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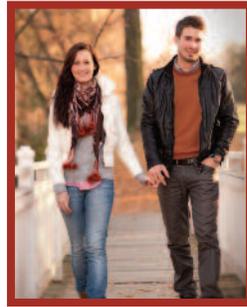
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WHAT'S THIS?

QR-code enabled smartphone users may scan this image to view this issue of *The Motivator* on their mobile device.



The Multiple Sclerosis Association of America is a leading resource for the entire MS community, improving lives today through vital services and support.

MSAA strives to provide useful, up-to-date information on matters of concern to MS patients and their families. This material is intended for general informational purposes only, and it does not constitute medical advice. You should not use the information presented as a means of diagnosis or for determining treatment. For diagnosis and treatment options, you are urged to consult your physician.

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A portion of this magazine has been printed on recycled paper using soy-based ink.



Douglas G. Franklin

In Appreciation of Volunteers

This time of year brings back-to-school and back-to-work to mind. Nowhere is this more important than recognizing the incredible work that volunteers perform to help make their communities better. I had the honor of serving for nine years on the Board of America's Charities. Volunteering for this vital organization was a pleasure and a privilege.

To better explain why I was so driven to volunteer for America's Charities, I want to provide some background information from their website. "America's Charities was organized by a handful of charities looking for a better way to engage in workplace philanthropy... Our members help millions of people in thousands of local communities every day by providing services that protect children, promote health, ensure civil and human rights, broaden educational opportunities, protect animals, and protect the environment...among a broad variety of other critically needed services. America's Charities is governed by an independent Board of Directors. Members of the Board are not compensated for their services. The Board includes corporate, charity and not-for-profit executives."

And this is where I came in! You can see why I have such a strong interest in this organization, which helps to keep more than 140 vital charities funded – including MSAA – so they in turn may provide urgent programs and services to millions of people throughout the United States. To all of the volunteers and donors who help us to help others every day, a big thank you and shout out of sincere appreciation from all of us here at MSAA! ♦

Doug Franklin joined MSAA as President & CEO in 1999. He has a distinguished career in nonprofit leadership and is a former national trainer in strategic planning for the Peter Drucker Foundation. A published international expert in social marketing and corporate social investment, he is a graduate of four universities and holds dual certifications in two professional associations. He currently serves on the National Board of the Key Philanthropic Organizations Committee of the American Society of Association Executives and as President of the Multiple Sclerosis Coalition.



May 22, 2013

Dear Doug,

As your term as an America's Charities Board Director comes to a close, we would like to express our deepest appreciation and thank you for your years of service, leadership, commitment, and contribution to helping America's Charities fulfill its mission of generating sustainable income through workplace giving for charities.

Since becoming a Director in 2004, you have volunteered your time, talents, and resources to America's Charities' success serving on the Health First - America's Charities Board as Secretary (2005) and Vice Chair (2009 - current) and on the Health First Executive Committee (2004 - current), America's Charities Strategic Planning Committee, Communications & Media Relations Committee, America's Charities Nominating Committee, Health First Nominating Committee, and Governance Task Force. Your knowledge, expertise, and vision have been invaluable as we chart the future path of America's Charities to achieve our vision of transforming philanthropy.

On behalf of the America's Charities Board Directors, thank you, Doug, for helping America's Charities fulfill its mission. You are leaving an enduring legacy of giving and sharing to preserve and improve the quality of life for all those served by our member charities.

Your board service has been exemplary, and you have been truly dedicated to providing the highest level of professionalism as a board member. It has been our privilege to have worked with you.

With appreciation,

A handwritten signature in black ink that reads "Marcia Bullard".

Marcia Bullard
Board Chair
America's Charities

A handwritten signature in black ink that reads "Steve Delfin".

Steve Delfin
President & CEO
America's Charities

Managing the

PHYSICAL SYMPTOMS of MS



Strategies to help to minimize the more visible symptoms of MS and improve your quality of life

Compiled and Edited by Susan Wells Courtney
Reviewed by Jack Burks, MD

In the Winter/Spring 2013 issue of *The Motivator*, the cover story provided information and strategies for managing the “hidden” or “invisible” symptoms of MS. This referred to symptoms such as pain, fatigue, sleep issues, cognitive changes, and visual problems.

In this second part of a three-part series, we address some of the more visible physical symptoms of MS. These include mobility issues, spasticity, tremor and balance, bladder and bowel problems, sexual dysfunction, difficulties with speech and swallowing, and weakness. In our next issue of *The Motivator*, we will discuss how to best manage the emotional changes that occur with MS.

These sections have been written and reviewed by top MS experts who are members of MSAA’s Healthcare Advisory Council, and then reviewed again by MSAA’s Chief Medical Officer Jack Burks, MD. Please note that while specific treatment strategies and medications are listed, this information may not be considered as specific medical recommendations or advice. The details provided in this article are for informational purposes only, and readers are strongly urged to see their physician before making any changes to their treatment regimen, exercise routine, or any other aspect of their healthcare or lifestyle.

Mobility and Ambulation

Written by Patricia G. Provance, PT, MSCS
Semi-retired physical therapist who specializes
in rehabilitation for individuals with MS

With MS, maintaining safe and independent mobility can sometimes be difficult. The result is often a marked decrease in overall activity – which leads to preventable disuse weakness and deconditioning. If inactivity continues, other problems can develop. These include: muscle tightness and/or weakness; increased spasticity; bowel problems (usually constipation); decreased heart and lung function; pressure sores; depression; and social isolation.

Everyone should have the goal of achieving, and then maintaining, the highest possible level of independent function. This includes safe mobility – both at home and in the community. My recommendation is for everyone with MS to receive a baseline evaluation from a physical therapist (PT) experienced in MS care.

An evaluation can spotlight many subtle symptoms that can be addressed before they worsen into significant issues. These symptoms might include:

- Fatigue/decreased endurance
- Foot drop/drag (especially later in the day)
- Weakness in leg(s) and/or trunk
- Deconditioning
- Mild spasticity (increased tone, which gets worse with fatigue)
- Muscle tightness from inactivity
- Compensatory movement patterns (such as “hiking” or lifting of the hip; leaning to

clear the weak leg when walking; or using arms to help stand up)

- Problems with balance (which may include falls, near-falls, and/or difficulty on stairs)
- Impaired vision or sensation
- “Wobbly” walking

All of the above problems will affect independent walking and can be targeted in a corrective program.

The invisible and disabling symptom of fatigue requires behavioral or lifestyle modifications, including wise, energy-management practices. Employing the “Four P’s” of PACING, PRIORITIZATION, PLANNING, and POSITIONING can be helpful. Additional wise, energy-management practices are to avoid over-heating, work toward appropriate strengthening and conditioning, employ good sleep practices, eat a healthy diet, and when needed, use an ambulation aid.

Evaluation of walking and gait training is extremely important and should be done both at the beginning and at the end of the therapy session to gauge the effect of fatigue. It is quite helpful if the therapy department has a variety of trial ambulation aids to see which (perhaps several) works best.

Understandably, many individuals with MS are initially quite reluctant to accept a walking aid and often delay going to therapy. From the standpoint of a PT, an “attitude adjustment” is often needed. I encourage my MS patients to view ambulation aids as tools that have the potential to normalize their walking pattern. By doing so, this can result

in less fatigue, improved posture and balance, less pain, more endurance, and the correct training of the walking muscles. I have witnessed dramatic improvement in patients' gait and endurance by initially using these aids for training, and later, just as needed for issues such as distance, energy conservation, and worsening symptoms during MS flare-ups.

Another factor often overlooked is shoe type. Shoes should be supportive (having an enclosed heel) as well as lightweight. A rubber sole can add to stability, and supportive sneakers with a good cushioned insole and arch support may be an excellent option. However, rubber soles or sneakers may not be appropriate for everyone – particularly if foot drag or slide might be a problem – because a rubber sole can cause the foot to occasionally stick.

Many different ambulation tools are on the market, so a professional should be involved in assessing and prescribing those best suited to each person's needs. The experienced PT can advise the physician regarding the needed prescription or letter of medical necessity (LOMN). It is not unusual for several aids to be prescribed in order to meet the varying needs for support, distance, and other factors. Some of the most popular ambulation aids are:

- Foot-drop brace (the new lightweight carbon models are popular, but expensive, and only work for certain types of foot drop)
- Folding canes (those with a “palm-grip” are the most comfortable)

- Lightweight forearm crutches (those with cushioned grips and full cuffs are best)
- Four-wheeled rolling walkers (for the active community user, a lightweight model is preferred, along with the following favorite features: a flip-up seat, no front-cross bar, user-friendly brakes, and a flexible backrest)
- Functional Electrical Stimulation ([FES] – this new wireless technology is only appropriate for some; it is also expensive and may not be covered by insurance; a PT evaluation is highly recommended before purchasing this type of aid)

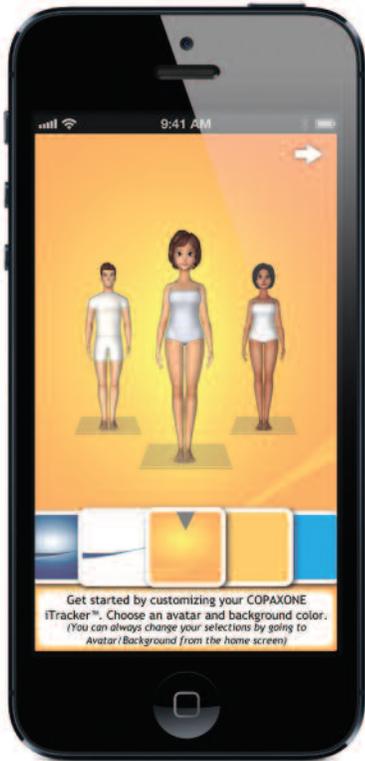
Achieving and maintaining smooth, safe, and independent ambulation will certainly result in improved health and quality of life. However, when that is not possible, many wheeled mobility options are available for those with limited or no ambulation abilities.

Medication for Mobility

Ampyra® (dalfampridine) is the only drug to date that has been approved for individuals with MS to improve walking speed. Ampyra is an oral, timed-release medication developed to improve the conduction of impulses between damaged nerves of the central nervous system (CNS). In earlier studies, larger doses of the drug were given and the risk of seizures became a concern. Given in extended-release tablets, the risk of seizures did not differ from the placebo group. However, patients still need to be aware of this potential risk and not take more than the prescribed dose. Side effects include dizziness, falls, back pain, insomnia, fatigue, nausea, and balance problems.

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Spasticity

Reviewed by Randall T. Schapiro, MD
President, The Schapiro MS Advisory Group
Clinical Professor of Neurology, University of
Minnesota (retired)

Spasticity is a common symptom in MS. It is a tightness or stiffness of the muscles – occurring typically in the legs (calf or thigh), groin, and buttocks. Although less common, some individuals may experience spasticity in their back. These are all muscles that help people to stand and balance in an upright position.

Spasticity in MS is a result of demyelination along the nerves of the brain and spinal cord that control movement. Sometimes the stiffness caused by spasticity is slight and can actually be helpful by giving individuals more support to stand or turn. Mild spasticity is not painful. However, when spasticity is more severe, it can become painful. More energy is needed to perform daily activities when spasticity is more pronounced, causing discomfort and limiting movement.

Through different treatment strategies, spasticity can be managed. And when one's spasticity is reduced, this in turn allows the individual to be more comfortable, stronger, and to move more freely. Fatigue is also reduced, as movements do not require as much effort. Coordination improves as well, because muscles are working together more efficiently.

Several strategies may be used to reduce the effects of spasticity. Initially, any other treatable issues that may contribute to this symptom should be addressed. For instance, if an individual is experiencing pain separate from spasticity – perhaps from an infection or a skin sore – these can worsen muscle tightness. Treating these types of underlying conditions can help to reduce spasticity.

The next step for many individuals in treating spasticity is to consult a physical therapist to help create an exercise plan, one which uses different stretching exercises that can be done at home. In the 5th edition of *Managing the Symptoms of Multiple Sclerosis*,



examples of helpful exercises are described, as follows:

“A thorough stretching program includes a series of exercises that are performed in certain sitting or lying positions that allow gravity to aid in stretching specific muscles. While in the sitting position, a towel or long belt may be used to pull on the forefoot and ankle to stretch the calf, or to stretch the thigh muscles when one is lying on the stomach. Certain muscles may be relaxed more effectively while one is lying on the stomach or side, or while lying on all fours over an exercise ball, rocking rhythmically forward and backward.

“The simplest and often the most effective way to reduce spasticity is passive stretching, in which each affected joint is slowly moved into a position that stretches the spastic muscles. After each muscle reaches its stretched position, it is held there for approximately a minute to allow it to slowly relax and release the undesired tension. This stretching program begins at the ankle to stretch the calf muscle, then proceeds upward to the muscles in the back of the thigh, the buttocks, the groin, and, after turning from the back to the stomach, the muscles on the front of the thigh.

“Range-of-motion exercises differ from stretching exercises in that the movement about the joint is not held for any specific length of time. Although range of motion is important, holding the stretch is significant, and patience is essential when doing the stretches.”

According to the book, the key to

managing spasticity is to continually increase the number as well as the type of movements used in these exercises.

However, care must be taken to use the least amount of effort possible while performing these exercises, so as to not overuse any muscle groups or cause fatigue.

Another strategy is to use complementary and alternative types of treatment, such as relaxation techniques, deep breathing, and guided imagery. The relaxation techniques involve the progressive tensing and then releasing of different muscles, along with deep breathing and guided imagery. Some individuals may also benefit from acupuncture, although the reason for its benefits has not been identified. In addition, some patients may benefit by using cooling devices or ice packs after exercise to reduce spasticity.

One very helpful method of reducing spasticity is aquatic therapy or aquatic exercise (both refer to forms of exercise in a swimming pool). The natural buoyancy from activity in the water enables participants to move with less effort. Both stretching exercises and range-of-motion exercise may be performed in a pool. MSAA is developing a new program that will emphasize the benefits of swimming/aquatic exercise for individuals with MS, so please watch for future announcements on this exciting program initiative.

Please note that the temperature of the water in the pool is very important for individuals with MS. If too cold, it can cause spasticity to worsen. If too warm, individuals may become fatigued. Experts

have determined that 85 degrees is about the ideal temperature for people with MS.

Beyond the treatment of underlying conditions, and an exercise plan that includes stretching, range-of-motion, and possibly aquatic exercise, certain devices may be of great assistance. These can be particularly helpful in avoiding contractures (causing reduced movement in a joint) by allowing muscles to relax while maintaining a proper position.

Examples include toe and finger spreaders as well as braces for the foot, hand, or wrist. These devices are referred to as orthoses and may be custom-made by an orthotist for an optimal fit. Many people are familiar with an ankle-foot orthosis (AFO), which holds and angles the foot and ankle in the best position for maximum comfort and mobility. It can also relieve stress on the knee.

Once exercise and devices have been employed, medication may be needed to further reduce spasticity. Baclofen is the most commonly prescribed medication to treat spasticity in MS and is usually very effective. It may be taken orally, or for individuals with more severe spasticity, given via an implanted pump that provides the medicine directly into the spinal fluid. Dosage often varies with each person and needs to be carefully monitored – since too much can cause fatigue and weakness, and too little is not effective. One benefit of the pump is that by going directly into the spinal fluid, a much smaller dose is needed to accomplish the desired effect.

Other medications are also available and may be more appropriate for some. These decisions can only be made through consultation with one's healthcare provider. Different therapies may also be used in severe cases that do not improve with the traditional treatments. These include procedures that temporarily block the nerve and muscle (Botox® or Myobloc™ injection), among other, more permanent treatments. Examples include chemically inactivating a muscle and surgically cutting specific nerves or tendons.

The following medications may be used to treat spasticity (as listed on MSAAs website at mysaa.org under symptoms). Please see MSAAs website for more information about these drugs, such as prescribing information and side effects.

- Baclofen (formerly available as Lioresal®)
- Zanaflex® tablets and Zanaflex Capsules® (tizanidine hydrochloride)
- Valium® (diazepam)
- Klonopin® (clonazepam)
- Dantrium® (dantrolene sodium)
- Neurontin® (gabapentin)
- Tegretol® (carbamazepine)
- Keppra® (levetiracetam)
- Requip® (ropinirole)

Reference

Schapiro, R. T., *Managing the Symptoms of Multiple Sclerosis*, 5th edition, (Demos Medical Publishing, 2007)

Tremor and Balance

Reviewed by Randall T. Schapiro, MD
President, The Schapiro MS Advisory Group
Clinical Professor of Neurology, University of
Minnesota (retired)

Tremor in MS

Tremor is a difficult symptom to manage. This is a back-and-forth or “oscillating” movement that usually affects the arms or legs, but can also (less frequently) affect the head or body (trunk). Individuals experiencing tremor may find that this symptom varies and is not always present. However, when tremor does occur, it can interfere with one’s balance and coordination. To follow are examples of how tremors vary:

- **Size of movements:** ranging from very small movements (fine tremor) to large movements (gross tremor)
- **Areas affected:** limbs, head, or trunk; can also affect speech
- **When they occur:** when the muscle is at rest or when intentionally moving
- **Speed of tremor:** ranging from slow to fast
- **Impact of tremor:** some may be barely noticeable and more of an annoyance; others may be significant, interfering with normal function and daily activities
- **Response to treatment:** some tremors may respond well to treatment, others do not

With so many variables, having the tremor evaluated by a neurologist or other healthcare professional is critical for determining the most effective treatment plan.

With MS, the most frequently seen tremor is caused by demyelination in the cerebellum,



which is located in the lower-back region of the brain. This area of the brain helps to control movement, coordination, balance, and muscle tone. This type of tremor tends to be a slow, gross tremor affecting a limb when moving intentionally (purposeful movement). Unfortunately, this type of tremor is the most challenging to treat. Additionally, stress and anxiety can worsen this type of tremor, which may improve when treated with a sedating type of medication.

Different strategies may be used in an effort to reduce tremors. These include:

Bracing: Braces can immobilize a joint and control extra movement. Bracing the ankle and foot can add stability for standing or walking; braces may also be used for the arm, hand, or neck.

Weighting: Adding extra weight to an affected area can help to stabilize a part of the body, such as the feet, ankles, wrists, and hands. Items can also be weighted, including

pens, pencils, eating utensils, a cane, or a walker.

Speech therapy: When tremors around the mouth (lips, tongue, and jaw) interfere with speaking, speech therapy may help. Strategies include techniques to slow speech, increase clarity, and control loudness.

Adaptive equipment: Employing special household items designed to be used in daily activities can be helpful. These can be easy to hold or keep in place with everyday activities – such as writing, dressing, and eating.

Medications: Several medications (listed below) are available to treat certain types of tremor; a healthcare professional can prescribe the one that is best suited for his or her patient.

Treatment plans will often include a combination of strategies to minimize the effects of tremors, but do not eliminate them. The following medications may be used to treat tremor (as listed on MSAA's website at mymsaa.org under symptoms).

- Atarax[®], Vistaril[®] (hydroxyzine)
- Klonopin[®] (clonazepam) and Buspar[®] (buspirone)
- Neurontin[®] (gabapentin)
- Inderal[®] (propranolol)
- Zofran[®] (ondansetron)
- Keppra[®] (levetiracetam)
- Mysoline[®] (primidone)
- Laniazid[®], Nydrasid[®] (isoniazid)

Balance Problems in MS

The cerebellum is located in the lower-back region of the brain, and helps to control movement, coordination, balance, and

muscle tone. While demyelination in this area can cause tremor for some individuals, it can cause balance problems as well. Other components, such as vision, hearing, and movement of the arms and legs, are also involved in balance. Problems with the functioning of any of these areas can worsen balance, but conversely, some of these areas may be able to compensate for other deficits in balance.

Unlike tremor, balance cannot be treated with medication. The only therapy for balance is through exercise. Physical and occupational therapists will often use an exercise known as patterning when treating balance issues. With patterning, the therapist guides the patient through repeated movements with the idea of retraining the muscles to gain more control and coordination while moving in that same pattern.

Another technique, known as vestibular stimulation, uses motion such as rocking, swinging, or spinning to challenge the brain stem where balance can be affected. This added stimulation helps the balance centers of the brain to function better. Another therapy that may be helpful for individuals who can stand is the SMART Balance Master[®]. Using a computer, this balance stimulation program tracks the movements of the patient's feet on the screen and helps to teach the patient how to improve his or her balance.

Reference

Schapiro, R. T., *Managing the Symptoms of Multiple Sclerosis*, 5th edition, (Demos Medical Publishing, 2007)

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IMPORTANT SAFETY INFORMATION

Do not take AMPYRA if you have ever had a seizure, or have certain types of kidney problems, or are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA.

Take AMPYRA exactly as prescribed by your doctor. You could have a seizure even if you never had a seizure before. Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50. Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking AMPYRA.

AMPYRA should not be taken with other forms of 4-aminopyridine (4-AP, fampridine), since the active ingredient is the same.

In two pivotal trials 35% and 43% of patients taking AMPYRA responded to treatment vs. 8% and 9% of patients taking placebo.

Talk to your doctor to see if AMPYRA may be right for you.

AMPYRA may cause serious allergic reactions. Stop taking AMPYRA and call your doctor right away or get emergency medical help if you have shortness of breath or trouble breathing, swelling of your throat or tongue, or hives.

Please see the full Patient Medication Guide on the following page.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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MEDICATION GUIDE FOR AMPYRA® (am-PEER-ah) (dalfampridine) Extended Release Tablets

Read this Medication Guide before you start taking AMPYRA and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about AMPYRA?

AMPYRA can cause seizures.

- You could have a seizure even if you never had a seizure before.
- Your chance of having a seizure is higher if you take too much AMPYRA or if your kidneys have a mild decrease of function, which is common after age 50.
- Your doctor may do a blood test to check how well your kidneys are working, if that is not known before you start taking AMPYRA.
- Do not take AMPYRA if you have ever had a seizure.
- Before taking AMPYRA tell your doctor if you have kidney problems.
- Take AMPYRA exactly as prescribed by your doctor. See “How should I take AMPYRA?”

Stop taking AMPYRA and call your doctor right away if you have a seizure while taking AMPYRA.

What is AMPYRA?

AMPYRA is a prescription medicine used to help improve walking in people with multiple sclerosis (MS). This was shown by an increase in walking speed.

It is not known if AMPYRA is safe or effective in children less than 18 years of age.

Who should not take AMPYRA?

Do not take AMPYRA if you:

- have ever had a seizure
- have certain types of kidney problems
- are allergic to dalfampridine (4-aminopyridine), the active ingredient in AMPYRA

What should I tell my doctor before taking AMPYRA?

Before you take AMPYRA, tell your doctor if you:

- have any other medical conditions
- are taking compounded 4-aminopyridine (fampridine, 4-AP)
- are pregnant or plan to become pregnant. It is not known if AMPYRA will harm your unborn baby. You and your doctor will decide if you should take AMPYRA while you are pregnant.
- are breast-feeding or plan to breast-feed. It is not known if AMPYRA passes into your breast milk. You and your doctor should decide if you will take AMPYRA or breast-feed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take AMPYRA?

- Take AMPYRA exactly as your doctor tells you to take it. Do not change your dose of AMPYRA.
- Take one tablet of AMPYRA 2 times each day about 12 hours apart. Do not take more than 2 tablets of AMPYRA in a 24-hour period.
- **Take AMPYRA tablets whole. Do not break, crush, chew or dissolve AMPYRA tablets before swallowing. If you cannot swallow AMPYRA tablets whole, tell your doctor.**
- AMPYRA is released slowly over time. If the tablet is broken, the medicine may be released too fast. This can raise your chance of having a seizure.
- AMPYRA can be taken with or without food.
- If you miss a dose of AMPYRA, do not make up the missed dose. Do not take 2 doses at the same time. Take your next dose at your regular scheduled time.
- If you take too much AMPYRA, call your doctor or go to the nearest hospital emergency room right away.
- Do not take AMPYRA together with other aminopyridine medications, including compounded 4-AP (sometimes called 4-aminopyridine, fampridine).

What are the possible side effects of AMPYRA?

AMPYRA may cause serious side effects, including:

- serious allergic reactions. Stop taking AMPYRA and call your doctor right away or get emergency medical help if you have:
 - shortness of breath or trouble breathing
 - swelling of your throat or tongue
 - hives
- kidney or bladder infections

See “What is the most important information I should know about AMPYRA?”

The most common side effects of AMPYRA include:

- urinary tract infection
- trouble sleeping (insomnia)
- dizziness
- headache
- nausea
- weakness
- back pain
- problems with balance
- multiple sclerosis relapse
- burning, tingling or itching of your skin
- irritation in your nose and throat
- constipation
- indigestion
- pain in your throat

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of AMPYRA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store AMPYRA?

- Store AMPYRA at 59°F to 86°F (15°C to 30°C).
- Safely throw away AMPYRA that is out of date or no longer needed.

Keep AMPYRA and all medicines out of the reach of children.

General Information about the safe and effective use of AMPYRA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AMPYRA for a condition for which it was not prescribed. Do not give AMPYRA to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about AMPYRA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about AMPYRA that is written for health professionals.

For more information, go to www.AMPYRA.com or call 1-800-367-5109.

What are the ingredients in AMPYRA?

Active ingredient: dalfampridine (previously called fampridine)

Inactive ingredients: colloidal silicon dioxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, and titanium dioxide.

Distributed by: Acorda Therapeutics, Inc.
Ardsey, NY 10502

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Bladder and Bowel Problems

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Although the literature reports that many people with MS experience bladder and bowel disturbance, I'm not sure how many people with MS actually talk openly about these symptoms with their healthcare providers. Bladder and bowel symptoms, once assessed, can be very successfully treated. There are many excellent treatment options that are available for bladder and bowel dysfunction, as well as many behavioral and dietary approaches that can reduce your symptoms.

Please keep in mind that like other MS symptoms, bladder and bowel problems can vary from person to person. It's important to have an assessment and develop a plan that addresses your particular symptoms and works for you.

Recent articles appearing in medical journals say that 80 percent of people with MS report bladder symptoms at the time of diagnosis and up to 90 percent of people with MS by 10 years after diagnosis. In one study that reviewed patients who share their MS experience in the NARCOMS database, only 43 percent of people with moderate to severe bladder symptoms had ever been evaluated by a urologist.

I know that many people don't talk about elimination problems with their healthcare provider, so as a nurse with more than 25 years of experience providing care for people with MS, I wonder why this is so. Maybe it's just too embarrassing to talk about with others. Maybe during a visit with your healthcare provider, the discussion of MRI or other medicines to treat MS take up most of the time. Maybe you think that bladder and bowel symptoms are a normal part of aging. Or maybe you think that there isn't much help for these symptoms. Whatever the reason, I encourage you to find a way to discuss these symptoms openly.

Bladder and/or bowel disturbances due to MS can be very distressing and limiting. There is an association between bladder and bowel symptoms and quality of life. Bladder and bowel dysfunction often results in people avoiding opportunities to socialize and restricting their normal daily activities. Constantly leaking urine can result in skin breakdown and infection. Bowel dysfunction can cause a great deal of discomfort. First let me discuss what happens in MS that causes these symptoms to occur. Let's start with the bladder.

Bladder Dysfunction

Bladder dysfunction in MS happens when nerve signals to the bladder and urinary sphincter (the muscles surrounding the opening to the bladder) are blocked or delayed because of MS lesions in the brain and/or spinal cord.

There are basically two major muscles involved in emptying the bladder: the detrusor muscle and the sphincter muscle. As a result of MS, the detrusor muscle in the wall of the bladder involuntarily contracts, increasing the pressure in the bladder and decreasing the volume of urine the bladder can hold. This causes symptoms of going frequently, urgently, leaking urine, or interfering with a good night's sleep.

In other words, the inability to store or hold urine in the bladder occurs when the bladder is unable to retain urine when it accumulates. Instead of expanding when urine collects, the bladder involuntarily contracts, which can make you feel as if you have an urgent need to go to the bathroom much of the time – even when there isn't much urine in the bladder.

The flow of urine is controlled by the sphincter in the bladder, the muscle which relaxes to open and contracts to close. An inability to empty means that even though a person senses that his bladder is full, the nerve impulse telling the muscle to open is interrupted and never reaches the urinary sphincter, and the sphincter muscle closes before all the urine is emptied from the bladder. If you're not emptying your bladder completely, you might feel the urge to void

often but have hesitancy when you try to void. You may also wake up at night often to void since the bladder is not completely empty during the day. Bladder infections or urinary tract infections (UTIs) can occur if urine, which is a waste product, sits in the bladder too long.

Leakage of urine can occur in some cases when the sphincter remains at least partially open, resulting in involuntary leaks. Sometimes the detrusor muscle and the sphincter muscle do not work in coordination and a person with MS can experience many bladder symptoms.

Many behavior modification techniques may be used to manage bladder symptoms. Here are a few suggestions:

- Drink 48 to 64 ounces of fluid a day (one and a half to two quarts) to keep well hydrated. Water is best.
- Drink six to eight ounces of fluid at regular intervals and then urinate on a regular schedule, rather than waiting for the urge. It takes about one and a half hours for fluid that you drank to get to the bladder, so try to void by the clock, every one and a half to two hours.
- Limit the amount of caffeinated beverages, alcohol, and orange juice. It's okay to have one cup of coffee or tea, but remember that caffeine can cause you to void more frequently and more urgently. Alcohol is also a bladder irritant.
- Stop smoking (yes, smoking is a bladder irritant too).
- Don't try to self-treat your bladder problems by drinking less fluid! This can lead to

constipation and/or urinary tract infections.

Assessing how your bladder works first involves a simple screening for a urinary tract infection (UTI), which is very common in MS and can cause many of the symptoms mentioned. If you have an infection, you will be treated with antibiotics to clear up the infection and symptoms may improve.

If you do not have an infection, then further evaluation of how your bladder works is important before suggesting treatments. After proper assessment, medications might be prescribed to allow the bladder to hold more urine or empty better. There are many medication options on the market now, so don't get discouraged if one doesn't work or causes too many side effects.

Another intervention is to learn the technique of intermittent self-catheterization to allow the urine to flow and empty the bladder if you are not emptying completely. Intermittent catheterization (IC) is a safe procedure that can help bring your urinary symptoms under control. Many people self-catheterize and report that it has improved their quality of life. It will allow you to completely empty your bladder at regular intervals, protect your kidneys from infection and damage, lower the risk of distending (stretching) the bladder, and eliminate the need for wearing a continuously draining catheter. However, some individuals would benefit from an indwelling catheter (Foley catheter) for a short period of time.

Other interventions can be offered by a urologist, including a suprapubic catheter. This is another type of urine drainage

catheter that is surgically inserted into the bladder so that urine can drain out. Instead of urine being passed through the urethra opening as usual, the suprapubic catheter is inserted through the abdominal wall just above the pubic bone and into the bladder.

There are also other surgical procedures that might be recommended by a urologist. More recently, Botox injections into the bladder have been approved by the FDA to help with managing symptoms.

Bowel Dysfunction

Bowel symptoms can affect nearly 70 percent of individuals with MS. Because MS interrupts or slows the transmission of signals to and from the brain and spinal cord, the electrical impulses to the muscles that are involved in emptying the bowel can become disrupted. MS may also prevent pelvic floor muscles from relaxing. These muscles are used to help void fecal matter. Also, MS may block the natural increase in activity of the colon following meals.

Most individuals experience constipation or slow bowel. Some people with MS have reported bowel incontinence (loss of bowel control) and diarrhea, although these latter symptoms are less common than constipation in individuals with MS.

Constipation is very common among people with MS. In general, inadequate daily fluid, not enough dietary fiber (less than 20 grams of fiber per day), and lack of physical activity all affect the digestive system. Medications and supplements may also contribute to constipation.

Constipation is characterized by infrequent bowel movements (usually fewer than three bowel movements per week), or by needing to strain to eliminate stool. Constipation can contribute to abdominal cramping, bloating, fullness, or discomfort.

A very distressing symptom, bowel incontinence is the loss of voluntary bowel control. This can range from occasionally leaking a small amount of stool and passing gas to completely losing control of bowels. Bowel retraining can help encourage normal bowel movements. Aspects of this routine may include setting aside time every day to try to empty the bowels, taking in enough daily fiber to keep stool formed, and avoiding foods that trigger loose stool for you.

Some individuals experience diarrhea. Diarrhea occurs when the bowel contents progress too rapidly along the digestive tract, resulting in frequent bowel movements that yield watery, loose stools. This is sometimes the result of allergies or sensitivity to spicy foods or dairy products, contaminated water or food, a change in activity level, or a stomach virus. Chronic diarrhea can also contribute to dehydration or poor nutrient absorption in people with MS.

Many behavior modification techniques may be used to manage bowel symptoms. Here are a few suggestions:

- Increase your fluid intake. Try to drink six to eight glasses of water daily.
- Drink something hot as the first beverage in the morning (tea, coffee, etc.) to stimulate a bowel movement (BM). Peristaltic activity (that moves food and

waste through the intestines) is increased after a hot beverage or meal.

- Try to maintain regularity. Establish a regular time for emptying the bowels. Plan trips to the bathroom immediately after meals, since eating is a natural stimulus for having a bowel movement. Take your time in the bathroom, but if after 10-15 minutes you do not have a BM, try again later. Try to wait no more than two to three days between bowel movements.
- Increase your fiber intake. Eating plenty of fresh fruits and vegetables as well as whole grain breads and cereals is the best way to increase the amount of fiber you eat. High fiber cereal can be eaten dry or sprinkled over other foods. You might try a high fiber supplement but real food is best.
- Be sure to exercise. Activity such as walking helps normalize bowel function.

The message here is that bladder and bowel symptoms can be treated once these symptoms are discussed openly and proper assessment is completed. It's important to share your concerns with your healthcare providers; if they are not able to help, ask for a referral to someone who can help. You may need a referral to a urologist to treat bladder symptoms or a gastroenterologist for bowel management.

The medications listed on the following page may be used to treat bladder and bowel problems (as listed on MSAA's website at mymsaa.org under Symptoms). Please see MSAA's website for more information about these drugs, such as prescribing information and side effects.

Bladder medications for failure to store:

- Ditropan[®] and Ditropan XL[®] (oxybutynin)
- Detrol[®] and Detrol LA[®] (tolterodine tartrate)
- Vesicare[®] (solifenacin)
- Enablex[®] (darifenacin)
- Levsinex[®] (hyoscyamine)
- Flomax[®] (tamsulosin) and other antihistamines
- Hytrin[®] (terazosin); Minipress[®] (prazosin)
- DDAVP (desmopressin)
- Botulinum Toxin (Botox[®])
- Myrbetriq[®] (mirabegron)
- Toviaz[®] (fesoterodine fumarate)

Medications to treat bladder infections:

- Bactrim[®] (sulfamethoxazole/trimethoprim)
- Septra[®] (sulfamethoxazole/ trimethoprim)
- Cipro[®] (ciprofloxacin)
- Macrochantin[®], Macrobid[®] (nitrofurantoin)

Medications for constipation:

- Stool softeners
- Colace[®] (docusate)
- Surfak[®]
- Chronulac[®]
- Bulk formers
- Metamucil[®] (psyllium hydrophilic mucilloid)
- Fibercon[®]
- Citrucel[®]
- Fiberall[®]
- Laxatives; oral medications
- Miralax[®]
- Pericolace[®]
- Milk of Magnesia[®] (magnesium hydroxide)

- Mineral oil
- Laxatives; rectal stimulants
- Glycerin suppositories
- Dulcolax[®] (bisacodyl) suppositories
- Enemeez[®] Mini Enema (docusate)
- Fleet[®] (sodium phosphate) Enema

Medications for diarrhea:

- Metamucil[®]
- Imodium[®] and related medications

Please note that long-term use of laxatives can be dangerous. Please consult your healthcare provider.

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Sexual Dysfunction

Written by Amy Perrin Ross, APN, MSN, CNRN, MSCN

Advanced Practice Nurse

Loyola University Medical Center

Sexuality and intimacy have an important impact on the quality of life for nearly everyone, including those with a chronic disease such as multiple sclerosis (MS). In MS, sexual dysfunction may be one of the less talked-about symptoms of the disease. It is important to recognize and understand this symptom in order to adequately address it.

Intimacy may be defined as anything that makes one feel closer to another, particularly in a personal and private way.¹ Intimacy plays an important role in the sexual lives of people with MS and their partners.

Males and females may experience sexual dysfunction. Some studies suggest it affects between 40 and 80 percent of women, and 50 to 90 percent of men.² Other studies suggest sexual dysfunction increases over time in people with MS and may be associated with some of the other physical symptoms of the disease, including limited mobility, spasticity, and bowel and bladder dysfunction.

People are at times reluctant to discuss sexual dysfunction with their MS care team as they may feel awkward discussing things that seem so personal. In order to address these problems, like others, it first must be recognized and discussed.

The causes of sexual dysfunction may be divided into three categories: primary, secondary and tertiary.



Primary sexual dysfunction is the result of damage to the central nervous system caused by MS. Motor and sensory pathways may be disrupted by damage to the neurons. This can result in a slowing of the impulses sent from the brain to the body and back. Symptoms that result can manifest as decreased sexual sensation, decreased vaginal lubrication, or erectile dysfunction.

Secondary sexual dysfunction can be the result of other symptoms of the disease. Limited mobility may result in the inability of the person with MS to maintain certain positions to engage in sexual activity. Fatigue is also a major contributor to sexual dysfunction. Often the demands of daily life combined with fatigue in MS result in a decreased libido and a decreased willingness to attempt to engage in physical sexual activity.

Spasticity may limit the types and number of positions a person with MS can maintain during sexual activity. A sudden onset of painful spasms can certainly interrupt attempts at sexual activity. Bowel and bladder dysfunction are also known to contribute to sexual dysfunction. People with MS who have difficulty controlling their bowels or bladder often avoid intimate contact fearing an embarrassing accident.

Depression has also been found to have a significant effect on sexuality. Many of the medications used by people with MS can also contribute to sexual dysfunction, including antispasticity and antidepressant drugs.

Tertiary sexual dysfunction results from primary and secondary causes and includes psychological disturbances, cognitive dysfunction, and depression. People with MS often focus a significant amount of time and energy on the other physical symptoms of the disease. This may leave them simply too tired to consider sexual activity. They may also be embarrassed by the use of other devices such as urinary catheters or extremity splints.

Some people with MS experience a loss of self-esteem or an altered body image. For example, a man who is no longer able to work and needs physical care from his partner may not imagine himself to be a sexual being and will thus avoid sexual contact. This may be true for care partners also.

Providing intimate physical care for a person with MS such as catheterization and then engaging in sexual activity with that

person may be overwhelming. Concerns about the possibility of pregnancy and having a child with MS can also impact sexual function.

There may be other possible causes that have nothing to do with MS yet should be considered. These problems may be associated with a normal aging process. Vaginal dryness and decreased libido may be the result of menopause in women. Lack of erectile function in men may be associated with aging or vascular disease, or medications such as anti-hypertension drugs.

Common symptoms of sexual dysfunction may include:

- decreased libido
- decreased sensation
- orgasmic dysfunction
- painful intercourse
- decreased vaginal lubrication
- erectile dysfunction
- ejaculatory dysfunction

The first step to managing sexual dysfunction is to recognize and discuss it with your partner and MS team or a sexual counselor. MS presents many physical challenges that can be recognized and managed, resulting in a more satisfying sexual life.

Another important first step is to review medications. Many impact sexual performance. A discussion of these with your healthcare team may result in some changes that can improve sexual function. Doses may be changed or medications may be switched if necessary.

Other simple measures can include avoiding beverages such as caffeinated drinks (coffee, tea, carbonated sodas) and spicy foods immediately prior to sexual intimacy, which can reduce the possibility of a bladder or bowel accident. Emptying the bladder and bowels immediately prior to a sexual encounter may also reduce the risk of elimination dysfunction during intimacy. Timing a sexual encounter is also important. Fatigue often worsens as the day progresses, so setting aside time early in the day may enhance the sexual experience.

Pelvic floor exercises taught by a physiotherapist can serve to strengthen the muscles used in many sexual encounters. Hot or cold therapy, biofeedback, and electrical stimulation may also help with mobility limitations or spasticity. Timing sexual encounters at least 30 minutes after a dose of antispasticity medications is important. Personal lubricants may be useful for women with vaginal dryness.

There are several medications available by prescription for erectile dysfunction. Men should discuss these and all medications with the MS team. It is important to remember that sexual function is more than just a physical action. In the next issue of *The Motivator*, the topic of emotional and psychological symptom management, including sexuality, will be addressed.

As noted at the beginning of this section, sexuality and intimacy have an important impact on the quality of life for nearly everyone, including those with a chronic disease such as MS. There are many ways to

manage sexual dysfunction in MS. The first step is recognizing and discussing sexual function with your MS healthcare team.

The following medications may be used to treat sexual dysfunction (as listed on MSAAs website at mymsaa.org under Symptoms). Please see MSAAs website for more information about these drugs, such as prescribing information and side effects.

For erectile dysfunction:

- Viagra® (sildenafil)
- Levitra® (vardenafil)
- Cialis® (tadalafil)

For vaginal dryness:

- Lubrication agents
- Estrogen-containing vaginal preparations
- Topical creams

References

1. Krawchuk LR Rediscovering Intimacy. *The Motivator* Fall 2004
2. Orton SM, Herrera BM, Yee IM, et al. Sex ratio of multiple sclerosis in Canada: a longitudinal study. *Lance Neurol.* 2006;5:932-936.
3. Association of Reproductive Health Professionals. "Sex Therapy for Non-Sex Therapists." Accessed August 31, 2013 at www.arhp.org/Publications-and-Resources/Clinical-Fact-Sheets/SHF-Therapy

Speech and Swallowing Problems

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Speech Difficulties

From a neurological perspective, speech abnormalities may be due to a disturbance of primary language function (aphasia) or due to mechanical disturbances of word formation (dysarthria). With aphasia, an individual may partially or fully lose the ability to communicate verbally or with written words, either temporarily or permanently, and this may be related to a loss of memory. With dysarthria, an individual will have difficulties speaking due to reduced control of muscles, often a result of nerve damage.

Speech disturbances in MS typically result from dysarthria, with true aphasia to be uncommon in my experience. Disturbances of the nerve supply that weaken the muscles of the lower face, lips, tongue, and throat can result in dysarthria. These are due to lesions in the brainstem, a part of the nervous system between the brain and cervical spinal cord.

More commonly, multiple small lesions in either of the two large lobes of the brain, known as the cerebral hemisphere, result in poor motor control and coordination of these muscles. Slurring and slowness of speech, with altered pronunciation, characterize dysarthria.

“Scanning speech,” characterized by long pauses between syllables and words with loss of melody in speech production, is another



type of dysarthria. The term “explosive speech” is sometimes used to describe intermittent episodes of loud, rapid speech production. These dysarthrias are attributed to lesions in the cerebellum, located in the lower-back region of the brain. Coordination between the muscles of articulation and exhalation, necessary for volume control, appears faulty in these dysarthrias. Speech pathologists are usually consulted to help manage these problems by training and coaching the patients to compensate for the deficits.

Some exercises can strengthen and improve the muscles involved in the production of speech, or improve breathing through relaxation of the affected muscles. A speech-language therapist can teach techniques to help slow speech so that it is more understandable, as well as techniques such as improving the way words are articulated and correctly pausing between words. One technique that is particularly helpful is to listen to your own voice using a tape recorder.

When speech difficulties are severe and cannot be corrected with exercise or speech modification, alternative means of speech production can restore the ability to communicate. These range from technology that amplifies the voice, to alternative communication systems such as computer boards.

No medications can specifically improve speech difficulties. However, medications that relieve symptoms such as spasticity may provide some improvement.

Swallowing Problems

I remember being quite surprised when a survey of multiple sclerosis (MS) patients conducted by MSAA several years ago revealed that 39 percent of respondents indicated they had some degree of swallowing difficulty. Fortunately, most of the swallowing (medically known as dysphagia) problems are mild and are self-managed by the patients.

For individuals who are more severely affected with associated coughing, a choking sensation, or breathing difficulties, tests that include swallowing studies – utilizing x-ray imaging and direct endoscopic visualization of the throat – may yield important information. Such testing can identify specific issues and ensure that problems other than neurological ones are not present.

Swallowing is a complex process starting with jaw and tongue movements, which prepare the solid or liquid (known as the bolus) for transport. Coordination between the tongue and upper throat muscles allows the portion of bolus to be actively moved to the back of the mouth and received by the

upper throat.

Coordinated contraction of some throat muscles is needed to protect the upper windpipe (larynx), while the relaxation of another muscle allows for the opening of the upper food transport tube (esophagus). This results in the transfer of the bolus to the esophagus. From this point, involuntary contraction of the esophageal smooth muscle moves the bolus down to the stomach, completing the process.

Disorders of the tongue and the throat muscles or their nerve supply will cause swallowing problems. MS patients may have lesions of the brainstem affecting the direct nerve supply to the tongue and throat muscles. More commonly in my experience, multiple lesions (MS plaques) involving both cerebral hemispheres of the brain cause a lack of coordination of the tongue and throat swallowing muscles. This results in a type of swallowing problem known as pseudobulbar palsy.

For many individuals with MS, altering the consistency of solid food and liquids may be very helpful and improve swallowing function. Retraining to swallow, usually carried out by speech pathologists to ensure advantageous head and neck posture during swallowing, is another useful tool for many people with MS. Other strategies for proper swallowing include: eating smaller, more frequent meals to avoid fatigue while eating; taking smaller bites and chewing these well to reduce the chance of choking; and consciously coordinating breathing with swallowing to reduce the risk of aspiration (inhaling food), which can result in pneumonia.

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Indication

GILENYA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. GILENYA can decrease the number of MS flare-ups (relapses). GILENYA does not cure MS, but it can help slow down the physical problems that MS causes.

Important Safety Information

You should not take GILENYA if in the last 6 months you experienced heart attack, unstable angina, stroke or warning stroke, or certain types of heart failure. Do not take GILENYA if you have certain types of an irregular or abnormal heartbeat (arrhythmia), including

a heart finding called prolonged QT, as seen on a test to check the electrical activity of your heart (ECG) before starting GILENYA. You should not take GILENYA if you take certain medicines that change your heart rhythm.

*GILENYA can result in a slow heart rate when first taken. Your first dose will be given in a medical facility where you will be watched for at least 6 hours. If you stop taking GILENYA for more than 14 days after your first month of treatment, you will need to repeat this observation.

Please see additional Important Safety Information on the next page and Brief Summary of Important Product Information on the following pages.



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Important Safety Information

GILENYA may cause serious side effects such as:

- Slow heart rate, especially after your first dose. An ECG will be performed before and 6 hours after your first dose. Your pulse and blood pressure should be checked every hour while you stay in a medical facility during this time. If your heart rate slows down too much, you might feel dizzy or tired, or feel like your heart is beating slowly or skipping beats. Symptoms can happen up to 24 hours after your first dose. After 6 hours, if your ECG shows any heart problems or if your heart rate is still too low or continues to decrease, you will continue to be watched by a health care professional. If you have any serious side effects after your first dose, especially those that require treatment with other medicines, you will stay in a medical facility to be watched overnight and for at least 6 hours after your second dose of GILENYA the next day. If you have certain types of heart problems, or if you are taking certain types of medicines that can affect your heart, you will be watched overnight after you take your first dose. If you experience slow heart rate, it will usually return to normal within 1 month. Call your doctor or go to the nearest emergency room right away if you have any symptoms of a slow heart rate. If you stop taking GILENYA for more than 14 days after your first month of treatment, you will need to repeat this observation.
- Increased risk of serious infections. GILENYA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping GILENYA. Your doctor may do a blood test before you start GILENYA. Increased risk of infection was seen with doses higher than the approved dose (0.5 mg). Two patients died who took higher-dose GILENYA (1.25 mg) combined with high-dose steroids. Call your doctor right away if you have fever, tiredness, body aches, chills, nausea, or vomiting.
- Macular edema, a vision problem that can cause some of the same vision symptoms as an MS attack (optic neuritis), or no symptoms. Macular edema usually starts in the first 3 to 4 months after starting GILENYA. Your doctor should test your vision before you start GILENYA; 3 to 4 months after you start GILENYA; and any time you notice vision changes. Vision problems may continue after macular edema has gone away. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye (uveitis). Call your doctor right away if you have blurriness, shadows, or a blind spot in the center of your vision; sensitivity to light; or unusually colored vision.
- Breathing problems. Some patients have shortness of breath. Call your doctor right away if you have trouble breathing.
- Liver problems. Your doctor should do blood tests to check your liver before you start GILENYA. Call your doctor right away if you have nausea, vomiting, stomach pain, loss of appetite, tiredness, dark urine, or if your skin or the whites of your eyes turn yellow.
- Increases in blood pressure (BP). BP should be monitored during treatment.

GILENYA may harm your unborn baby. Talk to your doctor if you are pregnant or planning to become pregnant. Women who can become pregnant should use effective birth control while on

GILENYA, and for at least 2 months after stopping. If you become pregnant while taking GILENYA, or within 2 months after stopping, tell your doctor right away. Women who take GILENYA should not breastfeed, as it is not known if GILENYA passes into breast milk. A pregnancy registry is available for women who become pregnant during GILENYA treatment. Call 1-877-598-7237 or visit www.gilenyapregnancyregistry.com for more information.

Tell your doctor about all your medical conditions, including if you had or now have an irregular or abnormal heartbeat; history of stroke or warning stroke; heart problems; a history of repeated fainting; a fever or infection, or if you are unable to fight infections; eye problems; diabetes; breathing or liver problems; or high blood pressure. Also tell your doctor if you have had chicken pox or have received the vaccine for chicken pox. Your doctor may do a test for the chicken pox virus, and you may need to get the vaccine for chicken pox and wait 1 month before starting GILENYA.

Tell your doctor about all the medicines you take, including medicines for heart problems or high blood pressure or other medicines that may lower your heart rate or change your heart rhythm; medicines that could increase your chance of infections, such as medicines to treat cancer or control your immune system; or ketoconazole (an antifungal) by mouth. If taken with GILENYA, serious side effects may occur. You should not get certain vaccines while taking GILENYA, and for at least 2 months after stopping.

The most common side effects with GILENYA were headache, flu, diarrhea, back pain, abnormal liver tests, and cough.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see additional Important Safety Information on previous page.



Please see Brief Summary of Important Product Information on next pages.

MEDICATION GUIDE
GILENYA™ (je-LEN-yah)
(fingolimod)
capsules

Read this Medication Guide before you start using GILENYA and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about GILENYA?

GILENYA may cause serious side effects, including:

- 1. Slow heart rate (bradycardia or bradyarrhythmia) when you start taking GILENYA.** GILENYA can cause your heart rate to slow down, especially after you take your first dose. You will have a test to check the electrical activity of your heart (ECG) before you take your first dose of GILENYA.

You should stay in a medical facility for at least 6 hours after you take your first dose of GILENYA.

After you take your first dose of GILENYA:

- Your pulse and blood pressure should be checked every hour.
- You should be watched by a healthcare professional to see if you have any serious side effects. If your heart rate slows down too much, you may have symptoms such as:
 - dizziness
 - tiredness
 - feeling like your heart is beating slowly or skipping beats
- If you have any of the symptoms of slow heart rate, they will usually happen during the first 6 hours after your first dose of GILENYA. Symptoms can happen up to 24 hours after you take your first GILENYA dose.
- 6 hours after you take your first dose of GILENYA you will have another ECG. If your ECG shows any heart problems or if your heart rate is still too low or continues to decrease, you will continue to be watched.
- If you have any serious side effects after your first dose of GILENYA, especially those that require treatment with other medicines, you will stay in the medical facility to be watched overnight. You will also be watched for any serious side effects for at least 6 hours after you take your second dose of GILENYA the next day.
- If you have certain types of heart problems, or if you are taking certain types of medicines that can affect your heart, you will be watched overnight after you take your first dose of GILENYA.

Your slow heart rate will usually return to normal within 1 month after you start taking GILENYA.

Call your doctor or go to the nearest emergency room right away if you have any symptoms of slow heart rate.

- 2. Infections.** GILENYA can increase your risk of serious infections. GILENYA lowers the number of white blood cells (lymphocytes) in your blood. This will usually go back to normal within 2 months of stopping treatment. Your doctor may do a blood test before you start taking GILENYA. Call your doctor right away if you have any of these symptoms of an infection:
 - fever
 - tiredness
 - body aches
 - chills
 - nausea
 - vomiting

- 3. A problem with your vision called macular edema.** Macular edema can cause some of the same vision symptoms as an MS attack (optic neuritis). You may not notice any symptoms with macular edema. Macular edema usually starts in the first

3 to 4 months after you start taking GILENYA. Your doctor should test your vision before you start taking GILENYA and 3 to 4 months after you start taking GILENYA, or any time you notice vision changes during treatment with GILENYA. Your risk of macular edema may be higher if you have diabetes or have had an inflammation of your eye called uveitis.

Call your doctor right away if you have any of the following:

- blurriness or shadows in the center of your vision
- a blind spot in the center of your vision
- sensitivity to light
- unusually colored (tinted) vision

What is GILENYA?

GILENYA is a prescription medicine used to treat relapsing forms of multiple sclerosis (MS) in adults. GILENYA can decrease the number of MS flare-ups (relapses). GILENYA does not cure MS, but it can help slow down the physical problems that MS causes.

It is not known if GILENYA is safe and effective in children under age 18.

Who should not take GILENYA?

Do not take GILENYA if you:

- have had a heart attack, unstable angina, stroke or warning stroke or certain types of heart failure in the last 6 months
- have certain types of irregular or abnormal heartbeat (arrhythmia), including patients in whom a heart finding called prolonged QT is seen on ECG before starting GILENYA
- are taking certain medicines that change your heart rhythm

If any of the above situations apply to you, tell your doctor.

What should I tell my doctor before taking GILENYA?

Before you take GILENYA, tell your doctor about all your medical conditions, including if you had or now have:

- an irregular or abnormal heartbeat (arrhythmia)
- a history of stroke or warning stroke
- heart problems, including heart attack or angina
- a history of repeated fainting (syncope)
- a fever or infection, or you are unable to fight infections. Tell your doctor if you have had chicken pox or have received the vaccine for chicken pox. Your doctor may do a blood test for chicken pox virus. You may need to get the vaccine for chicken pox and then wait 1 month before you start taking GILENYA.
- eye problems, especially an inflammation of the eye called uveitis.
- diabetes
- breathing problems, including during your sleep
- liver problems
- high blood pressure
- Are pregnant or plan to become pregnant. GILENYA may harm your unborn baby. Talk to your doctor if you are pregnant or are planning to become pregnant.
 - Tell your doctor right away if you become pregnant while taking GILENYA or if you become pregnant within 2 months after you stop taking GILENYA.
 - If you are a female who can become pregnant, you should use effective birth control during your treatment with GILENYA and for at least 2 months after you stop taking GILENYA.

Pregnancy Registry: There is a registry for women who become pregnant during treatment with GILENYA. If you become pregnant while taking GILENYA, talk to your doctor about registering with the GILENYA Pregnancy Registry. The purpose of this registry is to collect information about your health and your baby's health.

For more information, you can call the GILENYA Pregnancy Registry at 1-877-598-7237 or visit www.gilenyapregnancyregistry.com.

- Are breastfeeding or plan to breastfeed. It is not known if GILENYA passes into your breast milk. You and your doctor should decide if you will take GILENYA or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

Using GILENYA and other medicines together may affect each other causing serious side effects. Especially tell your doctor if you take:

- Medicines for:
 - heart problems or
 - high blood pressure or
 - other medicines that may lower your heart rate or change your heart rhythm
- Vaccines. Tell your doctor if you have been vaccinated within 1 month before you start taking GILENYA. You should not get certain vaccines while you take GILENYA and for at least 2 months after you stop taking GILENYA. If you take certain vaccines, you may get the infection the vaccine should have prevented. Vaccines may not work as well when given during GILENYA treatment.
- Medicines that could raise your chance of getting infections, such as medicines to treat cancer or to control your immune system.
- ketoconazole (an antifungal drug) by mouth

Ask your doctor or pharmacist for a list of these medicines if you are not sure.

How should I take GILENYA?

- Your first dose of GILENYA will be given in a medical facility where you will be watched for at least 6 hours after your first dose of GILENYA. See “**What is the most important information I should know about GILENYA?**”
- Take GILENYA exactly as your doctor tells you to take it.
- Take GILENYA 1 time each day.
- Take GILENYA with or without food.
- Do not stop taking GILENYA without talking with your doctor first.
- If you start GILENYA again after stopping for 2 weeks or more, you will start taking GILENYA again in your doctor’s office or clinic.

What are possible side effects of GILENYA?

GILENYA can cause serious side effects.

See “**What is the most important information I should know about GILENYA?**”

Serious side effects include:

- **Breathing Problems.** Some people who take GILENYA have shortness of breath. Call your doctor right away if you have trouble breathing.
- **Liver problems.** GILENYA may cause liver problems. Your doctor should do blood tests to check your liver before you start taking GILENYA. Call your doctor right away if you have any of the following symptoms of liver problems:
 - nausea
 - vomiting
 - stomach pain
 - loss of appetite

- tiredness
- your skin or the whites of your eyes turn yellow
- dark urine

The most common side effects of GILENYA include:

- headache
- flu
- diarrhea
- back pain
- abnormal liver tests
- cough

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of GILENYA. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store GILENYA?

- Store GILENYA in the original blister pack in a dry place.
- Store GILENYA at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep GILENYA and all medicines out of the reach of children.

General information about GILENYA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use GILENYA for a condition for which it was not prescribed. Do not give GILENYA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about GILENYA. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about GILENYA that is written for healthcare professionals.

For more information, go to www.pharma.US.Novartis.com or call 1-888-669-6682.

What are the ingredients in GILENYA?

Active ingredient: fingolimod

Inactive ingredients: gelatin, magnesium stearate, mannitol, titanium dioxide, yellow iron oxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

GILENYA is a trademark of Novartis AG.

Manufactured by:
Novartis Pharma Stein AG
Stein, Switzerland

Distributed by:
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

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Weakness

Reviewed by Randall T. Schapiro, MD
President, The Schapiro MS Advisory Group
Clinical Professor of Neurology, University of Minnesota (retired)

Individuals may experience weakness for different reasons. For people with MS, demyelination interrupts the flow of nerve impulses in the spinal cord or (less frequently) in the brain that keep a muscle or group of muscles functioning properly. As a result, muscles lose strength.

The management of this type of weakness is different from the management of weakness caused by inactivity, called “disuse weakness.” With the latter, a person may increase muscle strength by performing progressive resistance exercises through lifting weights. When demyelination is to blame, lifting weights or doing other repetitive exercise until tiring, strength will be further reduced – resulting in more weakness.

Should individuals with MS who are experiencing weakness perform any exercise? Absolutely, but seeing a physical therapist – one who is experienced with MS and muscle weakness caused by changes in nerve flow – is vital. While resistance exercise can worsen the problem, not using a muscle at all will result in disuse weakness or atrophy. This is seen when someone wears a cast for a period of time – the muscle shrinks while unable to exercise. A physical therapist can develop an exercise plan to keep muscles active without increasing weakness.

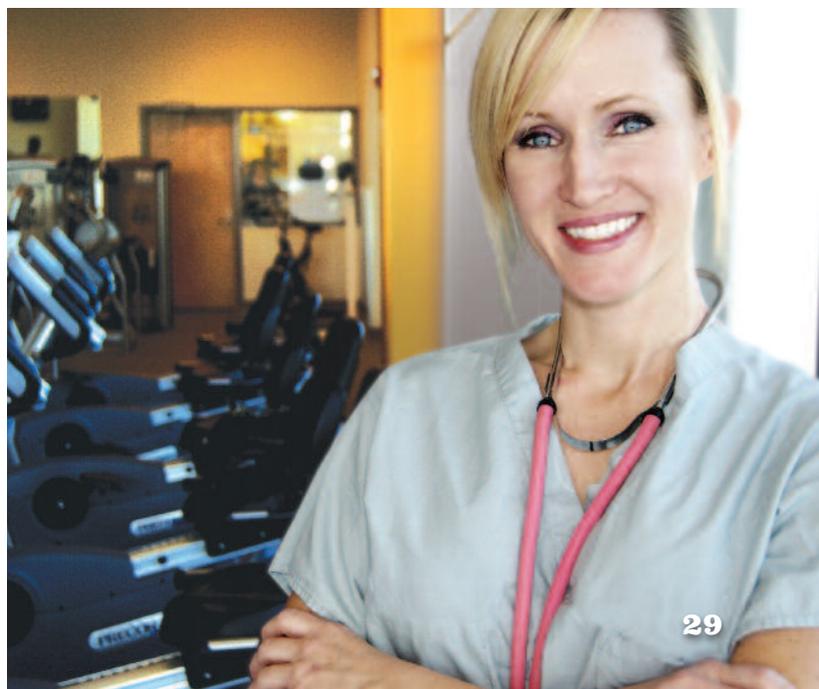
Other symptoms of MS and their treatments can also be involved with weakness. For instance, when taking medications for spasticity

(muscle tightness), a muscle can become stronger as it relaxes and uses less energy when moving. But if too much of a spasticity medication is taken, it can have the opposite effect of increasing weakness. A doctor should also test for other conditions that can cause weakness, such as diabetes, infection, or depression.

One other important strategy to reducing muscle weakness is to be conscious of any wasted energy. Planning ahead and reserving energy for your most important or enjoyable activities during the day will enable you to have the most strength when needed. Using assistive equipment that provides support and conserves energy can be of great help in managing weakness. Treating fatigue can also help to reduce weakness, and some people may benefit from taking Ampyra[®] (dalfampridine), a medication approved to increase walking speed in MS.

Reference

Schapiro, R. T., *Managing the Symptoms of Multiple Sclerosis*, 5th edition, (Demos Medical Publishing, 2007)



Overheating, Exercise, and Uhthoff's Syndrome



Dr. Jack Burks

Q: First, I would like to express my thanks for MSAA's magazine and website, which are very informative for all of us with MS. I read the most recent issue of *The Motivator*, and was happy to see a

section on vision. However, there was no mention of Uhthoff's syndrome. I know it is less common than the other vision issues and few experience this. Could you provide some information on this syndrome?

A: Uhthoff's syndrome is actually rather common, although it gets little "press." It indicates partial myelin damage in the optic nerve as the visual signal goes from the eye to the brain. It is described by patients as a dimming or reduced vision, usually associated with exercise or overheating. The visual problem improves with rest.

The treatment is to avoid overheating, which varies from patient to patient. Once you learn your limits, you may plan ahead and arrange your activities accordingly. For instance, if you enjoy participating in sports or other physical activities when outdoors, plan to do so when the weather is cooler (such as in the morning). This will help to reduce your risk of overheating. Knowing when to stop and take a break from physical activity is also important.

Q: I have several questions. (a) Can myelin-sheath damage be reversed? (b) Can you differentiate demyelination on a CAT scan versus an MRI? (c) Is it normal to have an aneurysm on the brain? (d) Is MS affected by humidity and heat? (e) What type of climate and environment is best to live in to avoid relapses?

A: (a) Can myelin-sheath damage be reversed? Yes, especially in early MS, your body has the ability to reverse (or repair) myelin-sheath damage. This is why people get better after a relapse. Ample evidence in animal models shows this is true. Clinical trials in progress right now are testing experimental treatments to stimulate remyelination, when the body no longer can do so on its own. We are all very hopeful that these types of treatments will soon become a reality for the MS population.

(b) Can you differentiate demyelination on a CAT scan versus an MRI? The CT or CAT scan is not a good way to measure demyelination; the MRI is far better.

(c) Is it normal to have an aneurysm on the brain? No, an aneurysm in the brain is not a normal finding, but some people have aneurysms and don't know that they do. Inadvertently, when tests are performed for

Editor's Note: Uhthoff's syndrome is now listed under symptoms on mysaa.org.

other indications, this type of unexpected finding can be discovered. If you have an aneurysm, you and your doctor will need to discuss your situation and decide upon the best plan of action. The treatment is often dictated by the location, size, and shape of the aneurysm.

(d) Is MS affected by humidity and heat? Humidity and heat are a major cause of a temporary worsening of symptoms for many but not all MS patients. We often refer to this as being “heat-sensitive.” That is why, for individuals who are heat-sensitive, we recommend that they avoid the heat whenever possible and use cooling apparel and accessories to minimize the affects of heat and humidity.

These types of items may be obtained through MSAAs Cooling Program (certain limitations apply; please see mysaa.org/msaa-help/cooling for more information) or through vendors who can offer similar options. These include cooling vests as well as wraps that can be put around your neck, waist, wrists, and ankles.

Some people will take a cool bath or shower during the heat of the day to refresh themselves. Sucking on ice chips or occasionally enjoying a frozen, non-alcoholic drink can also help to keep you cool during the warmest time of day.

(e) What type of climate and environment is best to live in to avoid relapses? Aside from relapses after an infection, we



Introducing a Practical Solution for Hip Flexion Weakness **The HFAD**

The Hip Flexion Assist Device

The Hip Flexion Assist Device (**HFAD**) is intended for individuals with Multiple Sclerosis (MS) who are currently ambulatory, but have difficulty initiating swing due to hip flexor weakness. The Hip Flexion Assist Device is designed to improve gait and consists of a comfortable waist band and two dynamic tension bands that attach to the shoe. The device may be worn over or under clothing and should only be used under the direction of a physical therapist or orthotist.

A recent study¹ funded by the National MS Society, and published in the *Archives of Physical Medicine and Rehabilitation*, indicated that for ambulatory patients with MS, the **HFAD** significantly improved gait performance, as well as **improved strength** in the limb fitted with the **HFAD**. Furthermore, the use of the HFAD was found to result in **increased daily activity level**.

To purchase an **HFAD**, a physician's prescription is required for **both** the *Hip Flexion Assist Device* and for *Gait Training*.

1. Sutiiff, Matthew H., PT; Jonathan M. Naft, CPO; Darlene K. Stough, RN; Jar Chi Lee, MS; Susana S. Arrigain, MA; and Francois A. Bethoux, MD. "Efficacy and Safety of a Hip Flexion Assist Orthosis in Ambulatory Multiple Sclerosis Patients." *Archives of Physical Medicine and Rehabilitation* 89 (2008): 1611-1617.



Please visit our website for more information.

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don't know what precipitates relapses. Many patients consider moving from a hot and humid climate to a cooler and dryer one. Unfortunately, that usually requires a relocation of jobs and a separation from family, which can significantly reduce one's quality of life. Therefore, most patients adapt to their less-than-ideal environment.

How can you adapt? Air conditioning, for example, for some people with MS, may be paid for by medical insurance. Avoiding the outdoors during the middle of the day and employing other strategies (such as the use of cooling apparel) can minimize the effects of a hot environment.

Keep in mind that many patients also have trouble with cold environments. This is especially true when snow and ice are involved, which can increase the risk of falling. Additionally, I recommend following a routine for a healthy lifestyle, including good nutrition, exercise, stress reduction, and adhering to MS medications prescribed by your doctor.

Q: I have been struggling with an embarrassing problem. My MS meds had been changed; first to Aubagio, then to Tecfidera. Beginning in April, I started having bowel accidents. Often there is no or very little advance notice and my bowels just empty themselves. My primary care doctor and I both feel it is the MS that is causing the problem; my neurologist insists it is not MS. My health history likely impacts this as I have had several surgeries on my intestines and lower abdomen.

A: A good bowel regimen from your doctor is a good start. Anti-diarrhea medications may or may not help; this is difficult to predict. I would inquire about Tecfidera, which may cause GI upsets in some people, including diarrhea similar to what you describe. This is usually temporary, but not always. Did your uncontrollable diarrhea start after you began Tecfidera? I would also inquire about other causes of diarrhea, such as parasitic infections. MS alone is an unlikely cause of this type of diarrhea. Our cover story discusses bowel dysfunction in MS. Please refer to page 15 for additional information, which may be of help to you.

Q: My question concerns optical coherence tomography (OCT). I understand that changes in retinal thickness mirror cortical gray matter changes, which in turn reflect the changes of progressive MS far better than MRI. I have secondary progressive MS and will be seeing my Mayo Clinic neurologist in about two months. Should I request a baseline OCT at my next neuro visit?

A: OCT is being used in many MS clinical trials and changes in the OCT are correlated with MS injury. However, it is not yet used by most neurologists in a non-research setting, although it is gaining popularity. I would ask the Mayo Clinic neurologist if he or she recommends OCT and ask if your insurance will pay for it. When an FDA-approved treatment for SPMS becomes available sometime in the future, I believe OCT might be helpful in evaluating the treatment.

Q: I was diagnosed with MS in June 2011. I was also diagnosed with breast cancer in March 2012. I had chemo and radiation treatments, plus a mastectomy in September 2012. I have horrible fatigue, balance difficulties, and slurred speech, which all worsened in October. I have seen my neurologist and had an MRI in October (no changes). I began Avonex in July 2011. I take Ritalin®, vitamin D3, B vitamins, and tamoxifen (for cancer). Do you have any suggestions to help relieve my symptoms?

A: I do not know if the chemotherapy (chemo) is amplifying your MS. For some patients, chemo has helped their MS. Certainly, fatigue can be aggravated by MS and chemo. I might recommend getting another MRI, since it is approaching one year since your last one. If your MRI shows more damage, that might help to explain your fatigue as well as your increased balance and speech problems.

Two other medications might be worth discussing with your doctor, if you have not done so already. First, while Provigil is not FDA-approved for MS-induced fatigue (or from fatigue related to chemo), my colleagues and I have found it to be helpful in many of our MS patients. Ask your neurologist. Second, Ampyra is a drug that is FDA-approved to increase walking speed in MS. While it does not help all individuals with MS, it might be worth considering with your doctor. It is important for your neurologist and your oncologist to work together in evaluating and treating your symptoms.

To Submit Questions...

Please submit your questions to:

MSAA
Questions for Ask the Doctor
c/o Dr. Jack Burks
706 Haddonfield Road
Cherry Hill, New Jersey 08002

Readers may also send in questions via email to askdr@mymsaa.org. Please be sure to write “Ask the Doctor” in the subject line.

A Note About the Shingles Vaccine

A few people have written to me asking about the safety of the shingles vaccine for individuals with MS. Because the shingles vaccine uses a live virus, the answer is not the same for everyone. I advise anyone with MS who is 60 years of age or older (this is the age group for which the shingles vaccine is recommended) to discuss the risks and benefits of this vaccine with his or her doctor. For more information, please see page 42 for the “Health and Wellness” column in this issue. ♦

Dr. Jack Burks is an international MS neurologist, writer, lecturer, and researcher, who assists with the development of new MS therapies and advises patients, families, MS organizations, and healthcare groups. Dr. Burks is a clinical professor of neurology at the Florida International University in Miami. He has written and edited three MS textbooks, as well as numerous chapters and articles on MS.

Research News

Treatments under FDA Review and Other News

Lemtrada Application Submitted to FDA

As MSAA previously reported, the United States Food and Drug Administration (FDA) had accepted an application in January for the review of Lemtrada™ (alemtuzumab, formerly known as Campath) for the treatment of “relapsing multiple sclerosis.” The FDA will review the efficacy and safety data from the clinical trials; a decision is expected sometime later this year.

Lemtrada is a humanized monoclonal antibody that targets a protein present on the surface of mature lymphocytes, and results in a rapid depletion/suppression of T and B cells. According to Genzyme, their team of scientists “...is also studying whether alemtuzumab, which has completed phase III studies for relapsing-remitting MS, can effectively treat progressive MS, a much more advanced form of the disease.”

A Phase II study of 334 individuals with early, active relapsing-remitting MS (RRMS) compared Lemtrada to high-dose Rebif (44 mcg). This trial is notable as Lemtrada-treated patients had the lowest relapse rate ever reported for an MS drug.

In a multi-year extension study of the 334 individuals who participated in the original Phase II study, Lemtrada yielded a 73-percent reduction in risk for sustained accumulation of disability, while 77 percent of Lemtrada-treated patients were relapse-free. A five-year assessment showed that 87 percent were free of sustained disability accumulation, 72

percent were relapse-free, and 65 percent were free of clinical-disease activity. These data indicate that Lemtrada's treatment effect is durable; it halts clinical-disease activity in a significant proportion of RRMS patients through five years – even though many of those patients did not require subsequent re-treatment with the drug.

For more information on this experimental treatment, please see this section of MSAA's *MS Research Update*, found at <http://mymsaa.org/publications/msresearch-update-2013/lemtrada/> (please note that portions of the information above were originally published in this update).

New Dosing Regimen for Copaxone Submitted to FDA

Teva Pharmaceuticals Industries, Ltd., the makers of Copaxone® (glatiramer acetate), announced on May 30, 2013 that the FDA had accepted a supplemental new drug application for Copaxone at a higher dose and reduced frequency. The present FDA-approved dose of Copaxone is 20 mg given daily via subcutaneous (under the skin) injection.

The new dosing under review is double the concentration (40 mg) and is given three days per week (also via subcutaneous injection) versus every day. Results of the Phase III Glatiramer Acetate Low-frequency Administration (GALA) trial were similar to those seen with the standard daily dose of Copaxone, with no new safety concerns. For

more information, please see this section of MSAAs *MS Research Update*, found at <http://mymsaa.org/publications/msresearch-update-2013/copaxone/>

Biogen Idec Submits a New MS Treatment to FDA

On July 19, 2013, Biogen Idec announced that the FDA had accepted their application for the marketing approval of Plegridy™ in the United States. This potential new disease-modifying therapy (DMT) for the long-term treatment of MS is a pegylated version of interferon beta-1a. Plegridy does not need to be taken as often as the presently approved self-injected DMTs for MS, which range from once daily to once weekly. This new

medication has been studied in two groups – with injections given subcutaneously either every two weeks or every four weeks. For more information, please see MSAAs online news article found at <http://mymsaa.org/news-msaa/889-new-treatment-plegridy>

Approval of Phase I Stem Cell Study in Progressive MS

The stem cell research division of the Tisch MS Research Center of New York has announced the FDA approval of a Phase I stem cell study in individuals with progressive MS. The study will use a patient's own stem cells, taken from his or her bone marrow, in an open label, Phase I clinical trial. According to the center's news article,

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approximately 20 progressive MS patients, recruited from the existing patient population of the International Multiple Sclerosis Management Practice (IMSMP), will be initially enrolled.

The article also notes that the Tisch MS Research Center stem cell trial is the first of its kind in the United States and incorporates several key advantages in terms of the type of stem cells being used and how they are administered (via multiple rounds of treatment into the cerebrospinal fluid). The center states that this FDA approval is the culmination of more than a decade of research into the therapeutic potential of stem cells for MS patients. Their initial (“proof of concept”) studies with an animal model of MS showed that the injected stem cells migrated to areas of demyelination and may have affected the rate of repair.

Continued Heart Monitoring Advised during and after Novantrone®

In June 2013, MSAAs posted a message online (at mymsaa.org) to warn individuals of the potential danger of Novantrone® (mitoxantrone) to the heart. The purpose of this message is to inform the MS community that the harm to the heart’s pumping action can appear while someone is being treated with the medicine or many years later. Individuals who have, are, or will be taking Novantrone need to have their heart tested before starting treatment and every year thereafter, even after discontinuing the medication. To read the entire message, please go to <http://mymsaa.org/news-msaa/911-fda-statement-novantrone>

Vaccine Safety and MS

Published studies to date continue to affirm the safety of several vaccinations for individuals with MS. These inactivated vaccines do not increase the risk of developing MS or exacerbating its symptoms. No evidence of a specific risk for relapse has been associated with any of these vaccinations:

- influenza (via the injected flu vaccine using inactivated viruses*)
- hepatitis B
- varicella (chickenpox)
- tetanus
- Bacille
- Calmette-Guerin

*Please note that flu vaccines are usually available in two forms: injected and intranasal. The injected type of flu vaccine uses the inactivated (or killed) viruses, and is considered safe for individuals with MS. People cannot develop the flu from the injected vaccines, since these contain non-infectious particles. The intranasal vaccine (FluMist), given by nose with a mist, contains live viruses and is NOT recommended for individuals with MS.

Before receiving any vaccine, individuals with MS should consult their physician to make sure that the specific vaccine and its timing is appropriate. If experiencing a relapse, patients may be advised to wait a period of time (approximately four to six weeks) before receiving a vaccine. For more information, please see MSAAs online article at <http://www.mymsaa.org/news-msaa/924-vaccine-safety-ms> ♦

More Help with Healthcare

MSAA Continues to Report on the Affordable Care Act and How it Affects You

Throughout 2013, MSAA has been working to research, inform, and educate our clients about the sweeping changes in healthcare reform under the Affordable Care Act (ACA), and its significant impact on the multiple sclerosis (MS) community. Along with a detailed article in the Winter/Spring 2013 issue of *The Motivator*, MSAA created a comprehensive section on our website at mysaa.org/aca.

Located under the About MS tab, the ACA “Changes in Insurance” section provides an overview of the new provisions covered by the law, a glossary of insurance terms, and specific information on Medicare, Medicaid, and the process of purchasing medical insurance through the new Marketplaces.

Because of the complex and expensive nature of evaluating, managing, and treating

MS, MSAA also dug deep into the ACA law to shed some light on critical issues that directly affect our constituents. These include access to medication through certain tier classifications and step-therapy pitfalls, as well as implications for MRI exams and common durable medical equipment.

As you may know, open enrollment for insurance coverage through the new Marketplaces begins on October 1, 2013, with policies taking effect in January 2014. At the time of this article, the news reported an unfortunate setback in one of the key provisions of the law.

As written into law, the limit on out-of-pocket costs, including deductibles and co-payments, is capped at \$6,350 for an individual and \$12,700 for a family. This provision, originally scheduled to go into

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effect in January 2014, has been pushed back one year. This is to allow insurers and employers more time to comply with the regulation and the resulting need to upgrade their computer systems.

If a drug plan does not currently have a limit on out-of-pocket costs, it will not be required to impose one for 2014. This setback may significantly impact the MS community due to the often high costs of disease-modifying

and symptom-management medications.

Recognizing the need to keep you updated on the continuously evolving aspects of this new law, such as the change to the out-of-pocket provision, MSAA has secured an unrestricted educational grant from Biogen Idec, with proposals to other corporations pending, to produce a series of ACA webinars and additional resources on this important topic. ♦

Please note that **MSAA has been approved as a Champion of Coverage** to partner with CMS (Centers for Medicare and Medicaid Services) to spread awareness of and encourage enrollment in the ACA Marketplace. Please check MSAA's website (mymsaa.org) for updates and information regarding the ACA.

Come Chat with Us!

MSAA's Client Services department features master's level social work and counseling professionals, skilled in helping individuals understand the ever-changing world of MS. In an effort to expand Client Services' availability and outreach, MSAA has created a dedicated email address, MSquestions@mymsaa.org, where visitors to our website may send questions directly to the Client Services department and receive timely responses.

More recently, MSAA added a Chat feature to the website. Launched in August, the MSAA Chat feature offers website visitors the opportunity to engage in an interactive one-on-one conversation with a Client Services representative during posted



business hours. The MS Chat feature is found on the bottom right-hand corner of many pages of the website and can be accessed by clicking the "Start Chat" tab.

"The Chat feature is a great way to get connected to resources and programs in a quick and convenient setting," explains Client Services Consultant Samantha Schech, MSS. "People seem to appreciate that the Chat transcript can be sent directly to their email to help capture the information discussed. We look forward to expanding the MS Chat feature and making it as easy and convenient as possible for the MS community to get the information and service they need."

In addition to the Chat feature, individuals may also connect to the Client Services department by calling our toll-free Helpline at (800) 532-7667. ♦

What Is a “Good” Charity?

There has been a lot of talk recently about good charities and bad charities. News reports have focused on charities that do little, if anything, to help alleviate social issues... and on companies who profit from the increasing need for funding to ensure missions are fulfilled. The nonprofit world is buzzing with words like “expense ratios,” “ratings,” and “overhead.” The result: We are now taking a new look at what being a good charity really means.

As an organization, MSAA welcomes this conversation. We believe in using our resources efficiently to best serve the needs of the MS community. We have worked hard over the years to streamline our processes and improve our program delivery. We also know that our effectiveness cannot be truly understood by looking at one number. Just as “you can’t judge a book by its cover,” we are now discovering you cannot judge a charity simply by its overhead.

Charities exist to ease suffering and help those in need. This current conversation is urging us to look beyond overhead ratios and take into consideration whether or not a charity is achieving its mission. What impact are they having on righting social wrongs, alleviating distress, or improving quality of

life? How many meals did they serve, how many children did they educate, how many lives did they improve?

Recently, three of the major agencies that provide ratings and information on charitable organizations produced a letter aimed at furthering this conversation. Signed by the CEOs of the BBB Wise Giving Alliance, GuideStar, and Charity Navigator,

“Thank you SO much for this wonderful gift (cooling vest). This was the first time in six years that I’ve been able to venture out for a bit in the summer to enjoy a trip to the zoo with my family and children. Words can’t express my gratitude. Keep up the wonderful work you are doing with people suffering with MS.”

— Mary T. from Texas

this letter urges donors to look beyond the overhead ratio.

These agencies are working to expand the evaluations they themselves perform on charities in order to help donors evaluate the true impact of their donations. To view this letter and learn more about the changes charity-rating agencies anticipate, please visit overheadmyth.com/letter-to-the-donors-of-america.

THE PRESIDENT'S *Circle*

The following thoughtful corporations, foundations and individuals have contributed generously to MSAA to improve the lives today for the entire MS community. Those providing gifts of \$10,000 or more are shown in this listing.

GUARANTORS (*\$500,000 and up*)

EMD Serono, Inc. and Pfizer Inc
Genzyme Corporation, a Sanofi Company

CHAMPIONS (*\$100,000 to 499,999*)

Acorda Therapeutics, Inc.
Allergan
Estate of Mildred M. Hughes
Novartis Pharmaceuticals Corporation
Questcor Pharmaceuticals, Inc.
Teva Pharmaceuticals

VISIONARIES (*\$50,000 to \$99,999*)

Anonymous
Genentech, Inc.
Medtronic Foundation

MOTIVATORS (*\$25,000 to \$49,999*)

Bayer HealthCare Pharmaceuticals
Biogen Idec

ADVOCATES (*\$10,000 to \$24,999*)

Carole C. Jenkins
Cody Optimist Club
The Kessler Foundation
Chris Laganke, MD
Bobby O'Brien
Catholic Human Services Foundation
Mr. John D. Mooney
Mrs. Barbara Kouris
Ms. Misty Sims
Rosemarie Bustard
Virginia T. Dashiell Charitable Foundation
Susan B. Stearns

Thoughts about Giving

Overhead includes necessary items that can improve the overall effectiveness of a charity, such as staff training, technology, and program evaluation. Without it, staff would not have the necessary tools to assist their clients. A lack of investment in this area has been linked to high turnover and poor work quality. In their letter, the above agencies state that investment in overhead is a necessity (like paying your light bill or fixing your roof) and can result in significantly more dollars being raised overall. More dollars means more meals, more books, and for MSAA, more lives improved.

We have all grown accustomed to looking at ratios and using these as a measurement of success. If this number doesn't tell the full story, how do we know if a charity is "good?" If "how much do you spend on overhead?" is not the question to ask, what is? The rating agencies are creating questions donors should ask that provide an opportunity to engage with an organization and learn about their collaborations, their plans, their goals and strategies, and other meaningful metrics.

This is not to say that ratios do not matter. It is the duty of a charity to be transparent and accountable to its donors. Extreme overhead ratios can be a signal to look more closely at governance and organizational oversight. Those organizations that have been shown to spend little on actually serving their mission, need to be called to task. That kind of behavior should not be tolerated. Fortunately, the majority of organizations do not fall into this category. We cannot let the "bad apples" spoil the whole bunch.

This conversation is just beginning. We expect you'll hear more in the coming months about ratios, ratings, and overhead. At MSAA, we are working to be sure we clearly communicate the results of our efforts and the impact we are having on the MS community. We want to share with you our stories, our successes, and our challenges. During the last fiscal year our impact includes:

- 10,363 people assisted through the Client Services Helpline
- 1,040,554 visits for vital information through our website
- 3,434 pieces of safety, mobility, and symptom-management equipment were distributed
- 1,389 people received financial support for necessary MRI scans
- Approximately 215,000 MSAA publications distributed to provide information and support
- 5,600 people attended our 156 nationwide in-person educational programs
- 66,596 views of our 36 on-demand video programs
- 7,174 new downloads for MSAA's smartphone app, "My MS Manager"

“Thank you so much for getting back to me so soon! After over two years of waiting and being passed off [by other organizations], my MRI is scheduled for a couple of hours from now! Thank you!

— Jordan R. from Colorado

In addition to the wealth of information and support MSAA provides, for those who would be unable to afford equipment or MRI scans on their own, MSAA's programs make a tangible difference in day-to-day quality of life. This is attested to time and time again in the unsolicited testimonials of our clients.

When making your charitable-giving decisions, we encourage you to look beyond the cover of the book that is MSAA. Take a look inside, read a page or two, review our website, call our staff, attend one of our educational programs. Together we can continue to be a leading resource for the entire MS community, improving lives today! ♦

“I want to thank you for the beautiful new wheelchair. I appreciate it so much. My old chair was being held together with duct tape and wasn't very safe. I was surprised that it arrived so soon after I sent in my application and also by the lack of red tape.”

— Donna C. from California

Shingles Overview and Vaccine Safety

Live, attenuated vaccines may be an issue for individuals with MS

Compiled by Susan Wells Courtney • Reviewed by Jack Burks, MD

Shingles: An Overview

Shingles is caused by the reactivation of the varicella zoster virus (VZV), which is the same virus that causes varicella (chickenpox). This usually occurs decades after the initial chickenpox infection. The reactivation of this virus causes a painful rash with clusters of fluid-filled blisters. Shingles is not contagious, but before the blisters dry, the virus-filled fluid can transmit chickenpox to someone who has not been previously exposed to the virus and comes in close contact with the open rash. Other symptoms of shingles can include fever, headache, chills, and an upset stomach.

Lasting for weeks, months, or even years, postherpetic neuralgia (PHN) is the most common complication of shingles, and can cause chronic, sometimes excruciating pain in the area where the rash occurred. This chronic, debilitating pain varies from mild to severe, disrupting one's sleep, mood, and activities of daily living. PHN can reduce one's quality of life, potentially leading to social withdrawal and depression; even suicide has been reported.

Scarring is another potential long-term complication of shingles, and in rare cases, a shingles infection can lead to pneumonia, hearing problems, blindness, brain inflammation (encephalitis), or death. While

most people only have one episode of shingles, second and third episodes are possible.

For older individuals with MS, the risk of shingles and its complications is just as great as for those without MS – and for individuals with MS who take immunosuppressive medications, the associated risks become even greater. Everyone's risk of shingles greatly increases as they get older, particularly after the age of 50. The risk of developing PHN (causing continued chronic pain) as a complication of shingles increases with age, as does the likelihood of experiencing longer lasting and more severe pain with PHN. Additionally, individuals with compromised or suppressed immune systems are also more likely to experience complications from shingles.

The Shingles Vaccine

According to the Centers for Disease Control and Prevention (CDC), the vaccine for shingles (also known as herpes zoster or zoster) is recommended for use in people 60 years and older to reduce the risk of shingles. This includes everyone in this age group who has no contraindications, as well as people who have had a previous episode of shingles and/or have chronic medical conditions. (The specific "chronic medical conditions" listed

by the CDC include kidney failure, diabetes, rheumatoid arthritis, and chronic pulmonary disease.) The shingles vaccine was approved by the Food and Drug Administration (FDA) in 2006 and is marketed under the brand name Zostavax®.

The shingles vaccine is given in one dose, subcutaneously (under the skin) in the arm. Common side effects from the vaccine include: redness, soreness, swelling, or itching at the shot site; and headache. After receiving the vaccination, individuals may be around infants and young children, pregnant women, or people with weakened immune systems; no reports have been made of someone getting chickenpox from another person who received the shingles vaccine. Some people may develop a chickenpox-like rash near the injection site. If this occurs, simply as a precaution, the rash should be covered until it disappears. The shingles vaccine does not contain thimerosal, which is a preservative that contains mercury and is sometimes used in vaccines.

No serious adverse events have been seen with the shingles vaccine, which has been tested in approximately 20,000 people (without MS) age 60 and older. The vaccine appears to be effective for at least six years, but may last longer. While older individuals may get the vaccine at any age, it appears to be the most effective in people 60 to 69 years. Studies have found that the shingles vaccine reduced the risk of shingles by 51 percent in older adults, reduced the risk of PHN by 67 percent, and also reduced the severity and duration of pain associated with PHN.

The safety of the shingles vaccine is more difficult to judge for individuals with MS.

The current data supporting its use are reassuring, but not complete because this vaccine has not been fully investigated in MS. The shingles vaccine has been more thoroughly investigated in other illnesses, including people whose immune system may be compromised by their disease or by the drugs used to treat their disease.

The shingles vaccine is a live, attenuated vaccine, which can be an issue for individuals with MS. Many vaccines use viruses that have been inactivated (i.e., killed), so the virus has no chance of infecting anyone. The shingles vaccine contains live viruses, but these have been “attenuated,” meaning that their strength has been reduced to a point where they can’t infect someone with a healthy, uncompromised immune system.

As with many individuals with various other health conditions, a large number of individuals with MS take medications that may modulate or suppress their immune system. A live-virus vaccine may conceivably be able to infect someone whose immune system is not fully functioning, a result of either an illness or medications given to treat an illness.

In addition to some of the FDA-approved long-term disease-modifying therapies for MS, large doses or extended use of steroids, which are frequently prescribed to treat MS relapses, can also suppress the immune system. Less common treatments to be considered when evaluating the safety of the

shingles vaccine include: experimental treatments for MS, such as those being studied in clinical trials with MS patients; off-label treatments, such as methotrexate and Imuran® (azathioprine); hematopoietic stem cell transplantation (HSCT); and antiviral medications.

Guidelines for Shingles Vaccine Safety

According to an extensive report from the Advisory Committee on Immunization Practices (Harpaz R., et al, 2006), different treatments need to be considered before the shingles vaccine may be considered safe for an individual. This report originated in the National Center for Immunization and Respiratory Diseases, and the Division of Viral Diseases, both a part of the Centers for Disease Control and Prevention.

To follow are some general guidelines. As a reminder, individuals are strongly advised to consult their physician on the safety of the shingles vaccine, as doctors need to look at each person's situation on a case-by-case basis.

Individuals who should not get the shingles vaccine, or who should wait, include:

- Anyone who has ever had a life-threatening or severe allergic reaction to gelatin, the antibiotic neomycin, or another component of the shingles vaccine
- An individual with a weakened immune system because of HIV/AIDS or other disease affecting the immune system, or someone who takes a medication that

weakens the immune system

- People on immunosuppressive therapy, including high-dose corticosteroids (20 mg or more per day of prednisone or equivalent) lasting two or more weeks, should wait for at least one month after discontinuing the therapy
- Anyone with a moderate or severe acute illness (including anyone with a temperature of 101.3 degrees Fahrenheit or higher) should usually wait until they recover before getting a vaccine

Individuals who may receive the vaccine include:

- Anyone with a minor acute illness (such as a cold) may be vaccinated
- People receiving short-term corticosteroid therapy: for less than two weeks; in a low-to-moderate dose (less than 20 mg per day of prednisone or equivalent); topically (such as those given via nasal, skin, or inhaled administration); or long-term alternate-day treatment with low to moderate doses of short-acting systemic corticosteroids – these are all considered to not suppress the immune system enough to cause concerns for vaccine safety
- Therapy with low-doses of methotrexate (equal to or less than 0.4mg/Kg/week) or azathioprine (equal to or less than 3.0 mg/Kg/day) is considered to not suppress the immune system enough to cause concerns for vaccine safety

Special groups and circumstances:

- People who have previously had shingles

may be vaccinated, although they need to wait until the rash is cleared

- People with a normal immune system who are anticipating immunosuppression* (please see next bullet point), without a prior shingles vaccine, should receive the vaccine as soon as possible, while their immunity is intact; the vaccine should be administered at least 14 days before initiation of immunosuppressive therapy, although some experts advise waiting one month
- According to MSAA Chief Medical Officer Jack Burks, MD, “Most MS drugs are not considered immunosuppressive, but are considered immunomodulating, which affects the immune system differently. Nonetheless, we recommend that patients

consult with their doctor regarding this CDC recommendation. For example, the recommendation for Gilenya® (fingolimod) is immunization 30 days before starting Gilenya.”

- In regards to individuals receiving recombinant human immune mediators and immune modulators (especially the antitumor necrosis factor agents adalimumab, infliximab, and etanercept), the safety and efficacy of the shingles vaccine administered concurrently is unknown. If not possible to administer the vaccine before initiation of therapy, patients should have their immune status assessed by their physician to determine the relevant risks and benefits. Otherwise, vaccination should be deferred for at least one month



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after stopping the medication. (This category would include the MS medication Tysabri® [natalizumab], as well as many of the experimental therapies presently in clinical trials, such as Lemtrada® [alemtuzumab, formerly Campath], daclizumab [also known as Zenapax®], Rituxan® [rituximab], ocrelizumab, and ofatumumab [also known as Arzerra®].

Individuals taking one of these drugs are advised to talk to their doctor, who can assess the risks and benefits of the shingles vaccine in conjunction with this type of disease-modifying therapy.)

- People receiving blood products (including antibody-containing blood products) may receive the shingles vaccine at any time before, during or after; the list includes intravenous immune globulin (IVIG); plasma exchange would also fall under this category, but is not specified in the report; patients receiving these types of treatment are advised to consult their physician before getting a shingles vaccine.
- Experience with individuals undergoing hematopoietic stem cell transplantation (HSCT) is limited and should be considered on a case-by-case basis; patients should have their immune status assessed by their physician to determine the relevant risks and benefits; if a shingles vaccine has been approved, it should not be administered until at least two years (24 months) after transplantation.
- Antiviral medications may interfere with the replication of the live-virus vaccine, so anyone taking Zovirax® (acyclovir), Famvir® (famciclovir), or Valtrex®

(valacyclovir) regularly, should discontinue these medications at least 24 hours before administration of the shingles vaccine, if possible. These medications should not be used for at least 14 days after vaccination.

Additional Notes about the Shingles Vaccine

According to the CDC, the shingles vaccine may be given simultaneously with other vaccines, including the flu vaccine. Each vaccine must be administered using separate syringes and different injection sites. If other vaccines are not administered at the same time, the shingles vaccine may still be given at any time before or after other vaccines – provided these are **inactivated** vaccines. If receiving another live, attenuated vaccine (in addition to the shingles vaccine), and are not doing so at the same time, **patients need to wait at least four weeks before or after the shingles vaccine, to receive a different live, attenuated vaccine.**

The shingles vaccine is **not** recommended for anyone who has received the varicella (chickenpox) vaccine. However, the chickenpox vaccine did not become available in the United States until 1995, so virtually all people who have received a vaccination against chickenpox are too young to receive a shingles vaccine. For this reason, The CDC states that healthcare providers do not need to inquire about one's varicella vaccination history, since virtually all persons in the recommended age group (and for at least the next decade) did not receive a chickenpox vaccine.

Additionally, the CDC notes that anyone 60 or older (without any contraindications) should get the shingles vaccine, regardless of whether or not he or she can remember having had chickenpox. Studies show that 99.5 percent of Americans age 40 and over have had chickenpox. Patients do not need to be asked about their history of chickenpox or have their blood tested for antibodies.

Insurance Coverage and Resources

The following information is provided on the CDC's website, www.cdc.gov.

The shingles vaccine is available in pharmacies and doctors' offices. To find local facilities that offer the vaccine, please visit www.zostavax.com.

- All Medicare Part D plans cover the shingles vaccine; the cost-sharing for vaccination varies.
- Medicare Part B does not cover the shingles vaccine.
- Medicaid may or may not cover the vaccine.
- Most private health insurance plans cover the vaccine for people age 60 and over; some cover people age 50 to 59.
- The Merck Vaccine Patient Assistance Program provides free vaccines to eligible adults (usually individuals without insurance). For more information, please visit www.merck.com/merckhelps/vaccines/home.html or call (800) 293-3881.
- Vaccine information statements are available in Spanish and other languages; please see www.immunize.org/vis

- Interested individuals may also go to the CDC's website for more information on shingles by visiting www.cdc.gov/vaccines/vpd-vac/shingles/default.htm
- For more information on vaccines and MS, please refer to MSAA's online article, "Vaccine Safety and MS" under News from MSAA

For More Information

In addition to MSAA's website, individuals may call MSAA at (800) 532-7667 for more information about MS and its treatments. Questions to MSAA's Client Services department may be emailed to MSquestions@mymxaa.org.

References

Much of the information for this article was obtained through the Centers for Disease Control (CDC) and Prevention.

Harpaz R, et al, *Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, 2006. ♦

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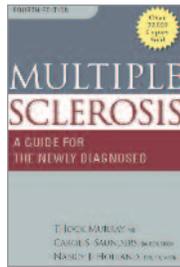


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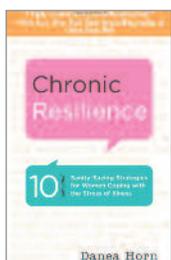
FOURTH EDITION

Written by T. Jock Murray, Carol Saunders, and Nancy Holland
Published by Demos Medical Publishing



MSAA Book #234

Written by top MS experts and now in its fourth edition, this book has been a staple for many individuals newly diagnosed with MS. Chapters cover a wide variety of important topics such as: the history of MS; diagnosis, potential causes, and treatments; employment; financial and life planning; clinical trials; and more.



Chronic Resilience: 10 Sanity-Saving Strategies for Women Coping with the Stress of Illness

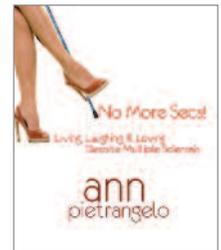
Written by Danae Horn
Published by Conari Press

MSAA Book #14

Professional speaker and author Danae Horn has faced medical challenges and illness her entire life – but this fact is soon forgotten when reading her upbeat and spirited writing. She approaches topics in a very down-to-earth and sometimes humorous manner, while giving sound advice on how to set goals, empower oneself, and live life to the fullest. In addition to her own experiences, she tells the stories of several other unique and insightful women who also cope with chronic illnesses.

No More Secs! Living, Laughing & Loving Despite Multiple Sclerosis

Written by Ann Pietrangelo
Published by WebCamp One LLC



MSAA Book #24

Author Ann Pietrangelo is a freelance writer who was diagnosed with MS at the age of 44. Throughout the book's 37 brief chapters, she presents an entertaining as well as insightful look at the many facets involved with learning about and coping with the changes associated with MS. Some of her amusing chapter titles include, “Discombobulation Sums It Up Rather Nicely,” and “Hitchcock Could Have Written This.”

MSAA Lending Library

To borrow books featured in this column or any other book in MSAA's Lending Library, please visit mysaa.org/library to view a list of books available and to complete a form. When ordering a book, please reference the book number listed. Readers may also call MSAA at (800) 532-7667 for more information.

MSAA and its clients greatly appreciate any donations made to help build the Lending Library. If you would like to donate one or more books to the Lending Library, please send these to:

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Art Showcase



Windmill
David Desjardins
Union, ME
2013 MSAA Art Showcase

MSAA welcomes artwork in oil, watercolor, and acrylic, as well as pastels and drawings in pencil and ink for its 2014 Art Showcase. In addition, we are now accepting digital artwork!

Artwork will only be accepted from individuals who have multiple sclerosis (MS). Submitted pieces must be two-dimensional. Although sculpture, pottery, fabric, and other types of three-dimensional works cannot be accepted, we truly appreciate all artists and encourage you to try something new!

The Art Showcase will first appear on MSAA's website during March 2014 in recognition of MS Awareness Month. Each month we will highlight one artist and his or her work.

Submissions will be accepted between October 15 and December 16, 2013.

For submission guidelines, visit support.mymsaa.org/artshowcase

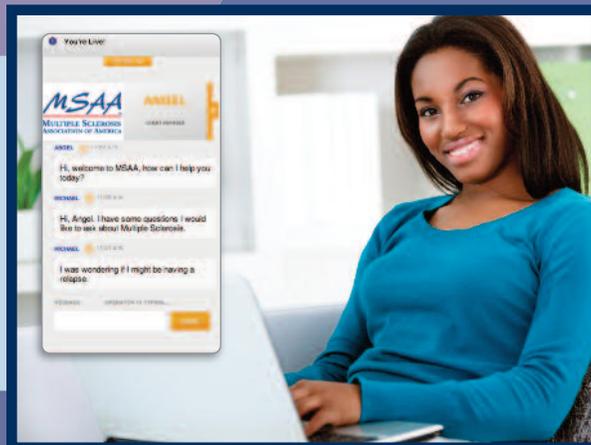
For more information, contact:

Angel Galiazzi, MSAA
706 Haddonfield Road
Cherry Hill, NJ 08002
Email: showcase@mysaa.org
Phone: (800) 532-7667, ext. 117

MSAA'S NEW WEBSITE FEATURES

Chat with MSAA

MSAA's new **Chat** feature enables website visitors to have a one-on-one conversation with a Client Services consultant. The MS Chat feature is found on the bottom right-hand corner of many pages of our website and can be accessed by clicking the "Start Chat" tab.



MS Relapse Resource Center

MSAA's new **MS Relapse Resource Center** provides detailed information on relapses and treatments. Found under the "Manage Your MS" tab on our homepage, you'll find relapse tools, a relapse media center, a survey section, and more. *The Relapse Resource Center has been developed through an unrestricted grant provided by Questcor Pharmaceuticals.*