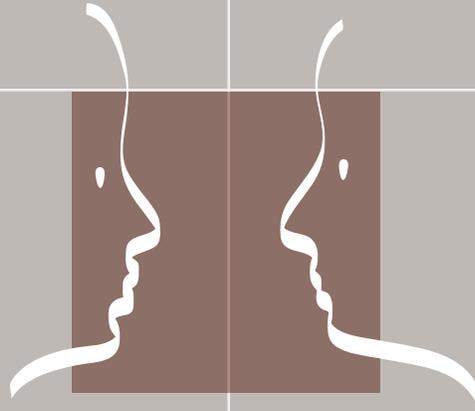




National  
Multiple Sclerosis  
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*Talking with Your  
MS Patients about  
Difficult Topics*



Talking about Initiating  
and Adhering to Treatment  
with Injectable Disease  
Modifying Agents

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The National MS Society's Professional Resource Center (PRC) has long been a resource for health professionals providing care to people with multiple sclerosis. The PRC, which houses a comprehensive library of MS information, provides continuing education opportunities and offers multidisciplinary expertise on MS disease process and management questions, health insurance issues, long-term care options, and the development of MS specialty clinics. The goal of these services is to enhance quality of care and increase access to care for people with multiple sclerosis.

Physicians are invited to consult via email with MS specialist colleagues who serve on our National Clinical Advisory Board

**MD\_info@nmss.org**

Allied health professionals are invited to consult via email with MS specialist colleagues

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## Introduction

To date, there are six disease-modifying agents (DMAs) that have been approved for the treatment of multiple sclerosis (MS). The National MS Society recommends that treatment with one of the four injectable medications—interferon beta-1a (Avonex and Rebif), interferon beta-1b (Betaseron), or glatiramer acetate (Copaxone)—be considered as soon as the diagnosis of MS with a relapsing course, or of a clinically-isolated syndrome, has been confirmed. This booklet is designed to facilitate conversations with your patients about the initiation of, and adherence to, the injectable DMAs. The intravenous medications, mitoxantrone (Novantrone) and natalizumab (Tysabri) will be discussed separately.

Talking to patients about starting an injectable treatment that will continue for the foreseeable future may present several challenges. Your patients may be reluctant to discuss initiating a DMA

early in the disease process—when they don't feel "sick enough"—in spite of evidence that these medications may be most useful early in the disease. Injectable medications with potential side effects raise anxiety in most people. 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. Since these medications do not show an immediate effect on patients' 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 DMA initiation and adherence with your patients may help to foster realistic expectations, active participation, and hope.

### 1. How and when should I address the topic of initiating a DMA?

- Engage in a discussion about the available treatments for multiple sclerosis as soon as a diagnosis of definite multiple sclerosis with active disease has been made, or when you have determined that a patient with clinically isolated syndrome (CIS) or a variant of MS may be a suitable candidate for treatment.
- Share with patients that most of these medications were tested only in relapsing-remitting MS (RRMS) and/or CIS, but that it is generally agreed that these treatments are appropriate for the relapsing forms of the disease where there is intermittent active inflammation (i.e., RRMS, secondary progressive MS (SPMS), and progressive relapsing MS (PRMS)).
- Explain to patients with primary-progressive MS (PPMS) that the DMAs have not been shown to be effective for their form of MS, while emphasizing the importance of symptom management, rehabilitation, and wellness strategies.
- While the decision to initiate a DMA and the selection of the specific DMA is a collaborative effort between clinician and patient, the clinician should provide guidance and specific recommendations based on disease course, diagnostic test

results, and patient's life style. Many patients who are left to choose among the DMAs, with no guidance from their physician, find the experience extremely stressful.

- Provide patients with information about efficacy and tolerance, including potential side effects. *They are more likely to adhere to the treatment when they know what to expect.*

- Describing your experience with other patients who have managed the medications successfully may allay some anxiety.
- Note the availability of devices that assist with the injections for those who may be concerned about self-administering the drug or have injection anxiety.

## 2. What are the most important points to discuss when initiating a DMA?

- By initiating and continuing treatment with the DMA, they are taking an active part in their disease management.
- Most patients generally tolerate the medications well, with few side effects—which can usually be managed effectively.
- The DMAs have been shown to alter the disease course in most patients.
- It is important that patients adhere to the treatment regimen faithfully.
- Although there is no definite way to specifically measure the effectiveness of the DMAs in controlling a person's disease, the individual's clinical presentation, neurological examination,

and magnetic resonance imaging (MRI) or other test findings will help to measure overall disease state.

- The DMAs differ in mechanism of action and in side effect profile. Tolerance of the DMAs and impact on disease are variable among patients.
- Learning to self-inject contributes 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.

## 3. How and when should the information about the DMAs 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 DMAs should be shared.
- In cases where the patient is a minor, seriously cognitively impaired, or physically impaired and unable to self-inject, family participation in the decision and the administration of the DMA 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 the patient to bring a family member to the training session when the patient learns about and gives him/herself the first injection.
- Assure patients *and* family members that they can call their MS team with any questions about the DMAs or their disease.

#### 4. What is the best format for providing information about the DMAs to my patients?

- Patients benefit from face-to-face time with their MS clinician (doctor, nurse, physician's assistant).
- Where circumstances allow, patients should meet with the social worker or counselor upon initial discussion of the DMAs or during the initiation of the DMA, based on their individual needs. This kind of contact allows more time for questions, reactions, and concerns to be expressed.
- Do not initiate discussion of DMAs over the telephone (although patients should be encouraged to discuss ongoing issues on the phone between office visits).
- Encourage patients to bring a list of questions and concerns about the DMAs to the office visit.
- Refer patients who are having significant anxiety about using the DMA 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 [www.nationalMSSociety.org/siac](http://www.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 websites contain accurate and reliable information.
  - Each of the pharmaceutical companies offers a telephone help line staffed by nurses, web-based information, and written materials about the use of their DMA. These support programs are listed in the resources section of this document.
  - The National MS Society website ([www.nationalMSSociety.org](http://www.nationalMSSociety.org)) offers accurate, up-to-date information about treatment, including booklets and learn-online programs that can enhance understanding and provide support.

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

- Patients may express a wide range of feelings in reaction to the discussion about the DMAs, upon initiation and over the course of time on the drug. Common reactions include:
  - Anger about the disease and the need for an injectable therapy
  - Optimism about the available treatments and current research in the field
  - Doubt that they will be able to self-inject
  - Fear of needles
  - Apprehension and doubt about the effectiveness of the treatment and the impact of the DMA on their quality of life
- Grief and sadness over the changes and losses in their lives and the disease-related threat to their self-image and self-esteem
- Guilt about the burden of the disease on family members and the need to rely on others for assistance
- Patients' concerns and feelings about the DMAs usually fluctuate along the disease course.
- The DMAs 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 very overwhelming for all of them. 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.

- The most common concerns voiced by patients about the DMAs include:
  - Choosing the “right” DMA
  - Uncertainty about the benefit of treatment on disease progression and level of disability
  - Managing the side effects effectively and comfortably
  - Assessing the risks associated with stopping the medication throughout pregnancy (and breastfeeding if the woman chooses to do so)
  - Managing the cost of the therapy

## **6. What can I do to promote adherence to treatment?**

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- Recognize the factors that promote adherence among patients with RRMS, including: hope, self-efficacy, and perceived support from their doctor.
- Reinforce the efficacy data regarding the DMAs.
- Suggest ways to incorporate the injections into their routine.
- Discuss the importance of follow-up.
- Encourage patients to call with any questions or concerns.
- Listen to patients comments/problems related to the DMAs.
- Troubleshoot problems related to the injections and side effects.
- Provide additional training, if necessary.
- Involve family members with patient’s permission.
- Recommend an alternate treatment option if the patient is unable to tolerate a specific medication.
- Instill hope and a sense of optimism in patients while discussing future therapy options and ongoing research.
- Give praise to patients and their partners for sticking with it.

## **7. How often should I see my patients once they have initiated a DMA?**

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- It is recommended that patients be seen within 4–6 weeks after initiation of a DMA, or sooner if necessary, based on individual needs or concerns.
- When patients are comfortable giving themselves the injections and are tolerating them well, they can be seen less often. Stable patients are typically seen every 3–6 months.

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

- Instruct patients about different strategies and techniques to control side effects.
- Educate patients who are taking an interferon medication about the importance of periodic blood tests to identify potential early complications.
- Remind patients to make full use of the support programs offered by the pharmaceutical company that manufactures their medication.
- Refer patients to support groups where they might share strategies with others taking a DMA.
- Reassure patients that they may switch to another medication if all strategies have failed and the intolerance issues continue.

## 9. What is the most important information to convey to my patients about the other approved medications:

- Natalizumab (Tysabri) is approved as a monotherapy for the treatment of patients with relapsing forms of MS.
  - Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML), a viral infection of the brain that usually leads to death or severe disability. Although the cases of PML in the early MS trials occurred only in patients who were also taking another immunomodulating agent, post marketing use of Tysabri as a monotherapy has also been associated with cases of PML.
  - Because natalizumab increases the risk of PML, *it is generally recommended for patients with relapsing forms of MS who have had an inadequate response to, or cannot tolerate, any of the other disease-modifying therapies that are available for treating MS.*
- Mitoxantrone (Novantrone) is approved for use in secondary-progressive MS, progressive-relapsing MS, and worsening relapsing-remitting MS.
  - Because of possible cardiac toxicity, the lifetime cumulative dose is limited to 140 mg/m<sup>2</sup> (approximately 8–12 doses over two to three years). Cardiac function must be evaluated prior to starting treatment with mitoxantrone and left ventricular ejection fraction (LVEF) measured prior to each dose.
  - Mitoxantrone appears to increase the risk of secondary acute myelogenous leukemia, particularly in those people who have previously received other types of chemotherapy.

## 10. What resources are available to educate and support my patients?

- Chapters of the National MS Society (1-800-344-5867) offer:
  - Educational programs and support groups
  - Referrals to professionals who specialize in coping and adjustment issues in MS
  - Printed materials about a range of topics, available free of charge (also available from the National MS Society website: [www.nationalMSSociety.org/](http://www.nationalMSSociety.org/) Brochures)
- National MS Society website ([www.nationalMSSociety.org](http://www.nationalMSSociety.org)) offers information on a wide variety of topics (e.g., disease-modifying therapies, symptom management, research), as well as access to local resources and events.

### • Additional Recommended websites:

- Multiple Sclerosis Society of Canada. [www.mssociety.ca](http://www.mssociety.ca)
- Multiple Sclerosis International Federation. [www.msif.org](http://www.msif.org)
- Pharmaceutical Company Support Programs
  - Betaseron  
BETAPLUS  
[www.betaseron.com](http://www.betaseron.com)
  - Avonex  
MS Active Source  
[www.msactivesource.com](http://www.msactivesource.com)
  - Copaxone  
Shared Solutions  
[www.sharedsolutions.com](http://www.sharedsolutions.com)
  - Novantrone  
[www.novantrone.com](http://www.novantrone.com)
  - Rebif  
MS Lifelines  
[www.mslifelines.com](http://www.mslifelines.com)

- Tysabri  
TOUCH Prescribing Program  
[www.tysabri.com](http://www.tysabri.com)
- Clinical trials
  - CenterWatch Clinical Trials Listing Service [www.centerwatch.com](http://www.centerwatch.com)
  - National Institutes of Health (NIH) Clinical Trials Listing Service.  
[www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)

### • Recommended reading:

- Kalb R (ed.). (2006). *Multiple Sclerosis: A Guide for Families* (3rd ed.). New York: Demos Medical Publishing.
- Kalb R (ed.). (2008). *Multiple Sclerosis: The Questions You Have, The Answers You Need* (4th ed.). New York: Demos Medical Publishing.

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Prior to joining the Center, Ms. Ben-Zacharia worked as an acute nurse practitioner in rehabilitation medicine, caring for inpatients with diverse acute medical problems, with an emphasis on rehabilitation. She has published work 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.

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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.

**Rosalind Kalb, PhD**, is Vice President of the Professional Resource Center at the National Multiple Sclerosis Society in New York City, providing educational materials and consultation services for healthcare professionals. Dr. Kalb has authored or edited a number of National MS Society publications—the *Knowledge is Power* series for newly-diagnosed patients and the Cavallo Professional Education book series for health professionals. She has edited two books—*Multiple Sclerosis: The Questions You Have; The Answers You Need*—now in its 4th edition—and *Multiple Sclerosis: A Guide for Families*, now in its third edition. She is the senior author of *Multiple Sclerosis for Dummies*, and co-author with Dr. Nicholas LaRocca of *Multiple Sclerosis: Understanding the Cognitive Challenges*.

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