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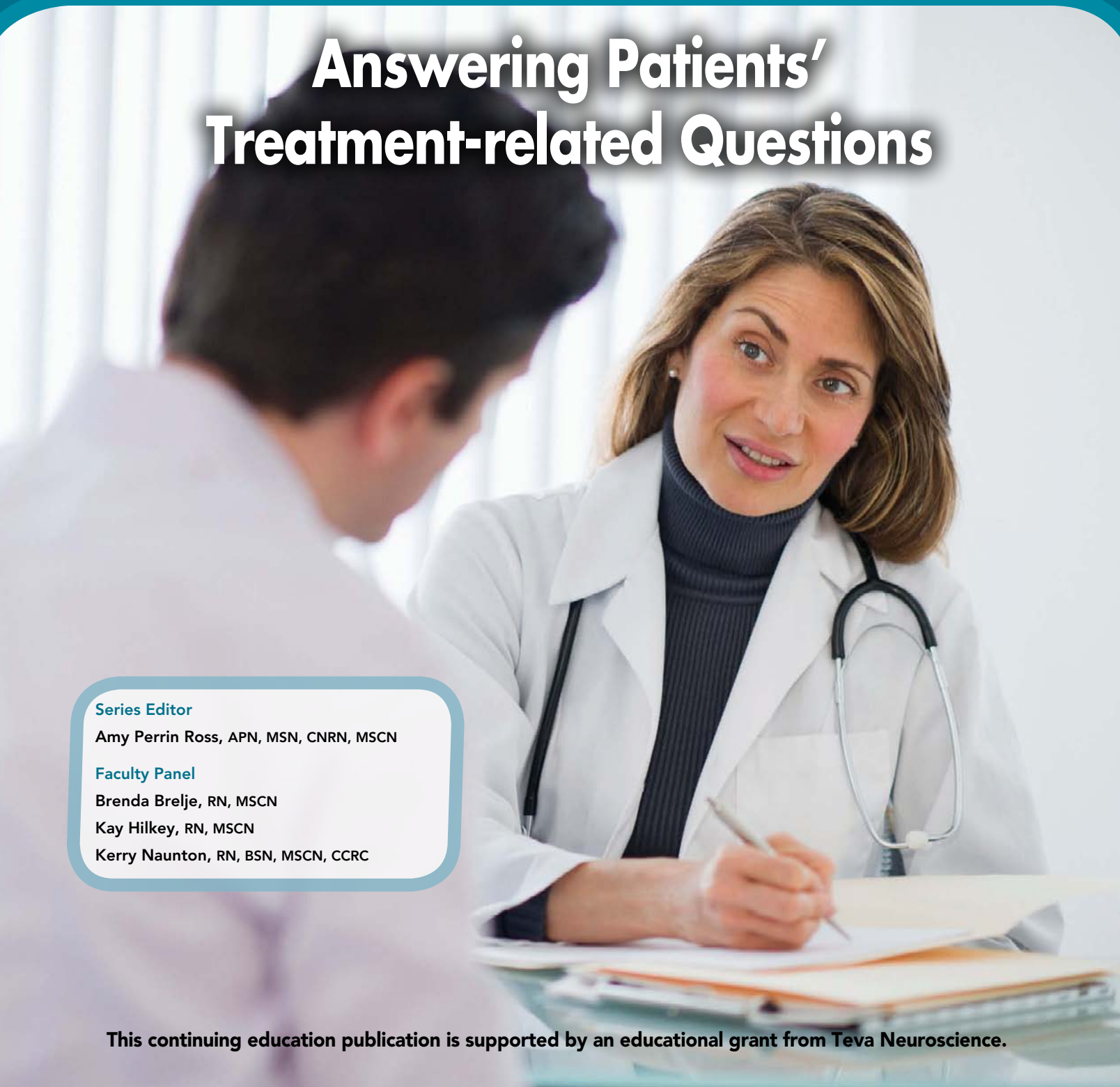
Counseling Points™

Enhancing Patient Communication for the MS Nurse

Answering Patients' Treatment-related Questions



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Counseling Points™

Answering Patients' Treatment-related Questions

Continuing Education Information

Target Audience

This educational activity is designed to meet the needs of nurses who treat patients with multiple sclerosis (MS).

Purpose

To provide MS nurses with information and tools for counseling patients about disease-modifying therapies (DMTs).

Learning Objectives

Upon completion of this educational activity, the participant should be able to:

- Advise patients about the importance of initiating therapy for clinically isolated syndrome or early MS
- Describe decision-making steps for patients who have relapses or magnetic resonance imaging (MRI) activity while on therapy
- Evaluate the balance between safety and efficacy for MS treatments
- Review recommended protocols for follow-up with patients on MS therapies

Continuing Education Credit

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In order to earn credit, please read the entire activity and complete the posttest and evaluation at the end. Approximate time to complete this activity is 60 minutes.

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Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any medications, diagnostic procedures, or treatments discussed in this publication should not be used by clinicians or other health care professionals without first evaluating their patients' conditions, considering possible contraindications or risks, reviewing any applicable manufacturer's product information, and comparing any therapeutic approach with the recommendations of other authorities.

welcome

Dear Colleague,

Counseling patients and answering questions about multiple sclerosis (MS) and its treatment are among the most challenging—but also the most rewarding—aspects of MS nursing. Some questions come up so frequently that we almost wish we had a button we could push to provide the "usual" answer. Yet each person's questions warrant thoughtful consideration of how his or her own unique circumstances may apply.

Some of the challenges faced by nurses who treat MS include:

- remaining positive and hopeful while still providing realistic and accurate information;
- sometimes "bursting a patient's bubble" if he or she is not a candidate for a particular therapy, or is not benefitting from a current therapy;
- providing information that is balanced and unbiased amidst a barrage of print materials, Internet information, and social media; and
- finding time to answer questions that arise over the phone or email while attending to patient care, paperwork, and other responsibilities.

Ensuring that our patients are well informed is one of the most important steps we can take as nurses. Research has shown that patients who are well educated about MS and who feel empowered to take charge of their own care are more likely to stay on therapy, follow through with appointments and monitoring, and report any concerning symptoms or side effects.[1,2] It's sad but true that educating people about a serious condition like MS does not fit well into the time slot designated for a patient visit. However, the extra time spent making sure a person understands—and has absorbed—what you are conveying often can prevent mistakes, misunderstandings, and potentially urgent phone calls down the road.

Counseling Points™ is now entering its 8th year as an educational service for nurses who treat people with MS. We hope that you gain valuable insight from the series and that the current issue assists you in answering some of the common MS treatment-related questions relevant to today's practice.

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Answering Patients' Treatment-related Questions

Answering patients' questions about multiple sclerosis (MS) is a significant part of a nurse's job. As treatment options become more complex, this is an increasingly important yet time-consuming responsibility. While patients' questions must be answered differently for each individual, there are many educational concepts in MS that are applicable to a broad population. For this issue of *Counseling Points*™, a panel of MS nurses explored and discussed several common treatment-related questions that apply to a variety of clinical scenarios and MS disease stages.

Common Treatment-related Questions by MS Stage

Clinically Isolated Syndrome (CIS)

Question: If I have had just one attack, do I really need to be on a medication?

CIS is defined as a first neurologic episode lasting at least 24 hours caused by inflammation or demyelination in one or more sites in the central nervous system (CNS).[3] Nearly 30% of those diagnosed with CIS will develop clinically definite MS (CDMS) within 12 months, and 85% to 90% will do so within a few years.[4,5]

Being told you may have MS is frightening and confusing for anyone. This initial stage is a time when people seek support and a voice of reason amidst an avalanche of information—some of it relevant to them, some of it irrelevant or inaccurate. The CIS stage is a critical point for answering patients' questions honestly and accurately, since the steps taken at this point can set the stage for the clinical course over the long term.[4-6]

Damage to the axons in the CNS is thought to begin well before symptoms of MS become evident.[7] Treatment with a disease-modifying therapy (DMT) during CIS has been shown to significantly reduce the chances that a person will convert to CDMS during study periods ranging from 2 years to 5 years **(Table 1)**.[8-11] Reducing the number of active lesions and/or relapses in the earliest stages of MS have been shown to correlate with better long-term outcomes, so patients with CIS should be encouraged to begin a DMT.

Tips for talking to patients: With a designation of CIS, some people will be eager to do whatever they can to help themselves as soon as possible, while others will proceed cautiously, electing to wait for more diagnostic information or further signs of disease progression. Still others will reject therapy outright. People with CIS need to understand that MS therapies essentially *prevent* neurologic damage from getting worse, rather than erasing damage that

Table 1. Pivotal Clinical Trials of Disease-modifying Therapies in CIS*

		% Converting to CDMS		
Trial Name	**Agents Tested**	**Placebo**	**Treatment**	**P value**
• CHAMPS[8]	IFN beta1-a (IM)	50%	35%	*P*=0.02
• PreCISe[9]	Glatiramer acetate	43%	25%	*P*<0.0001
• BENEFIT[10]	IFN beta-1b (SC)	45%	28%	*P*<0.0001
• ETOMS[11]	IFN beta-1a (SC)	45%	34%	*P*=0.09 (low dose)

*Results cannot be compared across studies because of differences in trial design, baseline populations, and study duration.
CDMS=clinically definite MS; IFN=interferon.

already exists.[12,13] A person with an early-stage cancer that is likely to spread would usually not want to wait until the condition deteriorated before deciding to treat it. With MS (as with cancers and many other diseases) it is not possible to predict how fast the condition may progress in any given individual. Treating early is better than waiting until it's too late and the damage is done.[13]

New Diagnosis of MS

Question: How long will I have to be on this drug?

With changes in the selection of therapies available for MS in recent years and more change expected in the near future, this is not an easy question to answer. A logical response might be, "You should remain on this therapy until a better choice becomes available for you." Some of the newer options offer the possibility of alternative dosage forms or, in some cases, longer dosing intervals.

An increasing volume of study results demonstrates significantly improved outcomes for people whose MS is treated over a long-term period. These include published 15-year data for glatiramer acetate (GA, Copaxone®) treatment and interferon beta-1a, and 16-year study results for interferon beta-1b (Betaseron®).[14,15] Outcomes in these trials show that people with MS who have longer durations of treatment have significantly lower annualized relapse rates and take longer to reach disability "milestones" as measured by the Expanded Disability Status Scale (EDSS) compared with people who drop out of therapy. For example, in the 15-year study of GA, patients who remained on GA continuously had a mean disease duration of 22 years and a mean age of 50 years, yet 66% had not transitioned to secondary-progressive MS during that time period, 57% had stable or improved EDSS scores, and 82% remained ambulatory without the need for mobility aids **(Table 2)**.[15] Sixteen-year data for interferon beta-1b showed that those with the highest exposure to the interferon (taking it for 80% or more of the trial interval) had a time from diagnosis of EDSS 6 (need for cane) of 13 years, versus 7 years for those with low exposure to the study drug **(Table 3)**.[14] New information from the long-term interferon beta-1b trials, released at a European meeting in 2011 but not yet published in the medical literature, shows a significant reduction in mortality related to treatment.[16]

Table 2. Efficacy Findings from Glatiramer Acetate 15-year Study[15]

	Intent to Treat	Ongoing	Withdrawn
Mean exposure to drug	8.6 years	13.6 years	4.8 years
Disease duration	17 years	22 years	13 years*
Patients with stable or improved EDSS score	54%	57%	52%*
% reaching EDSS:			
4.0	39%	38%	40%*
6.0	23%	18%	27%*
8.0	5%	3%	6%*

*While on glatiramer acetate therapy.
EDSS=Expanded Disability Status Scale.

Table 3. Time from Diagnosis to Confirmed EDSS 6.0 for Patients on Long-term Interferon Beta-1b[14]

Group	Years
Low exposure (<10% of 16-year study duration)	7
Medium exposure (10% to 80% of study duration)	10
High exposure (>80% of study duration)	13

EDSS = Expanded Disability Status Scale.

Tips for talking to patients: Many clinicians can remember how different patient outcomes were when DMTs were not available for MS. With the presently available therapies, we do not yet know the "end game"—that is, at what point the therapies may no longer be effective for treating relapsing or progressive forms of disease.[17] Many clinicians elect to keep patients on DMTs until the person's condition has progressed to a point where they are no longer having relapses and do not appear to derive benefit from the treatment. With no cure available at present, the "end" of DMT is not something to look forward to, but something to be delayed to the greatest extent possible.

Stable, Relapsing-remitting MS (RRMS)

Question: How do I know if my therapy is working?

One of the more frustrating aspects of treating MS is the inability to determine, when the disease appears to be stable, whether the person is responding to treatment or whether MS would have progressed relatively slowly in that individual. RRMS is characterized by clearly defined episodes of clinical relapse followed by partial or complete recovery.[18] Even with optimal adherence to therapy, most people with RRMS will eventually exhibit some disease progression. Progression (or worsening) of MS has been defined as a "change in EDSS score of 1.0 sustained over 90 to 180 days."[19] There is evidence that subclinical progression of MS occurs in the absence of relapses or between relapses.[20,21]

Normal signs of disease progression are very difficult to distinguish from a suboptimal response to therapy. What defines a suboptimal response to therapy has been a source of debate in the MS community. Some of the generally accepted parameters for suboptimal response are outlined in **Table 4**.[22,23]

Tips for talking to patients: It's important for people with MS to understand that results from large clinical trials can be applied to groups, but do not help predict an individual's response.[24] Thus each person's "success" on therapy must be evaluated individually. Patients can be informed of the basic guidelines and parameters for how disease progression is monitored, with local and institutional variations taken into account. It is also important that people with MS have a realistic attitude about treatment. While most patients do better while on therapy than off, DMT does not eliminate symptoms of MS such as fatigue and cannot guarantee that relapses will not occur. If a person has what the MS care provider believes to be an excessive number of relapses or an unstable pattern of MRI lesions, a change in therapy may be recommended.[22,23]

Table 4. Definition of Suboptimal Response to Therapy[22,23]

- Clinical and MRI activity after the initial 6-month to 1-year treatment period
- More than 1 relapse per year, or the failure of a given treatment to reduce the relapse rate from the pretreatment level
- Incomplete recovery from attacks
- Patients with recurrent brainstem or spinal cord lesions (known to be associated with an elevated risk for sustained, severe impairment)
- A significant increase in T2 disease burden while a patient is on therapy

MRI=magnetic resonance imaging.

Progressive Forms of MS

Question: What are the options for people with progressive forms of MS?

Progressive forms of MS are defined in **Table 5**.[18] Axonal loss early in the disease course has been shown to be more prevalent in primary-progressive MS (PPMS), whereas inflammation and demyelination predominate in RRMS.[25] At present, existing DMTs have not proved as effective in progressive forms of MS as in RRMS; thus, the management

Table 5. Progressive Forms of MS: Definitions[18]

Primary-progressive MS
- Disease progression from onset with occasional plateaus and/or temporary minor improvements
- No discrete clinical relapse or attacks

Secondary-progressive MS
- Initial relapsing-remitting course followed by progression with or without occasional relapse, minimal remission, or plateaus
- Baseline progression between relapses

Progressive-relapsing MS
- Disease progression from onset with occasional discrete clinical relapses and complete or near complete remissions
- Continued progression between clinical relapses

of symptoms is paramount. MS clinicians should explore the range of therapeutic options for these patients and set appropriate expectations about symptomatic treatments.

People with progressive forms of MS as well as RRMS often respond to extended-release dalfampridine (Amypra®), which has been shown in clinical trials to improve walking speed in approximately 1/3 of people with MS who have ambulatory impairment.[26] Dalfampridine is believed to work by restoring conduction by way of blocking certain potassium channels in demyelinated axons.[26] Because this drug does not treat the underlying disease, the patient's disability may progress despite improvements in gait.[27]

Tips for talking to patients: While progressive forms of MS seem to have been neglected in research, more hope for people with progressive MS is on the horizon. Many current and ongoing research studies are exploring novel therapeutic options specifically for this population, including stem cell therapies, monoclonal antibodies, oral medications, and combination therapies.[28]

Newer Therapeutic Options

Question: Can I stay on natalizumab (Tysabri®) even if I convert to JCV-positive status?

When this question arises, it's important for the patient and family to understand the facts about progressive multifocal leukoencephalopathy (PML) and the risks and benefits of continued treatment.

As many as 50% to 70% of the population carries antibodies to the usually-harmless John Cunningham virus (JCV).[29] The Food and Drug Administration (FDA) confirmed to health care professionals in January 2012 that testing positive for anti-JCV antibodies has been identified as a risk factor for PML.[30] The FDA notice stated, "The risks and benefits of continuing treatment with Tysabri should be carefully considered in patients who are found to be anti-JCV antibody positive and have 1 or more of the other known risk factors for PML."[30] These risk factors are:

1. The presence of anti-JCV antibodies, reflecting prior exposure to JCV;
2. Treatment with natalizumab for a period of longer than 2 years;
3. Prior treatment with immunosuppressive medications such as mitoxantrone, azathioprine, methotrexate, cyclophosphamide, or mycophenolate mofetil.[29-31]

People with all three known risk factors have an estimated risk of PML of 11 in 1,000 users.[30]

The "Stratify JCV Antibody ELISA" is sensitive for a very low titer of antibodies.[32] This test can help to assess the risks and benefits of continuing natalizumab treatment, but should not be used on its own as a basis for determining PML risk.[32] Importantly, patients need to understand that this test is not used to diagnose PML itself.

Currently, there is no treatment, prevention, or cure for PML, and no definite way to predict who will develop it.[32] Prior immunosuppressive therapy

increases the risk of PML by 2- to 4-fold.[33] Of patients treated with natalizumab who developed PML, 46% had received previous autologous bone marrow transplantation (mostly European), while up to 25% (13% in the United States, 24% in Europe) had prior chemotherapy treatment with agents such as mitoxantrone, azathioprine, methotrexate, or mycophenolate mofetil.[33]

PML is related to cumulative exposure to natalizumab, with the incidence increasing according to the number of infusions received.[29] PML has *not* been seen thus far in patients treated with natalizumab for 6 months or less. After 6 months of therapy, new gadolinium-enhancing lesions are rare (unless the patient has neutralizing antibodies to natalizumab), so any new MRI lesions in such a patient should be considered suspicious for PML.[33] Some centers monitor for neutralizing antibodies at 6 months in all natalizumab-treated patients to help make this distinction.[29]

Symptoms of PML develop in affected patients whose duration of therapy ranges from 6 to 81 infusions, and may develop well before PML is diagnosed.[33] The most common presenting symptoms are cognitive, motor, language, and visual impairments, but these can be difficult to distinguish from MS symptoms. Patients should be instructed to report to an MS care professional any new or worsening symptoms lasting more than 24 to 48 hours. Gadolinium-enhancing lesions are observed at presentation in about 1/2 of patients. Seizures and paroxysmal events can occur at presentation, which helps to differentiate PML from an MS relapse. PML usually causes death or severe disability. The mortality associated with natalizumab-related PML was 19% (29 deaths among the 150 confirmed cases) as of August 2011, but in cases with at least 6 months of follow-up, mortality increased to 60%.[34] Many who survive are left with serious morbidity and permanent disability.[30]

Some patients elect to stay on the therapy despite converting to JCV-positive status, especially if they have experienced disease progression while on other MS therapies.[29,31,35] The decision of whether to continue natalizumab after JCV antibody conversion should be guided by 1) the presence of other risk factors; 2) length of time on natalizumab therapy; 3) previous response to other DMTs; and 4) risk acceptance of the patient.[35]

Monitoring and Follow-up of Therapies

Question: Why do I need to have: blood work, ECGs, all these tests?

Keeping track of patients' safety monitoring requirements has added to the complexity of the MS nurse's job. Safety monitoring is a necessary step that cannot be overlooked by people with MS or those involved in their care. Monitoring requirements vary widely according to the type of treatment a patient receives. Patients on interferon beta (any formulation) should receive complete blood count and liver function tests at least once a year, as recommended in the prescribing information.[36-38] While these tests have often been overlooked, increasingly MS clinics and insurers are requiring that patients be up to date on blood work and other necessary tests before they will authorize or pay for prescription refills for MS drugs. Fingolimod (Gilenya®), the oral MS therapy approved in September 2010, has a more complex set of monitoring requirements at the initiation of the first dose and during therapy **(Table 6)**.[39]

Even though eye examinations and 3-month follow-up visits are clearly called for during fingolimod therapy, MS nurses often encounter patients who overlook or neglect these steps. This may be especially true among people whose MS disease activity is relatively low—they want to forget their therapy and get on with their lives. It's important to

Table 6. Monitoring Requirements for Fingolimod Therapy[39]

- Obtain ECG in all patients prior to dosing and at end of observation period.
- Before initiating treatment, obtain a recent CBC (within 6 months).
- Patients without a history of chickenpox or who have not been vaccinated against VZV should be tested for VZV antibodies. Monitor for infection during treatment and for at least 2 months after discontinuing therapy.
- Administer first dose in a setting with resources to manage symptomatic bradycardia.
  - Observe patients for 6 hours after the first dose for signs and/or symptoms of bradycardia.
  - Monitor pulse and blood pressure hourly.
  - Follow recommendations on labeling if bradycardia occurs (see prescribing information).
- Perform ophthalmic evaluation at baseline and 3 to 4 months after treatment initiation.
- If patients report visual disturbances at any time during treatment, order additional ophthalmologic evaluation. Patients with diabetes mellitus or a history of uveitis should have regular ophthalmologic evaluations while receiving fingolimod.
- Perform spirometric evaluation of respiratory function and evaluation of diffusing capacity of lungs for carbon monoxide during therapy if clinically indicated.
- Obtain recent (within 6 months) transaminase and bilirubin levels before initiation of treatment.
- Monitor liver enzymes in patients who develop symptoms suggestive of hepatic dysfunction.
- If therapy is discontinued for more than 14 days, follow guidelines in product labeling for heart rate monitoring with reintroduction of therapy.

CBC=complete blood count; ECG=electrocardiogram; VZV=varicella zoster virus.

explain to patients not only *what* safety monitoring steps are involved, but *why*. It may help to remind patients and family members that most complications of treatment do not come with a warning bell, but may be happening quietly, behind the scenes. The sooner any unexpected risks or adverse events are detected, the better the patient and the MS care team will be able to avoid more serious problems and make appropriate decisions about treatment.

Tips for talking to patients: Reinforcement of the message may be just as important as the initial education process. Studies of adherence in MS show that patients typically start off well with a new therapy, but are more likely to miss doses or discontinue treatment as more time progresses.[2,40] For a patient who fails to follow through with follow-up and monitoring visits despite reminder attempts, the clinician may elect to delay a prescription refill for the MS treatment until monitoring has been completed.

Question: Is oral therapy right for me?

There is a lot more to this decision than deciding whether a pill is better than an injection. The approved oral therapy, fingolimod, and some other oral MS treatments now in clinical trials may carry a greater risk of serious adverse effects than the current injectable therapies.[41,42] For patients who are considering oral treatment, the discussion will usually focus on factors such as:

- possible contraindications to therapy, such as heart rhythm abnormalities;
- whether the person understands and agrees to the monitoring requirements;
- how well the person is currently doing on injectable therapy (adherence and injection technique, disease control, skin health); and
- available insurance coverage or affordability.

People vary widely in terms of how much risk they are willing to accept based on personality traits, personal preferences, family priorities, and other issues. Some patients want the newest or "strongest" therapy notwithstanding the risks, while others prefer approaches with better long-term safety records. The nurse's role is to present the information and guide the patient in determining his or her own risk

Finding Time to Communicate

The time slot designated for the patient's appointment is rarely realistic for answering all of a person's questions about MS. How do MS nurses find the time to educate, advocate, comfort, and reassure?

Email or no email? Some nurses feel strongly that email is not an appropriate method for answering patient questions—and others say they couldn't live without it. The decision about whether to answer treatment-related questions via email may come down to an institutional directive and what the administration will allow. Those who do use email should set appropriate expectations: Some patients may want to fire off a question and expect an exchange every few minutes, but if a nurse is busy seeing other patients he or she is unlikely to be sitting in front of the computer. Clinicians who use email may want to consider setting a time frame for answering emails (e.g., "Email will be answered between 4:00 and 4:30 daily. If the matter is more urgent, please contact the office via phone.")

The phone. Friend or foe? Some MS nurses feel that a question about treatment has subtle nuances that only a phone or face-to-face conversation can pick up. Again, it can be helpful for people—particularly those newly diagnosed with MS—to be aware of the best times to call with questions and what options are available for any after-hours concerns. Support services provided by the manufacturers of MS therapies can be especially helpful in providing information about administration, side effects, and daily medication management. Many of these services have 24-hour helplines available.

Electronic medical record systems. Some institutions are turning to electronic systems such as EPIC to provide a limited amount of medical information (such as lab results) to patients. The systems may provide a link to allow emailing the organization, and some patients may use this as an avenue for inquiries related to their care. Organizations using these systems should be aware of the level of patient communication that is occurring, and decide up front on a system to best handle such inquiries.

tolerance related to a particular treatment option.

Because people may have a tendency to assume that an oral therapy is more benign than one that must be injected with a needle, patients need to be reminded that oral therapies for MS and other conditions are not without risks of serious adverse events. As of February 2012, 11 deaths have been reported among people receiving fingolimod therapy, four of them involving serious heart-related events (three heart attacks and one that involved a heart rhythm disturbance), and seven unexplained deaths.[43] A US patient who died within 24 hours of taking the first dose was among the latter seven mortalities.[44]

Fingolimod is known to be associated with heart-rhythm disturbances including bradycardia, which may be related to slowed conduction of electrical impulses from the upper chambers to the lower chambers of the heart.[39] Before beginning fingolimod therapy, patients should be asked if they are taking drugs used to treat abnormal heart rhythms, beta blockers, or calcium channel blockers, or if they have a history of heart-related problems such as low heart rate, heart rhythm disorders, congestive heart failure, or fainting.[39] Patients taking fingolimod should be counseled to immediately report any symptoms of heart problems, which may include chest pain, slow or irregular heartbeat, or feeling

dizzy.[44] If this occurs, the patient should not stop taking the medication without first consulting a health care professional.

New safety recommendations for Gilenya™ were updated jointly by the FDA and the European Medicines Agency in April 2012. This resulted in recent labeling changes with revised guidelines for patient selection and monitoring during the first dose and in case of treatment interruption, to better manage risk of bradycardia associated with this agent **(Table 6)**.[45]

Conclusion

The amount of information that a person with MS must absorb, especially after diagnosis, can be overwhelmingly complicated and frequently changing. Presenting the information in a way that the patient and family can understand is a challenge that varies according to the individual's background, educational level, and willingness to learn about the condition. It's important to help patients gain perspective that, despite the presence of risks seen with newer MS therapies, the benefits of treatment with a DMT outweigh the risks in most cases.

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Counseling Points™

Answering Patients' Treatment-related Questions

If I have had just one attack, do I really need to be on a medication?

Treatment during a clinically isolated syndrome (CIS) reduces the number of active lesions as well as relapses, and corresponds with better long-term outcomes. Treating early is better than waiting until it's too late and permanent damage to brain and nerve cells is already done.

How long will I have to be on this drug?

You should remain on this therapy until a better choice becomes available for you. More studies are showing significantly improved outcomes for people whose MS is treated over a long-term period. We do not yet know the point at which therapy may no longer be effective for treating relapsing-remitting MS (RRMS).

How do I know if my therapy is working?

Normal signs of disease progression can be difficult to distinguish from a suboptimal response to therapy. Signs suggesting a treatment is NOT effective include clinical and/or magnetic resonance imaging (MRI) activity after the initial 6 months to 1 year; more than one relapse per year; failure to reduce the relapse rate from the pretreatment level; incomplete recovery from relapses; and brainstem or spinal cord lesions.

What are the options for people with progressive form of MS?

Disease-modifying therapies (DMTs) have not proved as effective in progressive MS as in RRMS. Management of symptoms is paramount. Extended-release dalfampridine improves walking speed in approximately 1/3 of those with ambulatory impairment. Progressive MS has been neglected in research, but many new research studies are under way.

Can I stay on natalizumab even if I convert to JCV-positive status?

Some people elect to stay on the therapy despite converting to JCV-positive status, especially if they have experienced disease progression while on other MS therapies. The decision should be guided by: 1) the presence of other risk factors; 2) length of time on natalizumab therapy; 3) previous response to other DMTs; and 4) your level of risk acceptance.

Why do I need to have: blood work, ECGs, all these tests?

Complications of treatment do not come with a warning bell. Early detection of any unexpected risks or adverse events helps you to avoid more serious problems and helps us make appropriate decisions about your treatment. In addition, many clinics and insurers require that you be up to date on blood work and necessary tests before they will authorize or pay for prescription refills for MS drugs.

Is oral therapy right for me?

This decision must be made on a case-by-case basis. Just because a drug is taken via a pill does not mean it is safer than one injected with a needle. Some oral therapies for MS are associated with risks of serious adverse events that must be weighed on an individual basis.

Continuing Education Posttest

To receive contact hours, please read the program in its entirety, answer the following posttest questions, and complete the program evaluation. A certificate will be awarded for a score of 80% (9 correct) or better. A certificate will be mailed within 4 to 6 weeks. There is no charge for the CNE credit.

By Mail: Delaware Media Group, 66 S. Maple Ave., Ridgewood, NJ 07450

By Fax: (201) 612-8282

Via the Web: Applicants can access this program at the International Organization of MS Nurses' website, www.IOMSN.org. Click on *Counseling Points* and follow the instructions to complete the online posttest and application forms.

PLEASE SELECT THE BEST ANSWER

1. Among patients diagnosed with clinically isolated syndrome, what percentage has been shown to develop clinically definite multiple sclerosis (MS) within a few years?
A. 25%
B. 50%
C. 75%
D. >80%

2. According to pivotal trials, patients treated with interferon beta or glatiramer acetate during CIS have a ____% chance of converting to clinically definite MS within 12 months.
A. 5% to 10%
B. 25% to 35%
C. 40% to 50%
D. >50%

3. Long-term (15- to 20-year) MS trials show that—compared with patients who discontinue therapy—those treated over a longer duration have:
A. the same long-term outcome as those treated only 5 years
B. longer time before reaching disability milestones such as Expanded Disability Status Scale (EDSS) score 6
C. lower annualized relapse rates
D. both B and C

4. Treatment with MS disease-modifying therapies (DMTs) has been shown to affect long-term outcomes but has not been shown to impact mortality.
A. True
B. False

5. In relapsing-remitting MS, MS progression or worsening of disease occurs:
A. only during relapses
B. during relapses and subclinically between relapses
C. primarily after conversion to secondary-progressive MS
D. data are insufficient to determine when worsening occurs

6. Signs suggesting a DMT is NOT effective include:
A. clinical and/or MRI activity 6 months to 1 year after therapy initiation
B. clinical and/or MRI activity 1 to 2 years after therapy initiation
C. changes in EDSS score within the first 5 years of therapy
D. any changes in clinical status or MRI while on therapy

7. A patient whose MS is characterized by disease progression from the onset, with occasional plateaus but no evidence of discrete clinical relapse or attacks, would be diagnosed as having:
A. primary-progressive MS
B. relapsing-remitting MS
C. secondary-progressive MS
D. progressive-relapsing MS

8. Known risk factors for PML in a patient receiving natalizumab include all of the following EXCEPT:
A. anti-JCV antibodies
B. natalizumab treatment duration greater than 2 years
C. prior treatment with an interferon or glatiramer acetate
D. prior immunosuppressive therapy

9. The presence of new gadolinium-enhancing lesions in a patient treated with natalizumab for 9 months is suggestive of:
A. nonadherence to natalizumab
B. neutralizing antibodies to natalizumab
C. onset of PML
D. both B and C above

10. Monitoring recommendations for patients receiving treatment with interferon beta include:
A. herpes zoster antibodies
B. electrocardiogram
C. complete blood count
D. all of the above

11. Patients who are receiving the oral therapy fingolimod for MS should be advised to be especially aware of:
A. stomach upset
B. irregular heart rate or dizziness
C. skin reactions
D. changes in bowel habits

12. Ophthalmic evaluation is recommended for patients taking fingolimod at baseline and:
A. once a month for the first year of treatment
B. 3 to 4 months after treatment initiation
C. 1 year after treatment initiation
D. at 6 months only if visual disturbances are detected at baseline

Counseling Points™: Program Evaluation Form

Answering Patients' Treatment-related Questions

Using the scale provided (Strongly Agree = 5 and Strongly Disagree = 1) please complete the program evaluation so that we may continue to provide you with high-quality educational programming. Please fax this form to **(201)612-8282** or complete it online as instructed below.

5 = Strongly Agree 4 = Agree 3 = Neutral 2 = Disagree 1 = Strongly Disagree

At the end of this program, I was able to: *(Please circle the appropriate number on the scale.)*

1) Advise patients about the importance of initiating therapy for clinically isolated syndrome or early MS 5 4 3 2 1

2) Describe decision-making steps for patients who have relapses or magnetic resonance imaging (MRI) activity while on therapy 5 4 3 2 1

3) Evaluate the balance between safety and efficacy for MS treatments 5 4 3 2 1

4) Review recommended protocols for follow-up with patients on MS therapies 5 4 3 2 1

To what extent was the content:

5) Well-organized and clearly presented 5 4 3 2 1

6) Current and relevant to your area of professional interest 5 4 3 2 1

7) Free of commercial bias 5 4 3 2 1

8) Clear in providing disclosure information 5 4 3 2 1

General Comments

9) As a result of this continuing education activity (check only one):

❒ I will modify my practice. (If you checked this box, how do you plan to modify your practice?)_____

_____

❒ I will wait for more information before modifying my practice.

❒ The program reinforces my current practice.

Suggestions for future topics/additional comments: _____

_____

Follow-up

As part of our continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please check one:

❒ Yes, I would be interested in participating in a follow-up survey.

❒ No, I would not be interested in participating in a follow-up survey.

There is no fee for this educational activity.

Posttest Answer Key	1	2	3	4	5	6	7	8	9	10	11	12

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