



ADVOCACY

December 3, 2010	CC: Chapter Presidents
	Programs & Services
<u>Medicare Prescription Drug Plan Enrollment Now Open: 2011 Brings Welcome Changes, But Potential Pitfalls for ‘Specialty Drug’ Users</u>	

The annual enrollment period for Medicare Prescription Drug Plans began 11/15/10, and closes 12/31/10. With exceptions, this six week period is the only time most Medicare beneficiaries who do not have drug coverage from another source can enroll in, or switch plans to one that works better for them for the next year. Beneficiaries are urged to act well before the deadline.

Current enrollees should have received their ‘Annual Notice of Change’ from their current plan this fall, and should check it for changes in the list of drugs the plan will cover next year, as well as any increases to their premium, deductible, copay or co-insurance amounts. Many costs are going up, and beneficiaries on high cost drugs in particular should take special care with their prescription drug plan choices for 2011.

Help is available (and strongly recommended) to assist clients sift through the many choices of drug plans available to them through the IRC, Medicare (1800-MEDICARE/ www.medicare.gov), their State Health Insurance Counseling Program, and other resources listed on the Society’s website section on Medicare Prescription Drug Plans (www.nationalmssociety.org > Living with MS > Insurance & Money Matters > Medicare > Medicare Prescription Drugs).

Most beneficiaries’ premiums will remain about the same in 2011, and federal healthcare reform included expanded Medicare benefits. Nonetheless, people with MS and their caregivers should take particular note of the following:

- Co-insurance amounts for specialty drugs, such as the MS disease modifying treatments, could be even higher than in past years. An increasing number of plans (41%) are expected to cover some specialty drugs on a fifth tier, which will likely require the beneficiary to pay *at least* 25% in co-insurance.

- In addition to checking for changes in their plan, enrollees should make sure they are getting their prescriptions filled by pharmacies that work with their plan, and don't pay higher out-of-pocket costs unnecessarily.
- Fewer plans will be available overall, which will require a significant number to choose new coverage. This will ultimately benefit people in Medicare, as consolidation will help eliminate plans that are duplicative or of lesser value. Medicare Advantage (MA) plans, which are scheduled to receive lower reimbursement rates over time, will be rewarded with higher fees (and incentives) when they demonstrate superior outcomes.

The good news for Medicare enrollees includes the following:

- Starting January 1st, Medicare will cover the full cost of many preventative services, including mammograms, Pap tests and screenings for prostate and colorectal cancer.
- Every year, Medicare will also cover one "wellness" examination enabling beneficiaries and their doctors to focus on recommendations and strategies for avoiding illness, injury or disability, not just health care one might need after an illness or injury occurs.
- The coverage gap, (aka 'the donut hole') begins a slow phase-out, and will be completely eliminated by 2020. Beginning in 2011, brand name drugs needed during the donut hole period will cost 50% less and generic drugs will be reduced by 7%.

For additional information, contact the IRC.



CHAPTER PRESIDENTS

December 3, 2010	CC: Development
<u>Class of 2011 MS Clinical Care Physician Fellows Recommended: Funding From Regions, Chapters and Donors Needed</u>	

As a result of surveying over 10,000 individuals touched by MS to inform the Society’s 2011-2015 Strategic Response, we know that one of the major themes expressed was a call for the Society to attract, train and retain the next generation of MS scientists and clinicians. The number of neurologists and physiatrists with specialized focus in MS clinical care is currently inadequate. This shortage of specialists results in delayed diagnoses and inadequate or less optimal treatment for many people with MS. The quality of life experienced by people with MS and quite possibly their future prognosis depends on the medical care that is available.

The Multiple Sclerosis Clinical Care Physician Fellowship program was initiated in 2003 to address this critical shortage of neurologists and physiatrists with the special knowledge and skills needed to provide the care so integral to the quality of life of people with MS. For 2011, 12 highly-qualified physicians have been approved for awards. We cannot, however, commit to these awards until funding is secured. All funds to support these fellows must be raised through gifts from individuals, corporations, chapters or regions. The total amount needed to fund all fellows is \$900,000.

This year-long program for board eligible/certified neurologists or physiatrists provides fellows with the opportunity to perform new patient consultations and follow-up evaluations under the supervision of an MS specialist physician. They also participate in multidisciplinary team activities, lectures and professional meetings leading to the acquisition of skills and knowledge necessary to provide quality care to individuals with MS.

The Class of 2011 Fellows Includes:

- A candidate inspired to become a master in comprehensive MS care after seeing the profound impact that an MS specialist had on her mother’s diagnosis and treatment. .
- Applicants with interest in pediatric MS and its unique treatment for this underserved patient population.
- Several candidates drawn to the complexities of treating MS and the impact of comprehensive care on a patient’s quality of life.

- Candidates who ultimately wish to pursue academic careers, dividing their time between clinical practice, research and teaching. These candidates desire to join or establish MS centers and to contribute to the training of even more MS specialists.
- Applicants who have completed residencies in physical medicine and rehabilitation who desire to leverage that knowledge to expand treatment options for patients with MS.

The Class of 2011 Fellows Training Locations:

- University of California, San Francisco, California
- Cleveland Clinic Foundation, Cleveland, Ohio
- University of Washington, Seattle, Washington
- Children's Hospital, Boston, Massachusetts
- Corrine Goldsmith Dickinson Center for MS, New York, New York
- University of Utah, Salt Lake City, Utah
- UT Southwestern Medical Center, Dallas, Texas
- Stanford University Hospital and Clinics, Stanford, California
- University of Colorado, Denver, Colorado
- Ohio State University, Columbus, Ohio
- The University of Chicago, Chicago, Illinois
- Kaiser Permanente Southern California, Los Angeles, California

The Class of 2011 Fellows will conduct their fellowships at some of the most prestigious MS training sites around the country. Based on a survey of past fellows, we know that almost all fellows remain in the field of MS care, and many will practice in various states of the country during their career.

The training of these fellows benefits all living with MS, regardless of location, and every region and chapter can have a part in fulfilling the Society's promise to train the next generation of MS scientists and clinicians, thus improving the lives of people living with MS for generations to come. The Society can only meet our funding goal through donations from regions, chapters or donors, either to support a specific fellow or to support the program in general.

Questions or More Information Needed?

If you have questions about the Clinical Fellows Program or how you or a donor can ensure the entire class of 2011 receives funding, please contact Carrie Radant at 303.698.6139 or carrie.radant@nmss.org or Mary Milgrom at 303.698.6103 or mary.milgrom@nmss.org.



CHAPTER PRESIDENTS

December 3, 2010	CC:
North Florida Chapter Announces New Chapter President: Corrina Steiger	

We are very pleased to announce that Corrina Steiger has accepted the position as the Chapter President in the North Florida Chapter. She has assumed her new duties as of November 29, 2010

Corrina began her National MS Society career in 2001 and has served the North Florida Chapter and the Society in a number of capacities, with her most recent position being the chapter's Executive Vice President. Corrina started with the Chapter as the Marketing and Recruiting Coordinator, recruiting participants, volunteers and teams for a variety of chapter events. She then moved into the programs area, eventually being promoted to the position of Vice President of Programs and Services. Most recently, as EVP, Corrina has been responsible for the roll out of the Golden Circle Campaign in North FL securing 55 charter members for the chapter. Throughout her career Corrina has shown the ability to develop effective collaborations and ensure ongoing relationships to maintain and further develop key chapter services and events.

Corrina, along with the other staff in the chapter, has done an outstanding job in ensuring that our programs, services and events have continued uninterrupted during our transition in seeking a new chapter president. During the search process she impressed the Committee with her vision for the Chapter's future and her ability to work collaboratively with other leaders in the Southeast Region. Equally important was her passion for serving people with MS, which she has demonstrated throughout her career,

Please welcome Corrina to her new role within the Chapter and the Society.

Jennifer Lee
Executive Vice President, Southeast Region
904-923-2254
Jennifer.Lee@nmss.org



National
Multiple Sclerosis
Society
News Sheets

DEVELOPMENT

December 3, 2010

CC: Marketing

Mission Possible Artwork Submissions Requested for 2011 Award Plaque

We are now accepting submissions of artwork for the 2011 Mission Possible Award.

Artwork should be created by someone connected to (but not employed by) the National MS Society and should reflect the Society's positive messages of hope, empowerment, and movement.

Please send your submissions electronically to Sarah Klein at sarah.klein@nmss.org by December 17th. The winner will be chosen by a committee and will be notified in early January.

As you know, "Mission Possible" provides chapters the opportunity to recognize the outstanding fund raising efforts of their top donors. Most chapters market Mission Possible to event participants and position it as a mission-focused award that can be attained by raising \$1 for every client served locally.

If you have questions regarding this valuable donor recognition strategy, please contact Sarah Klein, at 518.952.4153 or sarah.klein@nmss.org.



DEVELOPMENT

December 3, 2010	CC: Chapter Presidents
	Marketing
Virtual December Walk MS and Bike MS New Staff Training – Registration reminder!	

The December Mass Market Workshop will be offered virtually again this winter in order to make training more accessible to all chapters by minimizing budget impact. The training will highlight the latest “how-to’s” for creating an exceptional event experience, strategies for more effectively utilizing our newest tools to cultivate participants and raise more money, key risk management info, team strategies, and event research findings. Attendees will walk away with a big picture understanding of the National MS Society and our signature events: Walk MS and Bike MS. Although hosted virtually, this will be a highly interactive training for all participants and will provide a great networking opportunity.

This workshop is designed primarily for new Development staff who have not previously attended a regional mass market workshop, but veteran staff who would like a refresher on event core strategies are welcome to attend as well.

Participants will take part in seven seventy-five minute calls which will take place over the course of two weeks. All trainings will start at 11 am PST, Noon MST, 1 pm CST and 2 pm EST. The dates of the trainings are: December 6, 7, 8, 9, 13th, 14th and 16th. Staff who register for the trainings are committing to all seven of the workshop sessions.

The training series fee is only \$30 for telecom changes.

Register here -

<https://meetings.nmss.org/attendee/event/December2010VirtualWalkandBikeNewStaffTraining.wv>

If you have questions, please contact Rachael Nuwash at 303-698-6100 x 15136.



CHAPTER PRESIDENTS

December 3, 2010	CC: All
MS Navigator Assessment Progress Update	

Background

The goal of the MS Navigator program is to ensure a seamless and supportive experience for individuals needing information and assistance related to living with MS. The MS Navigator Assessment work team was established to conduct a strategic review and develop a vision for this important work utilizing the experience and skills of volunteers and staff.

The MS Navigator Assessment work team met in Denver on November 1 and 2, 2010, with a packed agenda that began with a full day of ride alongs in the IRC. Facilitator John Paul led the group in an initial discussion of expectations for the meeting and the work team, the development of operating principles for the group, and a review of the decision-making and consensus process.

On day two of the meeting the work team engaged in discussion of issues around the MS Navigator program that included: gaining an understanding of who we are serving as well as who we are not connecting with; what the program is and what do we want it to be; and what does “MS Navigator” mean to those outside the Society. We described what success of the work team would look like at the end of the project, and what the ideal MS Navigator program would look like.

Issues – Just a few of the issues that came out of the group’s discussion were identified as follows:

- 1) Confusion over what MS Navigator is; provide role clarity.
- 2) How value of the service is prioritized and balanced against efficiency?
- 3) What is the context in regards to future technology?
- 4) Who and why do people choose not to contact the Society through MS Navigator?

Success Statements – A sampling of member opinions of what “success” of the work team means:

- 1) Best practices implemented to ensure the Society is a part of the conversation given the progress and pace of technology.

- 2) Provide MS Navigator services for the future – reaching people in the ways that are best for them so that we can be their MS Navigator.
- 3) Create organization-wide ownership of the experience of every person seeking/needing help living with MS.

Ideal Statements – When we are at our best...

- 1) Our internal processes are cost effective and highly efficient.
- 2) We are reaching a greater number of clients who will then utilize our services.
- 3) We are available in a format that is comfortable to all constituents.
- 4) We don't wait passively for people to find us; we go where they are.
- 5) Society staff and volunteers of all functions and levels readily identify MS Navigator as the Society's resource to people living with MS and know how to connect people to it.
- 6) We are an organic service – a single Society team across the country with the needs of the people with MS in the center.
- 7) We will be the place that everyone knows can help.

Outcomes

The larger MS Navigator Assessment work team was divided into three smaller work teams to work on distinct initiatives.

- 1) Expressing the value and benefits of MS Navigator.
- 2) Process improvements and technology enhancements for efficiency gains.
- 3) MS Navigator as the Society entry point for constituents, both internal and external.

The small work teams are meeting in December to identify their team leader, finalize their respective charges, and develop their tasks.

A vision statement for the MS Navigator program was created to help us keep our focus on the goals and outcomes of our work:

We provide information and resources to help people navigate the challenges that MS creates – ensuring ease of access and connection wherever and however support is needed.

The full work team will reconvene in January to check on the progress of each of the small work teams and determine any adjustments that need to be made on each group's work.

Expense-related decisions and outcomes will be finalized by early spring in time for the Society's budget process. A more complete description on the MS Navigator Assessment project can be found on SharePoint:

http://intranet.nmss.org/Documents/10_22_10_MS_Navigator_Assessment.pdf

If you have any questions please contact Lisa Custy, MSCIR, Associate VP, Programs & Services at 303-698-6100, ext. 15266 or Lisa.Custy@nmss.org.



National Multiple Sclerosis Society
733 Third Avenue
New York, New York 10017-3288
Tel +1 212.986.3240
Fax +1 212.986.7981
E-mail nat@nmss.org
Nationalmssociety.org

RESEARCH/CLINICAL UPDATE

cc: Chapter President, Programs

December 3, 2010

EMD Serono Announces FDA Extension of Review of Oral Cladribine

-- Approval decision now expected by end of February

The makers of oral Cladribine, a drug currently under review by the U.S. Food and Drug Administration for the treatment of relapsing MS, have announced (http://www.marketwatch.com/story/emd-serono-announces-extension-of-fda-priority-review-period-for-Cladribine-tablets-for-the-treatment-of-relapsing-forms-of-multiple-sclerosis-2010-11-26?reflink=MW_news_stmp) by press release that the FDA has extended its review by three months to consider additional information provided by the company. The FDA has until February 28, 2011 to make a decision about whether oral Cladribine will be marketed in the U.S.

Background: Cladribine can interfere with the activity of lymphocytes, a subset of white blood cells that underlie the immune attacks that cause the unpredictable symptoms of MS. Injectable Cladribine is used to treat hairy cell leukemia.

The phase III trial of oral Cladribine (EMD Serono), known as the CLARITY study, showed that the drug reduced relapse rates significantly more than inactive placebo in a study involving 1,326 people with relapsing-remitting MS. The results were published in the *New England Journal of Medicine* (2010; 362:416-426, <http://www.nejm.org/doi/full/10.1056/NEJMoa0902533>). Read more (<http://nationalmssociety.org/news/news-detail/index.aspx?nid=2569>) about the CLARITY results.

In November 2009, EMD Serono announced that it had received a “refuse to file” letter from the FDA, indicating that its application requesting approval of Cladribine for MS was incomplete. On June 8, 2010, the company announced that it had resubmitted its application to the FDA for approval of Cladribine, and on July 28, the agency granted Priority Review status to the application, which was to have shortened the review period with an expected

decision by the end of November. The review process has now been extended by the FDA to the end of February to provide more time for a full review of additional information provided by the company. Cladribine has been approved for MS treatment in Russia and Australia, but was disapproved by the European Medicines Agency.

In addition to a two-year extension study of CLARITY, other ongoing studies of oral Cladribine funded by EMD Serono include the ONWARD study, an investigation of the safety and effectiveness of adding high or low doses of oral Cladribine to interferons in a trial in people with relapsing forms of MS; and the ORACLE MS study, designed to evaluate oral Cladribine in people who have experienced a neurological episode that puts them at risk for developing MS. Both are ongoing.

The landscape of MS therapies changed with the recent approval of fingolimod capsules (Gilenya,[™] Novartis International AG) for reducing the frequency of clinical relapses and delaying the accumulation of physical disability in relapsing forms of MS, making it the first oral disease-modifying therapy approved in the U.S. for the treatment of multiple sclerosis.

Gilenya is a trademark of Novartis International AG



National Multiple Sclerosis Society
733 Third Avenue
New York, New York 10017-3288
Tel +1 212.986.3240
Fax +1 212.986.7981
E-mail nat@nmss.org
Nationalmssociety.org

RESEARCH/CLINICAL UPDATE

cc: Chapter President, Programs

December 3, 2010

Small, Early Study Suggests Skin Patch Can Suppress MS Immune Activity

A small study in people with relapsing-remitting MS showed that applying a skin patch containing components of myelin, the material that surrounds nerve fibers and is the target of immune attacks in MS, succeeded in suppressing immune activity. Maciej Juryńczyk MD, Krzysztof Selmaj MD, PhD (University of Lodz, Poland) and colleagues report their findings in *Annals of Neurology*. (2010;68:593-601, <http://onlinelibrary.wiley.com/doi/10.1002/ana.22219/abstract>) Further studies will be needed to determine whether this approach is safe and effective for treating MS.

Background: Multiple sclerosis involves immune attacks launched against the brain and spinal cord. A main target of this attack is myelin, the substance that insulates nerve fibers and facilitates proper nerve impulse conduction. Researchers have long explored whether the immune system could be trained to ignore myelin by inducing “tolerance.” One approach is to inducing tolerance is to injecting people with MS with myelin peptides, that is, fragments of proteins found in myelin.

The results of such studies in MS have been mixed and have not yet shown this to be a safe and effective therapeutic strategy, although work in this area continues. For example, a previous large clinical trial of orally administered myelin protein altered some immune activity but was clinically ineffective, as was a more recent clinical trial of an injected myelin peptide in secondary-progressive MS (<http://nationalmssociety.org/news/news-detail/index.aspx?nid=1854>).

The Study: In this placebo-controlled study, the team enrolled 30 people with relapsing-remitting MS (<http://nationalmssociety.org/about-multiple-sclerosis/relapsing-ms/relapsing-remitting-ms-rrms/index.aspx>). Treatments were administered via an adhesive patch placed on the right upper arm. Participants were randomly assigned to receive either an inactive placebo

patch; a patch containing a mixture of 1 mg each of proteolipid protein (PLP), myelin oligodendrocyte protein (MOG), and myelin basic protein (MBP) peptides; or a mixture containing 10 mg each. The patches were changed once each week for four weeks, and then once each month for 11 months. Immune cell reactions were determined via skin biopsies and blood samples. The study was not designed to detect a clinical impact of the treatment, but rather to look for signs of altered immune responses.

The results suggest that treatment activated dendritic cells in the skin and in the lymph nodes. Dendritic cells are powerful stimulators of T cells, the major players in the MS immune attack; dendritic cells can determine whether T cells are activated to attack, or are suppressed. In this study, T cells that react to myelin were shown to be reduced, and T cells known to help regulate immune responses were shown to increase, in people treated with the myelin peptides.

Comment: MS experts Lawrence Steinman, MD, and Scott Zamvil, MD, PhD (Stanford University, CA) comment on the study in an accompanying editorial, noting that this study's success might be due to the use of several myelin peptides rather than just one. "The success of this approach," they write, "would amount to the use of a truly 'smart weapon' – a weapon that would only regulate the pathological immune responses, while leaving the rest of the immune system intact." Further studies will be needed to determine whether this approach is safe and effective for treating MS.

Fast Forward, the National MS Society's drug development subsidiary, has developed a partnership with Apitope to explore the use of myelin components to treat MS. Read more (<http://www.nationalmssociety.org/fast-forward/who-weve-funded/download.aspx?id=23269>).