currently involved with several new clinical research protocols on promising agents for treating various aspects of MS and is the national Coordinating Investigator for a multi-center trial of combination therapy in MS. Dr. Lublin was chairman of the National MS Society's advisory committee on clinical trials of new drugs in Multiple Sclerosis as well as the Society's Research Programs Advisory Committee, and worked with his Society colleagues to re-define the clinical course definitions of MS. He has also chaired a task force on the ethics of placebo-controlled trials in MS.

Other resources for
Talking with Your MS Patients include:

Cognitive Dysfunction
Diagnosis of Multiple Sclerosis
Progressive Disease
Elimination Problems
Sexual Dysfunction
Depression and Other Emotional Changes
Initiating and Adhering to Treatment with Injectable Disease Modifying Agents
Family Issues
Reproductive Issues
The Role of Rehabilitation
Life Planning
Primary Progressive MS (PPMS)
Palliative Care, Hospice and Dying
Wheeled Mobility



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