THE OUTLOOK

25 YEARS AS YOUR MYOSITIS ASSOCIATION

WINTER 2018
Quarterly Newsletter

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THE OUTLOOK

A quarterly publication of The Myositis Association

Cover Photo
Dr. Jens Schmidt
TMA Medical Advisor

Published by: TMA, Inc
THE MYOSITIS ASSOCIATION
1940 Duke Street,
Suite 200
Alexandria, VA 22314
P: 800-821-7356
F: 703-535-6752
E: tma@myositis.org
W: www.myositis.org
Bob Goldberg, *Executive Director*
Linda Kobert, *Editor*

Bob Goldberg, Executive Director

The mission of The Myositis Association is to increase support, awareness, and funding for the myositis patient, caregiving, and research community.

Milestones

Twenty-five years ago, Betty Curry formed a myositis organization to help those who suffer from myositis and to seek treatments and a cure. A quarter-century later, we have a number of treatments for all forms of myositis, except inclusion body myositis, and we are still seeking a cure for the myositis diseases. While 25 years is a long time, it is not long in the world of medical research due to the difficulty in finding effective and safe treatments and then getting approval from the Food and Drug Administration for their use in the US. This issue of *The OutLook* presents updates on myositis research and offers good news regarding brightening prospects for finding treatments for IBM.

TMA continues to grow its research efforts and expand its reach in the international myositis research community. You will find in this issue brief profiles of four new myositis experts who have joined TMA's Medical Advisory Board and a listing of four new research grants and fellowships TMA made in 2017.

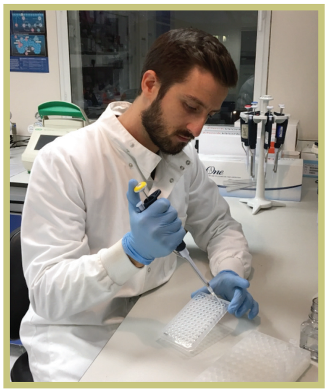
TMA is celebrating its 25th Anniversary throughout 2018 and further information will be shared with our members during the year. The anniversary activities are opportunities to bring further attention to our disease and to acknowledge the past efforts of those who have enabled this rare disease organization to grow and serve the myositis patient and physician communities.

As Executive Director of TMA for the past 15 years, I have been privileged and honored to help lead the organization through much of its growth. There is much more that remains to be done, and, with my retirement, I plan to turn over the reins to a new executive later this year. A search firm, The Batten Group, has been hired to find my replacement, and I am confident they will find someone equally committed and determined to help those with myositis while we seek a cure.

2018 will be a monumental year in many respects, and your support and encouragement will help our Board of Directors, Medical Advisory Board, and staff provide the level of service and attention you rightly deserve. You can find a 25th anniversary logo on the cover of this *OutLook*, and you will notice the reference to "Your Myositis Association." TMA is Your Myositis Association.

We look ahead confident that this may well be the best year ever for TMA, and we enter the next quarter-century with great hope and optimism.

TMA funds new research



TMA research fellow Simon Rothwell

It has been fifteen years since The Myositis Association started funding research to understand the underlying causes and natural progression of myositis, develop better treatments, create more effective therapies, and ultimately to find a cure for this collection of disabling diseases. In that time, TMA has approved more than 50 research projects, including grants and fellowships, totaling about $7 million.

Funds for this research effort come to TMA primarily from myositis patients, their families, and friends. Each year, TMA solicits proposals for basic and applied research projects as well as applications for fellowships from young scientists who have an interest in a career studying myositis. Based on recommendations from TMA's Medical Advisory Board of myositis experts, TMA's Board of Directors chooses the most promising of these proposals to fund.

This year, the following projects were awarded funding:

Melissa Morales, PhD – $100,000 fellowship to search for urine biomarkers in juvenile dermatomyositis

Tahseen Mozaffar, MD – $50,000 grant to complete a phase I study of dalazatide in sporadic inclusion body myositis

Simon Rothwell, PhD – $100,000 fellowship to conduct high resolution cellular phenotyping of myositis patients starting rituximab therapy

Victoria Werth, MD – $100,000 grant to explore IL-31 and its mechanism of action in the itch associated with dermatomyositis

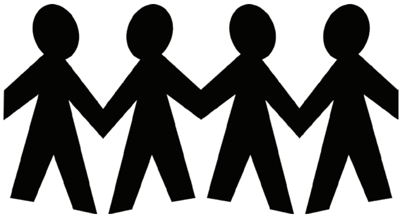
TMA introduces MYO-Connect

Sharing your concerns with others who know what you are going through is one of the most important ways for those with myositis to cope with the many challenges of the disease. Many TMA members, however, live in sparsely populated areas where there is not yet a TMA Keep in Touch (KIT) support group established. Others are physically unable to travel to attend local KIT group gatherings. But TMA doesn't want to leave these folks behind. That's why TMA has created the MYO-Connect program.

MYO-Connect is a network of those with myositis who have the same diagnosis and connect by phone or email as a way to give and receive emotional support. Like TMA KIT groups, this group is a safe place where patients can feel free to share their honest feelings without judgement. It's also a place to share tips, strategies, and devices that help you overcome particular difficulties.

The goal of MYO-Connect is to provide an alternative means for patients struggling with myositis to feel supported. Whether you are newly diagnosed or a patient who has been living with myositis for years, everyone copes better when they feel supported, heard, and understood.

If you are unable to attend local myositis support group meetings and feel you would like to be in contact with others who share your diagnosis, please email TMA's Member Services Manager, LaDonna Johnson, at **TMA@myositis.org**. Please include your contact information.



Conference videos and presentations available

For the past four years, TMA has video recorded presentations at our Annual Patient Conference to share this valuable information with those who were not able to attend the Conference in person. TMA has also posted to its website the PowerPoint slides of the presenters who were not videotaped.

More than 170 videos and 150 PowerPoint presentations are now available on TMA's website. The videos can be viewed through the TMA site or directly on YouTube at The Myositis Association channel. These videos have now been viewed nearly 177,000 times.

The presentations are part of TMA's efforts to educate patients about myositis and bring the latest myositis research and insights to TMA members. While this rich repository of information is available to the public, all the videos are proprietary and are not to be shared without attribution to The Myositis Association.

Those who have attended a TMA Annual Patient Conference know that there is much learning and sharing of information that takes place outside of these formal presentations, and being at the Conference is a unique opportunity for you to learn how best to cope with your disease. If you have not been to TMA's Annual Patient Conference, you owe it to yourself to attend one if you are able.

To register for the 2018 Conference in Louisville, go to **www.myositis.org**. To view the videos or PowerPoint presentations, go to **http://www.myositis.org/your-myositis-community/annual-patient-conference**.

Myositis support around the world

TMA is part of a world-wide network of international myositis patient support groups, helping to spread the word about these rare diseases and offering the encouragement and validation that helps patients cope with this difficult journey.

Daniel Ponce reports that the **French Idiopathic Inflammatory Myopathies (IIM) Group of Interest**, a part of the French Muscular Dystrophy Association known as AFM-Téléthon, is thriving. The group, which was initiated through the efforts of TMA medical advisor Dr. Olivier Benveniste, is small and run by volunteers, but it functions throughout the country to assist families affected by myositis diseases.

In addition to providing patient and family support and education, the IIM Group of Interest helps to prepare families for clinical trials; establishes connections between patients, physicians, and researchers; hosts national patient conferences and local support group gatherings; and works to promote research into myositis diseases.

Among the goals of the group is to participate in major myositis meetings as a way to enhance the connection among international myositis patient groups. This year, for example, Daniel and others from his organization participated in the Global Conference on Myositis (GCOM) near Washington, DC, in May, as well as TMA's Annual Patient Conference in San Diego in September.

Silke Schlüter serves as chair of the **German Myositis Diagnosis Group** (Vorsitzende der Diagnosegruppe Myositis) in association with the German Society for Muscle Diseases (der Deutschen Gesellschaft für Muskelkranke [DGM]). The group was founded in 2010 as a patient initiative by Dr. Jens Schmidt (a TMA medical advisor), IBM patient Dr. Martin Taylor, and his wife Sigrun Matthiesen. Eleven volunteers are active in the group, supporting patients and their families who live with inclusion body myositis, necrotizing myopathy, polymyositis, orbital myositis, antisynthetase syndrome, and dermatomyositis.

Members of this group communicate mostly by telephone or e-mail. Patients can find information about myositis from their website **www.dgm.org/diagnosegruppe/myositis**, as well as printed material. The group leads discussion groups for patients and families and hosts patient education days, medical symposia, and training courses for physical therapists. In October 2016, the GMDG hosted a workshop with Chicago psychotherapist Dr. John Rolland called “In sickness and in health: Love and partnership under the influence of chronic disease.”

In the future, GMDG hopes to support more research, bring more public awareness to myositis, create patient brochures about living with myositis, and engage more active participation by members. They also hope to reach out to more physicians, to inform them about myositis diseases and to build a network between doctors, therapists, and patients. The first step in this is the Myositis Network **(www.myositis-netz.de)**, a platform to promote interdisciplinary cooperation among healthcare professionals.

“Our biggest success is the new Junior Myositis Award,” says Silke. Funded by private donations from members of GMDG and in cooperation with the DGM and the Myositis network, this myositis research grant will be awarded for the first time in March 2018.

Silke and others from her group also attended the GCOM in May 2017 and they are very proud that the GCOM 2019 will be in Berlin, Germany.

Elaine Dicken and Chelsey Dawes report that, in February, **Myositis Canada/ Myosite Canada** launched their annual #GiveMeMuscle campaign, a national effort to encourage anyone affected by myositis to post online a video or photo of themselves doing exercise to “give muscle” (and awareness) to myositis.

Myositis Canada also hosted several events to recognize May as Myositis Awareness Month. Among these was a successful effort by members to have a bridge in Edmonton, Alberta and a stadium in Montreal, Quebec lit up with myositis blue.

The organization awarded member Martin Jarry their “Got A Lot Accomplished” (GALA) award for raising over $35,000 and raising awareness of myositis during a 10K run in Ottawa in May. Martin has IBM but was able to run wearing a Keeogo exoskeleton device made by B-TEMIA. Some TMA members may have seen him demonstrate the device at TMA’s Annual Patient Conference in San Diego in September.

And on May 27, Myositis Canada/Myosite Canada announced the awarding of a $10,000 research grant to two researchers at McGill University, Dr. Marie Hudson and Dr. John Di Battista. Their project, “Quantitative/qualitative proteomic analysis of inflammatory myopathy with mitochondrial pathology and sporadic inclusion body myositis,” is a pilot project focused on the range of proteins expressed in muscle biopsies from patients with sIBM. The project will use state-of-the-art technology and bioinformatic tools to identify biomarkers that could be used to improve the diagnostic process.

TMA's MAB are the world's experts on myositis

For nearly two decades TMA has had the world's foremost myositis researchers, scientists, and clinicians serve on its Medical Advisory Board (MAB). Who are these myositis experts? They are the leaders in the medical community focused on myositis. They recommend to TMA's Board of Directors which research projects are worthy of funding. (TMA has now funded more than 50 projects for a total of about $7 million.)

MAB members also consult with physicians needing advice on how to treat myositis. They help TMA staff write educational materials for patients and physicians to help them better understand myositis. They are volunteers who are not compensated for the time they devote to MAB meetings, committee meetings, TMA's Myositis Symposium, and other activities such as going to medical schools to teach medical students about myositis.

Why do they do this? Because they are committed to helping find better treatments and ultimately a cure for myositis. They do this through sharing information and insights with each other. They are rheumatologists, neurologists, dermatologists, immunologists, and rehabilitation specialists, collaborating to help advance the understanding of myositis to improve treatment of the disease until a cure can be found.

Starting with this issue of *OutLook* and during the next 12 months, TMA will profile four members of our MAB in each issue. This issue has profiles of the four most recent additions to the MAB. The MAB currently has 22 members, and TMA rotates some members off each year so that new members can be added to ensure a fresh influx of ideas and perspectives.

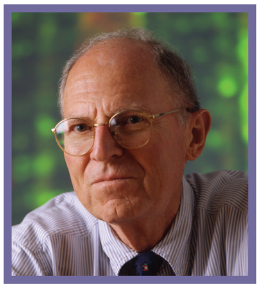
Tahseen Mozaffar, MD

Specialty: Neurology with subspecialty training and certification in neuromuscular disorders and neuromuscular pathology

Institution: Department of Neurology, University of California, Irvine

Research interests: Myositis (antibody-associated myositis, inclusion body myositis, autoimmune necrotizing myopathies)

Personal: Three children, 22, 19, and 7; avid history and movie buff; follows LA Chargers and New England Patriots



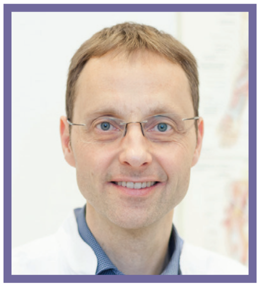
Paul Plotz, MD

Specialty: Rheumatology with training in laboratory research in cellular and molecular biology

Institution: The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Research interests: Understanding the clinical manifestations, pathogenesis, and therapy of inflammatory muscle diseases (all forms of myositis, including dermatomyositis, polymyositis, and inclusion body myositis) and of genetic diseases of the muscle, particularly lysosomal storage diseases and several metabolic muscle diseases in the family of muscle dystrophies

Personal: Family, especially my wife, Judith, who is a scholar and professor of literature; two sons: John, who is a scholar and professor of literature and is married to a math teacher, and David, who is the CEO of the website *Atlas Obscura* and is married to an NPR journalist. We live in Washington, DC, and have an old farmhouse in northern Vermont where I have developed as a gardener.



Jens Schmidt, MD

Specialty: Consultant and professor of neurology; Head of the Neuromuscular Center; Head of the Muscle Immunobiology Group

Institution: Department of Neurology, Neuromuscular Center at the University Medical Center Goettingen, Germany

Research interests: Immunobiology of the muscle with specific interactions between inflammatory and degenerative pathomechanisms

Personal: Two daughters, bike riding, soccer

Perry Shieh, MD, PhD

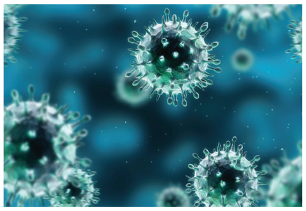
Specialty: Neurology with subspecialty certification in neuromuscular medicine, electrodiagnostic medicine, and neuromuscular pathology

Institution: University of California, Los Angeles (UCLA)

Research interests: Clinical research (including clinical trials) for muscle diseases (myositis, myasthenia gravis, muscular dystrophy, and other myopathies)

Personal: Three children: Elliott (5), Preston (4), and Vivienne (7 months); musicals, classical music, ballroom dancing

More information will be provided about TMA's 25th year of serving the myositis community and the 25th Anniversary Celebration to take place at the Annual Patient Conference in Louisville.



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1993-2018

Myositis classification criteria are a breakthrough

The ability to diagnose myositis diseases and treat them properly just improved immensely. For more than 40 years, the criteria physicians have used to diagnose most myositis diseases has been based on expert opinion, not hard science.

The most frequently used guidelines are known as the "Bohan and Peter criteria." They combine physical symptoms with information from laboratory and other tests to define polymyositis (PM) and dermatomyositis (DM). But they do not recognize inclusion body myositis (IBM), necrotizing myopathy (NM), or amyopathic dermatomyositis (ADM). They may also erroneously identify some muscular dystrophies as myositis.

The good news is that recently a group of myositis researchers from around the world set out to develop a wholly new set of classification criteria for adult and juvenile myositis diseases based on data from more 1,600 patients (972 with myositis, 624 comparators). The results of this years-long effort has recently been published along with a web-based calculator that can be used, with or without biopsy data, to determine the probability of a particular diagnosis based on statistical data.

This evidence-based, approach developed through analysis of a large patient base, offers a faster, more accurate path to diagnosing myositis diseases and treating them properly, which will spare patients a great deal of anxiety and suffering. These classification criteria can also be used in clinical research to more accurately identify patient cohorts and will generate more useful research findings.

Not only are these new classification criteria a breakthrough that will enable progress in the diagnosis and treatment of myositis diseases and research, they also represent a monumental achievement of international and interdisciplinary scientific cooperation. TMA helped to fund this effort and applauds the 100 myositis experts of the International Myositis Classification Criteria Project (IMCCP) that produced this milestone achievement, which will have a lasting impact on those who live with myositis.

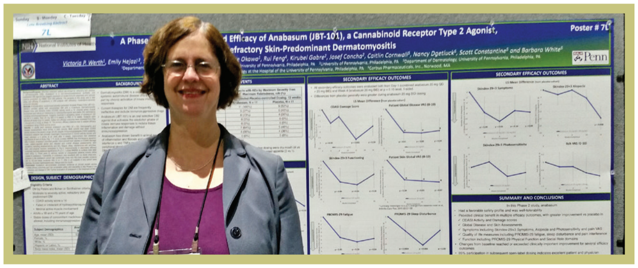
You can find the IMCCP report on the TMA website under "Published Research." The calculator can be accessed at: **http://www.imm.ki.se/biostatistics/calculators/iim/**

Anabasum shows promise for DM skin disease

Corbus Pharmaceuticals, a young company with a novel drug that offers promise for dermatomyositis patients, recently reported exciting results. The findings of a phase 2 clinical trial of the drug anabasum showed significant improvement in DM skin disease for patients taking the drug versus patients taking placebo.

A number of TMA members participated in this clinical trial, which was led by former TMA medical advisor Dr. Victoria Werth at the University of Pennsylvania. Results also indicated improvements in other quality of life measures important to patients, including improved ability to sleep and reduced itching. Anabasum was well tolerated and demonstrated no significant adverse effects.

Unlike other treatments for DM, anabasum (also known as ajulemic acid) is not an anti-inflammatory medication, so it does not cause the kinds of troubling side effects seen with drugs such as prednisone and methotrexate. Anabasum is an oral, non-psychoactive endocannabinoid-mimetic drug that is believed to "turn off" chronic inflammation and fibrotic processes without causing immunosuppression. Its effects are also being studied in systemic sclerosis, cystic fibrosis,



Dr. Victoria Werth presented the results of the anabasum clinical trial at the meeting of the American College of Rheumatology.

and lupus. Additional clinical trials will be needed before FDA approval is granted.

More information can be found at the company's website: **https://www.corbuspharma.com/**.

New myositis biomarker identified

A team of researchers at the Johns Hopkins Myositis Center have confirmed that an antibody biomarker in a group of patients with myositis is associated with cardiac involvement. The team, led by former TMA medical advisor Dr. Lisa Christopher-Stine, noted the presence of antimitochondrial antibodies (AMA) in a small group of myositis patients who also have severe cardiac disease.

The researchers found that patients with AMA-associated myositis have a more chronic disease course, with years of worsening muscle weakness prior to diagnosis. Heart disease in these patients took the form of myocarditis (inflammation of the heart), severe arrhythmias (abnormal heartbeat), or cardiomyopathy (enlargement of the heart). Although the heart disease was often not recognized as being related to the myositis, when patients were treated with immunosuppressants for myositis, their cardiac symptoms also improved.

This new antibody biomarker may help doctors diagnose this disease more quickly and will offer clues about potential future symptoms, effective treatments, and long-term disease prognosis.

https://www.hopkinsrheumatology.org/2017/10/matters-heart-newly-discovered-type-inflammatory-muscle-disease-heart-involvement/

Researchers optimistic about rapamycin for treating IBM

At the American College of Rheumatology (ACR) meeting in November, TMA medical advisor Dr. Olivier Benveniste reported the results of his research treating inclusion body myositis with rapamycin, a drug used to prevent organ rejection.

While patients in both treatment and placebo groups lost muscle strength over the twelve month course of the study, when compared to the placebo group, those in the study group showed no decrease in the six-minute walking distance test, IBM weakness was less degraded, and forced vital capacity (a test of diaphragm

Patients with active DM or PM needed

Bristol-Myers Squibb is currently recruiting adults with active dermatomyositis or polymyositis for a clinical trial. The goal is to evaluate the effectiveness and safety of a study drug, called abatacept, in combination with standard medicines in improving symptoms of active myositis. The effectiveness of this combination therapy will be compared to standard therapy for myositis.

This clinical trial is underway and aims to enroll 150 patients over a three-year period. Multiple study sites are available throughout the US and abroad. Participants will first receive either abatacept, the study drug, or a placebo via a weekly injection under the skin for 24 weeks. Then, all study participants will receive abatacept for 28 weeks. More information on this clinical trial can be found at ***www.MyositisTrial.com****.*

weakness) significantly improved. MRI showed additional positive impacts on muscle tissues.

While this clinical trial was small, and additional studies will need to be done before it is approved for use in IBM, researchers are optimistic about these results.

You can see the abstract of this research on the TMA website here: **http://www.myositis.org/storage/documents/IBM_Published_Research/Rapamycin_Vs_Placebo_for_the_Treatment_of_Inclusion_Body_Myositis_ACR_abstract_2017.pdf**

Attack My-ILD: A clinical trial

TMA medical advisors Dr. Rohit Aggarwal and Dr. Chester Oddis are recruiting patients for a clinical trial called abatacept for the treatment of myositis-associated interstitial lung disease (Attack My-ILD). Patients must have active interstitial lung disease (ILD) and antisynthetase antibody (Jo-1, PL-7, PL-12, EJ, OJ, KS), whether or not they have active myositis symptoms, to participate in this clinical trial testing the effect of adding abatacept to standard-of-care immunosuppressive therapy. abatacept is a biologic agent that is already FDA-approved for rheumatoid arthritis. Because there is evidence that activated T-cells play a role in myositis-associated ILD, researchers want to test its effect in this new disease indication.

The multi-center, double-blind, placebo-controlled study will enroll 20 patients to receive weekly subcutaneous injections of either the treatment or placebo over the six-month trial. Patients will continue their standard-of-care immunosuppressive therapy throughout the trial. Patients may opt to participate in a six-week, open-label extension, in which all patients will receive the treatment. The study entails five to six in-person visits at the study site.

Study sites include Cedars-Sinai Medical Center in Los Angeles, University of Colorado Anschutz Medical Center in Denver, Johns Hopkins Medical Center in Baltimore, Brigham & Women's Hospital in Boston, and the University of Pittsburgh.

More information, including study sites and inclusion criteria, is available at **https://www.clinicaltrials.gov/ct2/show/NCT03215927**.

Please contact study coordinator Courtney Ward at 412-648-9989 or **cow24@pitt.edu**.

ProDERM
A clinical research study

Are you affected by dermatomyositis?

If you are between 18 and 79 years of age and diagnosed with dermatomyositis, you may be interested in the ProDERM clinical research study.

ProDERM is a clinical research study that will evaluate the effectiveness of an investigational drug for the treatment of dermatomyositis.

To find out more, please contact the study team, or talk to your doctor.

Study sponsored by Octapharma Pharmazeutika Produktionsges mbH

Contact details: *Cheryl Bell, Clinical Study Manager* ***cheryl.bell@octapharma.com***

An ounce of prevention is worth a pound of cure

Safety tips for myositis patients

by Danielle D. Haines

It has been at TMA's Annual Patient Conferences that I have gained the most useful safety and practical information. At my first Conference in 2004, I wasn't using a cane yet but heard many tips that I have implemented along the way. With the muscle weakness that plagues those of us with myositis, it is vital to be honest with ourselves and to discern when certain strategies are needed to stay safe.

Steps

Walking up the steps may be the first sign of muscle weakness, but coming down the steps may be the most likely to cause an injury. So when your legs are not trustworthy, always turn around at the top of a flight of steps and descend backwards. This way you are more likely to fall forward onto the steps, which is less hazardous than falling forward *down* the steps.

If you don't have the muscle strength to lift your leg the whole way up a step, try the *Step Assist*. It's a cane with a rectangular plastic block attached that is about half the height of a standard step riser. It works going up or down steps by cutting in half the height one must step up or down.

At the sink

A stool in the kitchen and one in the bathroom might prevent a broken bone. Using an appropriate height stool allows you to sit comfortably and safely while you wash the dishes or brush your teeth.

A sturdy but lightweight folding stool can be purchased for about $12. We even take it along when we travel, which comes in handy in the shower when handicapped lodging is unavailable.

Restroom tips

Restrooms along the highway and even at some interstate rest stops may have low toilet seats or inconveniently placed grab bars. Standing in the stall solves the problem. This is not a problem for men, of course. But did you know that there is such a thing as a female urinal? This life-saver is easily available in a drug or medical equipment store.

I have a small shoe bag to carry the one-liter plastic urinal and a package of wet wipes. My shoe bag also goes with me to restaurants and to the homes of family and friends. Having the urinal at your bedside can also prevent a fall if you need to use the bathroom at night.

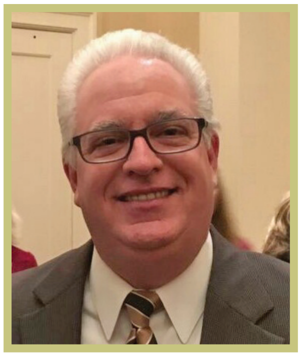
Driving

My scooter is stowed with a lift in the rear of our van. But I still need to make the trip from the rear of the van to the driver seat. So I keep a quad cane in the car to help me get from point A to point B, then I stow it behind the driver's seat where it's ready when I need to make the return trip.

Dannielle D. Haines served two terms on the TMA Board of Directors and worked for many years as a registered nurse. She lived with symptoms of IBM for 13 years before being diagnosed in 2002. She now lives in a retirement community where she still indulges her love of nursing by teaching residents her many tricks for staying safely active.

IVIg home infusion: Choosing a provider

by John May, RN, CRT



Navigating the healthcare system in today's environment can be a daunting task for most Americans. Add a complex chronic disease or illness such as myositis to the picture, and things can become quite complicated. If you've been told by your physician that you would benefit from IVIg infusion therapy in your home, choosing the right infusion company or specialty pharmacy can make a big difference in avoiding or dealing with much of the frustration.

Once the decision has been made that you will benefit from home IVIg therapy, your physician will likely suggest a few companies that provide the level and quality of care that he or she expects/demands for his or her patients. That said, it would be wise for the patient and family to obtain as much information about these recommended providers as possible. Every infusion provider has a website where you can learn more about the company and their services. Comparing different providers can help you understand some of the options available and can guide your decision-making process.

Once you've acquired information on two or three providers, it's time to look for the details that differentiate a good company from one that provides superior care for its patients. Don't be afraid to pick up the phone and call the contact number listed on the company's website. You will have many questions, and you'll need to talk with someone who can answer them fully.

One of the first questions to ask is whether the company specializes in IVIg therapy. If they do, they should have a team of benefit investigators, intake coordinators, pharmacists, patient advocates, and infusion nurses who are dedicated to providing only IVIg therapy. Problems happen and questions arise, and this usually doesn't happen between 9am and 5pm. So you'll also want to choose a provider that has professionals (pharmacists and registered nurses) available to help 24/7.

Ask up front about any special circumstances you may have in your life. If for example, you live in Massachusetts during the spring and summer, but spend the colder months in Florida, you'll want to choose a company that is able to accommodate these circumstances, one that can provide the drug and the nursing care in both states. Knowing this in advance will avoid any confusion or interruptions in treatment.

One of the most critical roles that an IVIg provider will play is as your advocate during the initial period of verifying insurance benefits and prior authorizations. At this stage it is very important that these advocates be experts in the reimbursement process, especially with IVIg. This is an expensive therapy, and insurance companies can make the approval process very challenging. In the event of a denial, you will want to choose a company that will be your advocate and fight for the fullest insurance coverage possible.

Sometimes, depending on your insurance company or insurance plan, all of the cost of IVIg may not be covered. In that case, it's important that the infusion provider you choose is aware of all of the drug manufacturer copay programs and is able to help you access these programs. For those covered by commercial insurance, these programs can save you thousands of dollars. (Unfortunately, patients who are covered by Medicare are prohibited by the federal government from participating in these co-pay assistance programs.)

In addition, for patients who have financial hardships, most IVIg infusion providers will have some sort of assistance program that will help the patient with managing these costs, if certain financial criteria are met. Companies cannot market these programs, so it is the responsibility of the patient to inquire about such programs. Be sure to ask about co-pay assistance and hardship assistance when speaking with providers initially; they will document this inquiry, which will be very helpful down the road.

In order to ensure that healthcare providers such as specialty infusion therapy companies meet certain criteria, standards, and quality outcomes, there are many accrediting agencies that provide the service. Some of the more recognizable accrediting agencies include the Joint Commission, Immunoglobulin National Society (IgNS), and URAC. Be sure to check the accreditation status of every provider you're considering. Most infusion companies will display accreditation information right on their website home page.

It's also helpful to network with fellow myositis patients about their experiences with IVIg therapy and various infusion companies. They can offer ideas and suggestions that you may never have thought of, which can be helpful as you make your decision.

Finally, we all know that the internet can be an extremely valuable tool. Like anything we read online, however, you must be careful about the accuracy of the information you find, especially when it comes to IVIg. If you have any questions regarding this therapy, please call your physician, pharmacist, specialty pharmacy, or nurse to be sure your information is correct.

John May, RN, CRT is a critical care nurse and respiratory therapist. For the past 24 years, he has worked in home care, infusion therapy, clinical management, and sales. He currently serves as a Territory Manager and Myositis Liaison for Soleo Health, a home infusion and specialty pharmacy service.

> *The TMA Community Forum is a secure, private platform where patients can exchange ideas with others in the myositis community about IVIg therapy and many other topics. You can find a link to the Forum under Community at* **www.myositis.org**. *In addition, if you have questions about IVIg therapy or need help accessing insurance benefits and co-pay assistance programs, TMA can put you in touch with someone who can help. Call 800-821-7356 or email* **tma@myositis.org**.

THE MYOSITIS ASSOCIATION

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