Winter/Spring 2024

THE Motivator

Published by the Multiple Sclerosis Association of America

A Closer Look at Diet and MS

A follow-up to MSAA's cover story, "The Importance of Diet and Nutrition in MS"

MULTIPLE SCLEROSIS ASSOCIATION OF AMERICA'S

10TH IMPROVING LIVES BENEFIT

MSAA is proud to announce our 10th Improving Lives Benefit at the BARNES FOUNDATION in PHILADELPHIA, PA. In addition, MSAA will be livestreaming the event, giving the MS community across the country the opportunity to view the event from the comfort of their homes!

WEDNESDAY, MAY 15, 2024

Mission Honoree:
Dr. Barry Hendin
MSAA's Chief Medical Officer

Corporate Honoree:
Antidote Technologies

antidote

Hosted by **Tyler Campbell**
MS Advocate and
Motivational Speaker

Presenting Sponsor

NOVARTIS

For more information or to purchase tickets, please visit

mymsaa.org/benefit

THE Motivator

Published by the Multiple Sclerosis Association of America

MSAA National Headquarters
375 Kings Highway North, Suite B
Cherry Hill, New Jersey 08034
(800) 532-7667
mymsaa.org

COVER STORY

DEPARTMENTS

msaa *Improving Lives Today!®*
Multiple Sclerosis Association of America

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

Innovative Research, Important Events, and Inspiring Programs

By Gina Ross Murdoch
MSAA President and CEO

In many of our "Up Front" columns, I talk about the specific details of our strategic planning – and the importance of implementing dynamic programs that follow these crucial directives. One of our newer initiatives is a perfect example of how our strategic plan guides us in developing programs aimed at Improving Lives Today for the entire MS community. Titled the "Multiple Sclerosis Implementation Network™" (MSIN™), this practice-based research network (PBRN) is a collaboration between MSAA and Novartis Pharmaceuticals Corporation.

Independent MSIN investigators will be conducting and interpreting the vital research for this initiative, which is designed to serve as a model for evidence-based care for individuals with MS. Through MSIN, participating healthcare professionals will share data and experiences, while also giving people with MS a prominent voice in evaluating the many options and treatment plans. Please see "Program Notes" on page 28 for more information on this urgently needed research.

In other news, one of our most exciting fundraisers is fast approaching. On Wednesday, May 15th, we will be holding our 10th Improving Lives Benefit at the Barnes Foundation in Philadelphia. This year's event will not only host attendees at the venue, but will also be available virtually through a livestream for everyone to attend from the comfort of one's home.

At our Improving Lives Benefit each year, we proudly recognize two honorees who have made a significant impact on the MS community. This year, we are thrilled to

Gina Ross Murdoch is a seasoned executive in non-profit management. Her career includes leadership positions with chapters of the Leukemia and Lymphoma Society as well as the American Diabetes Association. Earlier, she spent 14 years overseeing development activities at a large chapter of the National Multiple Sclerosis Society, leading explosive growth initiatives and ground-breaking strategic projects. An active member of the community, Ms. Murdoch has held several town positions and volunteers for her college alma mater, Drew University.

recognize our Mission Honoree, Dr. Barry Hendin, MSAA's Chief Medical Officer. Dr. Hendin is a highly accomplished neurologist who specializes in MS and plays an important role for our organization – guiding us on several vital program initiatives as well as reviewing all medical information that ultimately is provided to individuals with MS and their families.

In addition to our Mission Honoree, we will also be recognizing our Corporate Honoree, Antidote Technologies. This innovative, digital patient engagement company, provides online access to clinical trial information on a wide range of research in a user-friendly format. We greatly value our partnership with Antidote Technologies and applaud the contribution they have made to the MS community.

Anyone who has attended our Improving Lives Benefit in recent years will surely remember our enthusiastic and dynamic host, Tyler Campbell! We are excited to announce that Tyler, an MS advocate and motivational speaker, will once again be hosting this year's event. Whether attending in-person or virtually, Tyler's incredibly upbeat personality and life-changing inspirational messages will be a highlight of the evening for everyone to enjoy. For more information on our Improving Lives Benefit, please see our "Thoughts About Giving" column on page 31.

I am honored to have participated in January with members of Team MSAA once again for the Walt Disney World® Marathon Weekend Presented by State Farm and the Disneyland® Half Marathon Weekend. Our participation in these events helps to raise vital funds for MSAA's free programs and direct services. The highlight of this experience for me was, of course, spending time with members of the MS community and hearing their inspirational messages.

I am also very pleased to announce that this year's MS Awareness Month, with the theme of "Improving Lives Through Supportive Connections," was successful in providing much-needed resources and information to the MS community. If you missed any of the MS Awareness Month programs, you may access them at **mymsaa.org/awarenessmonth**.

Also in March, we launched our 2024-2025 Art Showcase on MSAA's website. This online art gallery features a vast collection of inspiring works of art created solely by individuals living with MS. For more information and to view this newest art collection, please visit **mymsaa.org/artshowcase2024**.

As a final note in this edition of "Up Front," I would like to highlight the importance of this issue's cover story, "A Closer Look at Diet and MS," a follow-up to MSAA's previous cover story, "The Importance of Diet and Nutrition in MS." This edition's cover story takes a more in-depth look at the components of popular diets and provides important details on studies that measure the impact of certain diets on MS. I hope our readers will find this information to be helpful. ■

For people living with relapsing multiple sclerosis (RMS)

briumvi®
ublituximab-xiiy 150 mg/6 mL injection for IV

1-HOUR INFUSION TWICE PER YEAR[a]

PROVEN TO REDUCE MS RELAPSES IN TWO CLINICAL STUDIES

STUDY 1

59% ▼

FEWER RELAPSES

with BRIUMVI compared to teriflunomide*

STUDY 2

49% ▼

FEWER RELAPSES

with BRIUMVI compared to teriflunomide*

"My doctor says I am doing really well on BRIUMVI, I haven't had any relapses or any new or enlarging lesions."

– Alex K. (clinical trial patient) has taken BRIUMVI since 2017

Individual results may vary.

See more study results at BRIUMVI.com/results

[a] Following the starting dose.
*teriflunomide is the active ingredient in AUBAGIO®. AUBAGIO® is a registered trademark of Sanofi or an affiliate.

INDICATION

BRIUMVI is a prescription medication used to treat adults with relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. It is not known if BRIUMVI is safe or effective in children.

IMPORTANT SAFETY INFORMATION

Who should not receive BRIUMVI?

Do not receive BRIUMVI if you have an active hepatitis B virus (HBV) infection.

Do not receive BRIUMVI if you have had a life-threatening allergic reaction to BRIUMVI. Tell your healthcare provider if you have had an allergic reaction to BRIUMVI or any of its ingredients in the past.

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

BRIUMVI can cause serious side effects, including:

- **Infusion reactions:** Infusion reactions are one of the most common side effects of BRIUMVI, which can be serious and may require you to be hospitalized. You will be monitored during your infusion and may be monitored after each infusion of BRIUMVI for signs and symptoms of an infusion reaction. Tell your healthcare provider if you get any of these symptoms:
  - fever
  - chills
  - headache
  - flu-like symptoms
  - fast heartbeat
  - hives
  - itchy skin
  - dizziness
  - feeling faint
  - swelling of tongue or throat
  - trouble breathing
  - wheezing
  - nausea
  - abdominal pain
  - throat irritation
  - redness of the face or skin

PLEASE SEE FULL PRESCRIBING INFORMATION AT WWW.BRIUMVI.COM AND ADDITIONAL IMPORTANT SAFETY INFORMATION ON THE FOLLOWING PAGE.

These infusion reactions can happen over 24 hours after your infusion. It is important that you call your healthcare provider right away if you get any of the signs or symptoms listed above after each infusion. If you get an infusion reaction, your healthcare provider may need to stop or slow down the rate of your infusion.

- **Infection:**
  - Infections are a common side effect, and upper respiratory tract infections are one of the most common side effects of BRIUMVI. BRIUMVI increases your risk of getting infections caused by bacteria or viruses that may be life-threatening or cause death. Tell your healthcare provider if you have an infection or have any of the following signs of infection including fever, chills, a cough that does not go away, or painful urination. Your healthcare provider should delay your treatment with BRIUMVI until your infection is gone.
  - Hepatitis B virus (HBV) reactivation: Before starting treatment with BRIUMVI, your healthcare provider will do blood tests to check for hepatitis B viral infection. If you have ever had hepatitis B virus infection, the hepatitis B virus may become active again during or after treatment with BRIUMVI. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure or death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop receiving BRIUMVI.
  - Weakened immune system: BRIUMVI taken before or after other medicines that weaken the immune system could increase your risk of getting infections.
  - Progressive Multifocal Leukoencephalopathy (PML): PML may happen with BRIUMVI. PML is a rare, serious brain infection caused by a virus that may get worse over days or weeks. PML can result in death or severe disability. Tell your healthcare provider right away if you have any new or worsening neurologic signs or symptoms. These symptoms may include weakness on one side of your body, loss of coordination in arms and legs, vision problems, changes in thinking and memory which may lead to confusion, and personality changes.
- **Low immunoglobulins:** BRIUMVI may cause a decrease in some types of antibodies. Your healthcare provider will do blood tests to check your blood immunoglobulin levels.

Before receiving BRIUMVI, tell your healthcare provider about all of your medical conditions, including if you:

- have or think you have an infection.
- take or plan to take medicines that affect your immune system. These medicines may increase your risk of getting an infection.
- have ever had hepatitis B or are a carrier of the hepatitis B virus.
- have had a recent vaccination or are scheduled to receive any vaccinations.
  - You should receive any required 'live' or 'live-attenuated' vaccines at least 4 weeks before you start treatment with BRIUMVI. You should not receive 'live' or 'live-attenuated' vaccines while you are being treated with BRIUMVI and until your healthcare provider tells you that your immune system is no longer weakened.
  - When possible, you should receive any 'non-live' vaccines at least 2 weeks before you start treatment with BRIUMVI. If you would like to receive any non-live vaccines while you are being treated with BRIUMVI, talk to your healthcare provider.
  - If you have a baby and you received BRIUMVI during your pregnancy, it is important to tell your baby's healthcare provider about receiving BRIUMVI so they can decide when your baby should be vaccinated.
- are pregnant, think that you might be pregnant, or plan to become pregnant. BRIUMVI may harm your unborn baby. You should use birth control (contraception) during treatment with BRIUMVI and for at least 6 months after your last infusion of BRIUMVI. Talk with your healthcare provider about what birth control method is right for you during this time.
- are breastfeeding or plan to breastfeed. It is not known if BRIUMVI passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take BRIUMVI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of BRIUMVI?

The most common side effects of BRIUMVI include:

- Infusion reactions, upper and lower respiratory tract infections, herpes infections, extremity pain, insomnia, and fatigue.

These are not all the possible side effects of BRIUMVI. Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**. You may also report side effects to TG Therapeutics at **1-877-TGTXINC (1-877-848-9462)**.

For more important information, go to **www.briumvi.com** or call **1-833-BRIUMVI (1-833-274-8684)**.

PLEASE SEE FULL PRESCRIBING INFORMATION AT WWW.BRIUMVI.COM

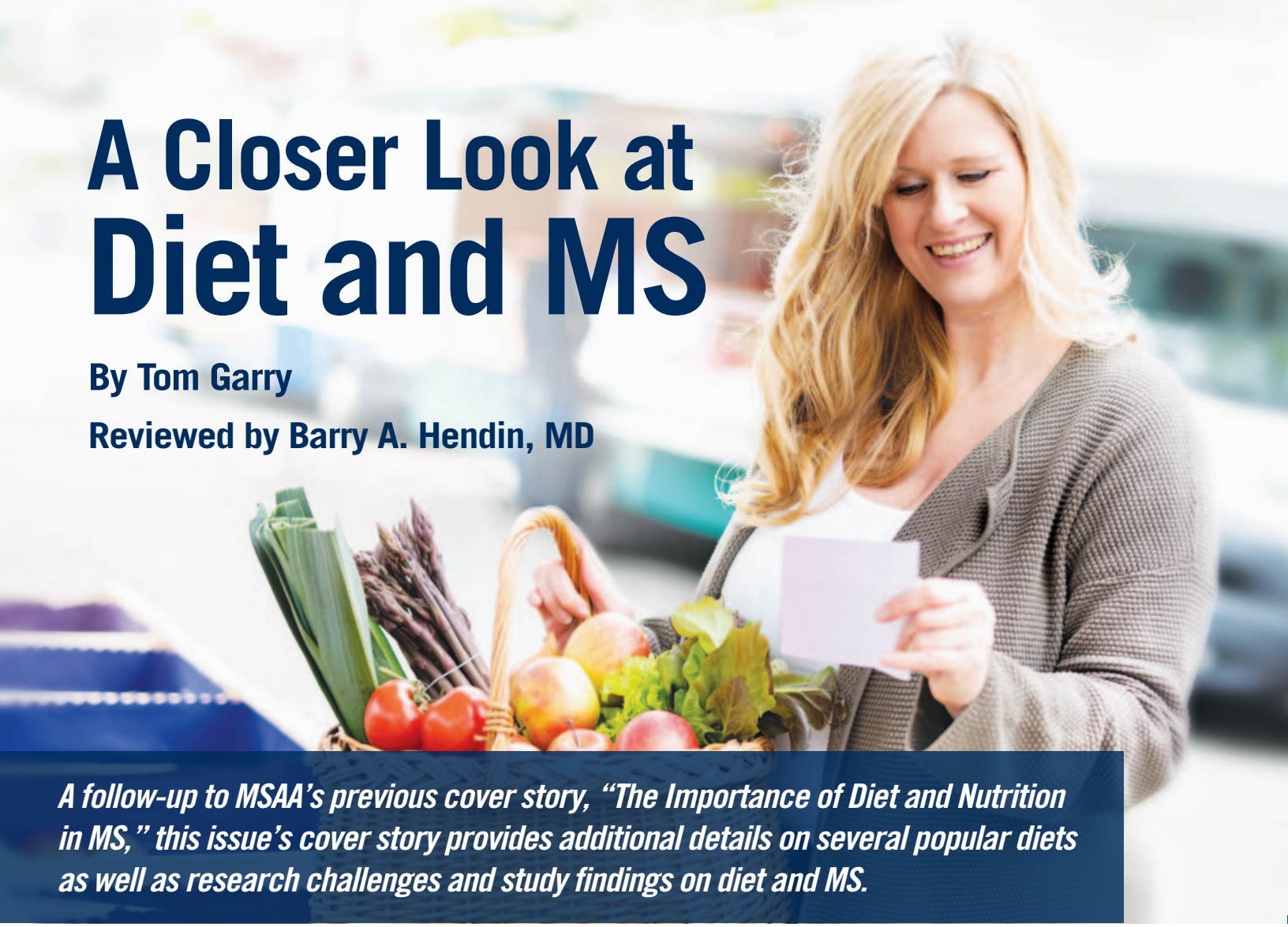
TG Therapeutics

briumvi®
ublituximab-xiiy 150 mg/6 mL injection for IV

A Closer Look at Diet and MS

By Tom Garry

Reviewed by Barry A. Hendin, MD



A follow-up to MSAA's previous cover story, "The Importance of Diet and Nutrition in MS," this issue's cover story provides additional details on several popular diets as well as research challenges and study findings on diet and MS.

In our last issue of *The Motivator*, our cover story focused on the importance of diet and nutrition in MS. Early research into the effects of diet on MS and dietary recommendations for good general health were featured. However, while a healthy diet rich in fruits and vegetables is recommended for individuals with MS, no specific diet has been proven to be effective for those with MS and more studies are needed. Please note that MSAA does not recommend or endorse any particular diet for the treatment of MS.

In this current cover story of *The Motivator*, we look more closely at the different types of diets that some believe could be of value to individuals with MS. We also examine the challenges of conducting research into diet and MS. Despite these challenges, several studies have been completed. Results from six of these trials are featured later in this article.

As noted in our previous issue, we caution readers not to make any changes to their diet without first consulting a medical professional. The information provided in this article should not be considered as medical advice. We recognize that individuals have their own specific requirements and preferences in terms of diet, and we hope that the details provided can be of assistance in customizing a diet that not only promotes good health for each individual, but will also provide enjoyment and a better quality of life.

PART ONE An Overview of Common Diet Plans

Advocates of various eating plans and researchers assessing those plans tend to agree on two things:

(1) Avoid processed foods as much as possible – these include meats that may be cured or smoked, canned foods and foods with colors or preservatives, as well as food and drinks containing highly refined ingredients with excess amounts of sugar, white flour, and/or salt.

(2) Eat plenty of fruits and vegetables – although some diet plans carry important caveats about which types of vegetables to eat; additionally, some individuals may need to limit the amount of natural sugar they take in through fruits.

When looking at different dietary options, experts say, it is valuable to talk with your MS clinician and/or primary care provider about how well a particular diet is suited to your overall health needs. It's also important to think about how easy or difficult a particular diet is to follow over the long term. And finally, beware of fads, extreme diets, and diets making claims that cannot be supported by study results.

You do not have to follow a specific diet in order to practice healthy eating. For those interested in adopting a diet, a number of common approaches are available. Please note that the diets to follow are not listed in any particular order.

VEGETARIAN OR VEGAN DIETS

Among the oldest dietary practices in the world, vegetarianism has been embraced by millions of people for ethical, religious, cultural, or health reasons, while vegan diets are somewhat newer and less widely adopted. Both diets have demonstrated their health benefits but can require a thoughtful approach to ensuring adequate intake of various nutrients.

Definitions vary, but as a general rule, vegetarians do not eat meat, poultry, game or fish, including shellfish, while vegans not only avoid those items, but also do not eat any other food products that come from animals, such as eggs, milk, and butter. Fruits and vegetables are a large part of these diets, which include soy, beans, and legumes.

MEDITERRANEAN DIET

This eating plan emphasizes plant-based foods, including vegetables, fruits, whole grains, beans and other legumes, nuts, herbs, and olive oil. Fish is also a key component. Small amounts of poultry, eggs and dairy are other sources of animal protein, while red meat is limited. Moderate consumption of wine with meals is allowed.

Interest in the Mediterranean diet grew after epidemiologists noted a lower incidence of chronic diseases, such as hypertension, diabetes, and coronary artery disease, in people in southern Italy, Greece, and other areas where people followed this approach to eating. Several studies have shown benefits in terms of cardiovascular health, and it has become a major focus of research into the impact of diet on MS.

DASH DIET

This eating plan was developed almost 30 years ago to help reduce high blood pressure (DASH stands for "Dietary Approaches to Stop Hypertension"). Like the Mediterranean diet, the DASH plan calls for people to center their diet on vegetables, fruits, whole grains, fish, poultry, beans, and nuts. It also entails reduced consumption of red meat, sodium, and foods and drinks with added sugars.

MIND DIET

This approach is the offspring of the union of the Mediterranean diet and the DASH diet: the Mediterranean-DASH diet Intervention for Neurodegenerative Delay, or "MIND" for short.

Developed in 2015 by researchers at Rush University Medical Center in Chicago and the Harvard TH Chan School of Public Health in Boston, this eating plan focuses on preserving the health of the aging brain. Because of the neurodegenerative component of MS, many have expressed interest in this diet, which emphasizes eating the vegetables, fruits, nuts, whole grains, and other items in its "parent" diets (the Mediterranean and DASH diets), while significantly limiting red meat, fried foods, sweets and pastries, and butter.

POLAR PRODUCTS

NEW COOLING KIT FOR THE MSAA COOLING PROGRAM!

COOL58® COOLING ACCESSORY KIT

Our accessories kit targets key cooling points with gentle 58° cooling packs. Accessories can be used separately as needed or all together for maximum cooling benefit.

KIT INCLUDES THE FOLLOWING COOLING PRODUCTS:

- **Cool58® Hat**: your choice of ball cap or bucket hat
- **Cool58® Deluxe Neck & Head Wrap**
- **Cool58® Performance Cooling Wrist Wraps**
- **Cool58® Bra, Under Arm & Groin Cooler:** two packs with covers, plus a complete extra set





ALSO AVAILABLE THROUGH THE MSAA COOLING PROGRAM:

CoolFit® Kit (Option B): Secrets Torso Wrap with Kool Max® Packs, Kool Max® Deluxe Neck Wrap, Pair of Kool Max® Ankle Wraps, Pair of Kool Max® Wrist Wraps, and an extra set of Kool Max® cooling packs for each product.

Kool Max® Zipper Front Vest Kit (Option C): Kool Max® Zipper Front Vest, Kool Max® Deluxe Neck Wrap, and an extra set of Kool Max® cooling packs for each product.

World-leading provider of MS cooling products for 40 years and proud supplier for the MSAA Cooling Program for 20 years.

polarproducts.com | 800.763.8423 | polar@polarproducts.com |

THE SWANK DIET

The first eating plan developed specifically for people with MS, this low-fat diet was developed by neurologist Roy Laver Swank, MD, PhD. The diet calls for avoiding processed foods containing saturated fats or hydrogenated oils, limiting saturated fats to 15 grams per day or less, and limiting unsaturated fats to 20 to 50 grams each day.

People are advised to not eat any red meats during their first year on the diet, and to consume only three ounces of red meat per week thereafter. Skinless white-meat poultry and white fish are permitted.

Dairy products generally are limited to those containing 1% or less of butterfat. People are encouraged to eat whole grain breads, rice, and pasta, and as many servings of fruits and vegetables as they wish. They also are encouraged to snack on nuts and seeds. In addition, this diet calls for people to take a multi-vitamin and mineral supplements daily, along with one teaspoon of cod liver oil or its equivalent in capsules.[1]

THE WAHLS PROTOCOL DIET

Developed by Terry Wahls, MD, who is a physician, medical researcher, and person living with MS, this approach emphasizes consumption of vegetables (particularly leafy greens), berries and other brightly colored fruits, meat and fish, and omega-3 fatty acids, plus other fat from animals and plants. People following this diet steer clear of sugar; dairy products and eggs; tomatoes, potatoes, and other "nightshade" vegetables; legumes, such as beans; and grains, such as wheat or rice.

Dr. Wahls reports that this diet dramatically improved her health and physical function.[2] The WAVES randomized parallel-arm clinical trial assessed the impact of the Wahls diet, as well as the Swank diet, on mood and mental health in people with MS. Please see, "Six Intriguing Studies on Diet and MS," starting on page 14, for a summary of the findings from this study.

The Wahls protocol is one form of a "paleo" diet. Short for paleolithic, the period of human development that lasted more than two million years until about 10,000 BC, the Paleo diet focused on foods that our distant ancestors ate before modern agricultural and food-processing practices predominated.

ANTI-INFLAMMATORY DIETS

Inflammation is a double-edged sword that the immune system can wield for good or ill. Under normal conditions, an inflammatory response is the body's way of protecting itself from infection, trauma, toxins, or other threats. In these circumstances, inflammation is beneficial and sometimes even lifesaving.

In other circumstances, however, the body mounts an inflammatory response when a threat is not present, or settles into a chronic state of low-level inflammation. Anti-inflammatory diets are designed to reduce inappropriate and potentially harmful inflammation. Like the Mediterranean and DASH diets, eating plans focused on reducing inflammation include abundant fruits and vegetables. Minimally refined, high-fiber whole grains, coffee and tea, herbs, and dark chocolate with a high percentage of cocoa solids are also components of these diets, which allow for moderate amounts of beer or wine.

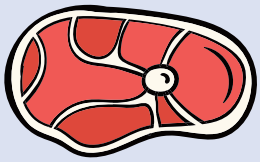
In addition, these diets place an emphasis on monounsaturated fats, such as those found in nuts, seeds, olive oil, and avocados, as well as polyunsaturated omega-3 fats, which are found in salmon, sardines, other fish, and walnuts. By contrast, anti-inflammatory eating plans call for little or no consumption of red meats, soda and other sweetened beverages, fried foods, bacon and other processed meats, and refined carbohydrates, such as pasta and white bread.

GLUTEN-FREE DIETS

Gluten is a protein found in some cereal grains, such as wheat, rye, and barley. Roughly 1% of the United States' population is estimated to have celiac disease, an autoimmune condition in which consuming foods with gluten can cause serious gastro-intestinal problems and, over time, significant systemic effects.[3]

While avoiding gluten is essential for people with celiac disease, many other people have become interested in adopting a gluten-free diet. This includes some people with MS, who note that both celiac disease and multiple sclerosis are autoimmune disorders and – as is the case with most autoimmune disorders – more common in women than men. However, as Ilana Katz Sand, MD, noted in our earlier cover story on diet and MS, research has not shown gluten to play a role in multiple sclerosis development or course, or to be detrimental to people with MS.

KETOGENIC "KETO" DIET

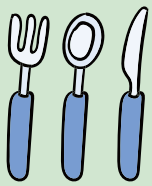


First developed almost 100 years ago in an attempt to reduce seizures in children with epilepsy, these low-carbohydrate, high-fat diets have been evaluated more recently for a role in managing conditions from cancer to Alzheimer's disease, as well as for weight loss. Carbohydrates provide the body with glucose, the primary energy source for cellular function. By significantly limiting carbohydrates, ketogenic diets prompt the liver to convert a back-up source of energy, ketones, from stored fats.

While there is no one "official" ketone (ketogenic) diet, many of these eating plans recommend deriving 70% to 80% of daily calories from high-fat sources such as red meat, processed meat, butter, and foods that contain unsaturated fats, including avocados, nuts, and oily fish. Keto diets typically limit carbohydrates to no more than 10% of caloric intake.

Like classic ketogenic diets, the Atkins diet was developed by cardiologist Robert C. Atkins in the 1960s and is based on low-carbohydrate intake. The South Beach diet, developed by cardiologist Arthur Agatson, MD, in 2003, distinguishes complex carbohydrates ("good carbs") in fruit, vegetables, whole grains, and beans, from the simple or "bad" carbs found in refined white flour, sugar, and baked goods.

INTERMITTENT FASTING AND CALORIC RESTRICTION



In these eating plans, the focus shifts from what you eat to when you eat (intermittent fasting) and to a very strong emphasis on how much you eat (caloric restriction). However, the intermittent fasting diet may cause some significant health risks.

According to a report from the American Heart Association (AHA) in March 2024, "A study of over 20,000 adults found that those who followed an 8-hour time-restricted eating schedule, a type of intermittent fasting, had a 91% higher risk of death from cardiovascular disease… Compared with a standard schedule of eating across 12-16 hours per day, limiting food intake to less than 8 hours per day was not associated with living longer."[4]

While caloric restriction was not included in this recent report, in January 2023, the AHA released this finding, "Eating less overall and fewer large meals may be a more effective weight management strategy than restricting meals to a narrow time window, such as intermittent fasting, according to a study that analyzed the electronic health records of about 550 adults who were followed for six years."[5]

CIONIC

Strong. Smart. **Mobile.**

CIONIC
Neural Sleeve

The first FDA-cleared bionic clothing to improve walking and strength.

Full-Leg Stimulation

4-muscle Functional Electrical Stimulation timed to your gait

Clinically Validated

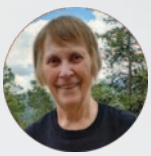
94% of participants experienced improved mobility

Personalized Care

Customize your experience and track progress in the CIONIC App

"In all those years and all that MS and physical therapy background,

this has been the #1 game changer for function."



– Patty
Retired physical therapist, living with MS

Check Eligibility ›

PART TWO Six Intriguing Studies on Diet and MS

The breadth, depth, and promise of current research into diet and MS are evident in several studies published or presented this year. As experts note, not all studies are created equal.

Prospective trials that follow people going forward are preferable to retrospective analyses. Randomized, placebo-controlled trials represent the gold standard for evaluating the impact of a diet, medication, or treatment strategy. And, as a rule, the larger the study and the longer it runs, the more reliable its findings.

With those caveats in mind, the following studies highlight the potential for diet to impact cognition, fatigue, mood, sleep, and many other aspects of MS, including risk for developing the disease.

Swank and Wahls Diets and Their Effects on Mood and Mental Health in People with MS

Developed by Roy Swank, MD, PhD, the Swank diet was perhaps the first eating plan designed specifically for people with MS. Among other things, it places an emphasis on fruits, vegetables, non-fat dairy products, and whole-grain cereals, while restricting saturated and unsaturated fats and oils.

More recently, Terry Wahls, MD, developed the Wahls Protocol, a variation on the Paleolithic diet that eliminates consumption of highly processed foods, grains, and dairy, in favor of meat, fish, and plant-based foods, such as fruits and nuts.

The WAVES randomized parallel-arm clinical trial previously showed that both diets were associated with a reduction in fatigue and improvement in quality of life in people with MS. A secondary analysis of that trial explored an association between these diets and depression as well as anxiety.

People with relapsing-remitting MS were observed on their regular diet and then randomly assigned to either the Swank diet or Wahls Protocol. People in both groups also received vitamin B9 and vitamin B12 supplements.[6]

After 12 weeks and then at 24 weeks, people following both the Swank arm of the trial and the Wahls arm had significant improvements from baseline on the Hamilton Anxiety and Depression Scale and the Mental Health Inventory, two validated measures of mood and mental health.

Three Reasons Why There Aren't More Large Trials of Diet in MS – and One Way You Can Help

Reason #1

Ilana Katz Sand, MD, says one of the main reasons for the lack of large, prospective studies is that "it's really, really hard to study human behavior." Dr. Katz Sand, an Associate Professor of Neurology at the Icahn School of Medicine at Mount Sinai in New York City, explains, "Healthy habits tend to 'hang together,' so that people who eat well often are also physically active and non-smokers. As a result, studies have to be thoughtfully designed to ensure that you're truly measuring the effects of diet, rather than the impact of another behavior or the cumulative effect of all those behaviors."

Further, she notes, when studying a medication, it is easy to "blind" the trial so that participants don't know whether they are receiving the medication or a placebo. "You obviously can't do that with food," she says, adding that dietary studies also are very dependent on participants being willing and able to accurately keep daily or weekly food diaries over several weeks or months.

Reason #2

Another challenge is securing adequate funding for large-scale research. Pharmaceutical companies invest millions of dollars in trials of their investigational medications in hopes of securing Food and Drug Administration (FDA) approval of those therapies and potentially recouping their investments. No single source has similar means or motives to fund dietary studies. Because of this, researchers often have to pursue funding from government agencies, such as the National Institutes of Health, and non-profit organizations.

Reason #3… and How You Can Help!

Finally, recruiting study participants can be difficult. The good news, however, is that this is one area where people with MS can make a real difference. The government-run website **clinicaltrials.gov** recently listed 17 studies on diet and MS that are recruiting participants. In addition, information on clinical trials and MS can be accessed through the easy-to-use Match clinical trials search tool offered by Antidote Technologies available on MSAA's website at **mymsaa.org/clinicaltrials**.

In Conclusion

Dr. Katz Sand says, "Many observational studies have shown an association between diet and various aspects of MS, but observational studies cannot establish a cause-and-effect relationship. That's why we need to do interventional studies where we randomize people at the start of the trial to one arm or another and follow them over time. With adequate numbers of people in those types of trials, we will be able to make recommendations based on solid, reliable evidence."

Intermittent Calorie Restriction and Cognition

A randomized clinical trial involving 42 people with relapsing-remitting MS found that study participants who practiced intermittent calorie restriction (iCR) saw a significant improvement in cognition over 12 weeks compared to those who did not follow any particular dietary plan.[7] Please note that iCR is different from "intermittent fasting," which has been found to carry cardiovascular risks.

Researchers randomized 22 people to iCR and 20 people to the control group. The study's primary outcome was the relative effect of calorie restriction on blood levels of leptin and adiponectin, two hormones released by adipose (fat) tissue. However, secondary endpoints included measures of cognition, including the Symbol Digit Modality Test, or SDMT.

Thirty-four of the 42 people who started the study completed the 12-week trial, including 17 people in the iCR group and 17 in the unrestricted diet group. In addition to seeing improvements in the hormone levels that were the main focus of the study, people who practiced intermittent calorie restriction showed greater gains on the SDMT over the study period than those eating an unrestricted diet.

Exploring the Impact of a Low-Fat Diet on Fatigue in MS

Twenty people with MS who followed a low-fat diet for 12 weeks had greater improvements on two measures of fatigue than did 19 other people with multiple sclerosis who kept to their regular diets during that period.[8]

This was the main finding from a recent two-arm, open-label, randomized controlled trial conducted by researchers from the Oregon Health & Science University and the VA Portland Health Care System. People in the low-fat diet group received one to two weeks of nutritional counseling at the start of the study and then strictly followed a low-fat diet for 12 weeks. Their adherence to that eating plan was monitored by a monthly food frequency questionnaire and 24-hour food recall.

At the end of the study, people in the low-fat diet group saw marked improvements in fatigue relative to the control group as measured by the Modified Fatigue Impact Scale and Fatigue Severity Scale. People in the low-fat group also had an average 11% reduction in calories from fat compared to the control group.

Investigators note that their findings, while encouraging, need to be followed up with trials involving more patients and running for a longer period of time.

Ketogenic Diet and Sleep in People with Relapsing MS

Sleep disturbances are common in MS, and can have a significant impact on quality of life. Based on studies showing an association between a ketogenic diet and improved sleep quality in people with epilepsy, a team of researchers decided to investigate whether there was an association between a modified Atkins ketogenic diet and better sleep in MS.[9]

Forty-five people with relapsing forms of MS enrolled in the study, agreeing to follow a modified Atkins plan for six months. The study participants' daytime sleepiness – a marker of poor sleep – was assessed at the start and end of the study with the Epworth Sleepiness Scale (ESS) and Sleep Disorders Symptom Checklist-25 (SDS-CL-25).

Thirty-nine of the 45 people completed the study, with full assessment data available on 36 study subjects. Those participants showed improvements in several areas, including reductions in the relative frequency of excessive daytime sleepiness, in their average insomnia score, and in their average obstructive sleep apnea score.

Mediterranean Diet Associated with Improved Cognition in MS

Ilana Katz Sand, MD, and colleagues from the Corinne Goldsmith Dickinson Center for MS at Mount Sinai and Johns Hopkins University examined the association between following a Mediterranean-style diet and cognition in 563 people with MS.[10] The study participants had an average age of 44.2 years. Seventy-one percent were women, and 108 had some degree of cognitive impairment.

The researchers found that higher scores on the Mediterranean diet Adherence Screener (MEDAS), a survey form that measures how closely people follow a Mediterranean-style diet, predicted a 20% lower risk for cognitive impairment compared to those with lower MEDAS scores. In fact, they noted, MEDAS was a better predictor of people's cognitive-performance scores than other health-related factors, such as body mass index, exercise level, and the presence of high blood pressure, high cholesterol, or diabetes.

Analysis of the results suggested that the cognitive benefits of following a Mediterranean-style diet were higher in people with progressive forms of MS than in those with relapsing disease.

continued on page 22

Indication

What is KESIMPTA (ofatumumab) injection?

KESIMPTA is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS) including clinically isolated syndrome (CIS), relapsing-remitting disease, and active secondary progressive disease.

It is not known if KESIMPTA is safe or effective in children.

Important Safety Information

Who should not take KESIMPTA?

Do NOT take KESIMPTA if you have active hepatitis B virus (HBV) infection.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

Important Safety Information (cont)

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

KESIMPTA can cause serious side effects such as:

- **Infections.** Serious infections, which can be life-threatening or cause death, can happen during treatment with KESIMPTA. If you have an active infection, your health care provider (HCP) should delay your treatment with KESIMPTA until your infection is gone. KESIMPTA taken before or after other medicines that weaken the immune system may increase your risk of getting infections. Tell your HCP right away if you have any infections or get any symptoms including painful and frequent urination, nasal congestion, runny nose, sore throat, fever, chills, cough, or body aches.
- **HBV reactivation.** If you have ever had HBV infection, it may become active again during or after treatment with KESIMPTA (reactivation). If this happens, it may cause serious liver problems including liver failure or death. Before starting KESIMPTA, your HCP will do a blood test to check for HBV. They will also continue to monitor you during and after treatment with KESIMPTA for HBV. Tell your HCP right away if you get worsening tiredness or yellowing of your skin or the white part of your eyes.
- **Progressive Multifocal Leukoencephalopathy (PML).** PML may happen with KESIMPTA. PML is a rare, serious brain infection caused by a virus that may get worse over days or weeks. PML can result in death or severe disability. Tell your HCP right away if you have any new or worsening neurologic signs or symptoms. These may include weakness on one side of your body, loss of coordination in arms and legs, vision problems, changes in thinking and memory, which may lead to confusion and personality changes.
- **Weakened immune system**. KESIMPTA taken before or after other medicines that weaken the immune system could increase your risk of getting infections.

Before you take KESIMPTA, tell your HCP about all your medical conditions, including if you:

- Have or think you have an infection including HBV or PML.
- Have ever taken, currently take, or plan to take medicines that affect your immune system. These medicines could increase your risk of getting an infection.
- Have had a recent vaccination or are scheduled to receive any vaccinations.
  - You should receive any required 'live' or 'live-attenuated' vaccines at least 4 weeks before you start treatment with KESIMPTA. You should not receive 'live' or 'live-attenuated' vaccines while you are being treated with KESIMPTA and until your HCP tells you that your immune system is no longer weakened.
  - Whenever possible, you should receive any 'non-live' vaccines at least 2 weeks before you start treatment with KESIMPTA.
  - Talk to your HCP about vaccinations for your baby if you used KESIMPTA during your pregnancy.
- Are pregnant, think that you might be pregnant, or plan to become pregnant. It is not known if KESIMPTA will harm your unborn baby. Females who can become pregnant should use birth control (contraception) during treatment with KESIMPTA and for 6 months after your last treatment. Talk with your HCP about what birth control method is right for you during this time.
- Are breastfeeding or plan to breastfeed. It is not known if KESIMPTA passes into your breast milk. Talk to your HCP about the best way to feed your baby if you take KESIMPTA.

Tell your HCP about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use KESIMPTA?
See the detailed Instructions for Use that comes with KESIMPTA for information about how to prepare and inject a dose of KESIMPTA and how to properly throw away (dispose of) used KESIMPTA Sensoready pens or prefilled syringes.

- Use KESIMPTA exactly as your HCP tells you to use it.
- Your HCP will show you how to prepare and inject KESIMPTA the right way before you use it for the first time.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with moles, scars, or stretch marks.

KESIMPTA may cause serious side effects including:

- **Injection-related reactions.** Injection-related reactions are a common side effect of KESIMPTA. Injecting KESIMPTA can cause injection-related reactions that can happen within 24 hours (1 day) following the first injections and with later injections. Talk with your HCP if you have any of these signs and symptoms:
  - **at or near the injection site**: redness of the skin, swelling, itching, and pain or
  - **that may happen when certain substances are released in your body**: fever, headache, pain in the muscles, chills, and tiredness.
- **Low immunoglobulins**. KESIMPTA may cause a decrease in some types of antibodies. Your HCP will do blood tests to check your blood immunoglobulin levels.

The most common side effects of KESIMPTA include:

- Upper respiratory tract infection, with symptoms such as sore throat and runny nose, and headache.
- Headache.

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 accompanying Consumer Brief Summary on the following page.

Consumer Brief Summary

The risk information provided here is not comprehensive. This information does not take the place of talking with your doctor about your medical condition or treatment.

To learn more about KESIMPTA (ofatumumab) injections, talk to your doctor or pharmacist. For more information and to obtain the FDA-approved product labeling, call 1-888-669-6682 or visit www.kesimpta.com.

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

KESIMPTA can cause serious side effects, including:

Infections. Serious infections, which can be life-threatening or cause death, can happen during treatment with KESIMPTA. If you have an active infection, your health care provider should delay your treatment with KESIMPTA until your infection is gone. KESIMPTA taken before or after other medicines that weaken the immune system may increase your risk of getting infections.

Tell your health care provider right away if you have any infections or get any symptoms including painful and frequent urination, nasal congestion, runny nose, sore throat, fever, chills, cough, or body aches.

- **Hepatitis B virus (HBV) reactivation.** Before starting treatment with KESIMPTA, your health care provider will do blood tests to check for HBV. If you have ever had HBV infection, the HBV may become active again during or after treatment with KESIMPTA. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems including liver failure or death. You should not receive KESIMPTA if you have active hepatitis B liver disease. Your health care provider will monitor you for HBV infection during and after you stop using KESIMPTA. Tell your health care provider right away if you get worsening tiredness or yellowing of your skin or white part of your eyes during treatment with KESIMPTA.
- **Progressive Multifocal Leukoencephalopathy (PML).** PML may happen with KESIMPTA. PML is a rare, serious brain infection caused by a virus that may get worse over days or weeks. PML can result in death or severe disability. Tell your health care provider right away if you have any new or worsening neurologic signs or symptoms. These may include weakness on one side of your body, loss of coordination in arms and legs, vision problems, changes in thinking and memory which may lead to confusion and personality changes.

Weakened immune system. KESIMPTA taken before or after other medicines that weaken the immune system could increase your risk of getting infections.

What is KESIMPTA?

KESIMPTA is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS) including:

- clinically isolated syndrome
- relapsing-remitting disease
- active secondary progressive disease

It is not known if KESIMPTA is safe or effective in children.

Do not use KESIMPTA if you:

- have active hepatitis B virus infection.

Before using KESIMPTA, tell your health care provider about all of your medical conditions, including if you:

- have or think you have an infection, including HBV or PML. See **"What is the most important information I should know about KESIMPTA?"**
- have ever taken, currently take, or plan to take medicines that affect your immune system. These medicines could increase your risk of getting an infection.
- have had a recent vaccination or are scheduled to receive any vaccinations.
  - **You should receive any required 'live' or 'live-attenuated' vaccines at least 4 weeks before you start treatment with KESIMPTA.** You **should not receive** 'live' or 'live-attenuated' vaccines while you are being treated with KESIMPTA and until your health care provider tells you that your immune system is no longer weakened.
  - **Whenever possible, you should receive any 'non-live' vaccines at least 2 weeks before you start treatment with KESIMPTA.**
  - Talk to your health care provider about vaccinations for your baby if you used KESIMPTA during your pregnancy.
- are pregnant, think that you might be pregnant, or plan to become pregnant. It is not known if KESIMPTA will harm your unborn baby. Females who can become pregnant should use birth control (contraception) during treatment with KESIMPTA and for 6 months after your last treatment. Talk with your health care provider about what birth control method is right for you during this time.
- are breastfeeding or plan to breastfeed. It is not known if KESIMPTA passes into your breast milk. Talk to your health care provider about the best way to feed your baby if you take KESIMPTA.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

Kesimpta®
(ofatumumab) 20 mg injection

How should I use KESIMPTA?

See the detailed Instructions for Use that comes with KESIMPTA for information about how to prepare and inject a dose of KESIMPTA and how to properly throw away (dispose of) used KESIMPTA Sensoready® pens or prefilled syringes.

- Use KESIMPTA exactly as your health care provider tells you to use it.
- KESIMPTA is given as an injection under your skin (subcutaneous injection), in your thigh or stomach-area (abdomen) by you or a caregiver. A caregiver may also give you an injection of KESIMPTA in your upper outer arm.
- Your health care provider will show you how to prepare and inject KESIMPTA the right way before you use it for the first time.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with moles, scars or stretch marks.
- The initial dosing is 20 mg of KESIMPTA given by subcutaneous injection at Weeks 0, 1, and 2. There is no injection at Week 3. Starting at Week 4 and then every month, the recommended dose is 20 mg of KESIMPTA administered by subcutaneous injection.

If you miss an injection of KESIMPTA at Week 0, 1, or 2, talk to your health care provider. If you miss a monthly injection, give it as soon as possible without waiting until the next scheduled dose. After that, give your KESIMPTA injections a month apart.

What are the possible side effects of KESIMPTA?

KESIMPTA may cause serious side effects, including:

See **"What is the most important information I should know about KESIMPTA?"**

- **Injection-related reactions.** Injection-related reactions is a common side effect of KESIMPTA. Injecting KESIMPTA can cause injection-related reactions that can happen within 24 hours (1 day) following the first injections and with later injections. Talk with your health care provider if you have any of these signs and symptoms:
  - o **at or near the injection site:** redness of the skin, swelling, itching and pain or
  - o **that may happen when certain substances are released in your body:** fever, headache, pain in the muscles, chills, and tiredness.
- **Low immunoglobulins.** KESIMPTA may cause a decrease in some types of antibodies. Your health care provider will do blood tests to check your blood immunoglobulin levels.

The most common side effects of KESIMPTA include:

- upper respiratory tract infection, with symptoms such as sore throat and runny nose, and headache. (See **"What is the most important information I should know about KESIMPTA?"**)
- headache

These are not all the possible side effects of KESIMPTA. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

How should I store KESIMPTA?

- Store KESIMPTA in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep KESIMPTA in the original carton until ready for use to protect from light.
- If needed, KESIMPTA may be stored for up to 7 days at room temperature, up to 86°F (30°C).
- Write the date taken out of the refrigerator in the space provided on the carton.
- If stored below 86°F (30°C), unused KESIMPTA may be returned to the refrigerator and must be used within the next 7 days. If this KESIMPTA is not used within those 7 days, then discard the medicine.
- Do not freeze KESIMPTA.
- Do not shake KESIMPTA.

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

General information about the safe and effective use of KESIMPTA.

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

You can ask your pharmacist or health care provider for information about KESIMPTA that is written for health professionals.

What are the ingredients in KESIMPTA?

Active ingredient: ofatumumab

Inactive ingredients: Sensoready pen and prefilled syringe: arginine, disodium edetate, polysorbate 80, sodium acetate trihydrate, sodium chloride, and Water for Injection. Hydrochloric acid may be added.

1/24 408080

Mediterranean Diet and Reduced Risk of Developing MS

Following a Mediterranean diet is associated with a roughly 40% reduction in risk of developing MS, according to a trio of researchers from the Karolinska Institute in Stockholm, Sweden.[11] The researchers arrived at their conclusion by examining the dietary habits of 1,953 people during the five years before those study subjects were diagnosed with multiple sclerosis. They also examined the diets of 3,557 people who served as a control group.

After adjusting for factors including ancestry, smoking, alcohol consumption, body mass index, physical activity, and sun-exposure habits, they found that a Mediterranean diet was associated with a 41% reduction in risk of MS relative to a traditional Western-style diet. That association remained significant even when excluding people who did not drink alcohol and those with a low degree of fish consumption. In addition, the researchers did not find a significant association between vegan/vegetarian or low glycemic index diets and reduced MS risk.

References

[1] Swank MS Foundation. The Swank Low-Fat Diet for the Treatment of MS. Available at http://www.swankmsdiet.org/the-diet. Accessed August 14, 2023.

[2] Wahls, T. My Story. Available at https://terrywahls.com/about/about-terry-wahls. Accessed March 2024

[3] Beyond Celiac. Celiac Disease: Fast Facts. Available at https://www.beyondceliac.org/celiac-disease/facts-and-figures/. Accessed August 16, 2023.

[4] American Heart Association, "8-hour time-restricted eating linked to a 91% higher risk of cardiovascular death," accessed at https://newsroom.heart.org/news/8-hour-time-restricted-eating-linked-to-a-91-higher-risk-of-cardiovascular-death. Press release dated March 18, 2024.

[5] American Heart Association, "Reducing total calories may be more effective for weight loss than intermittent fasting," accessed at https://newsroom.heart.org/news/reducing-total-calories-may-be-more-effective-for-weight-loss-than-intermittent-fasting. Press release dated January 18, 2023.

[6] Shemirani F, Titcomb TJ, Saxby SM, et al. Association of mood and mental health with changes in serum methylation markers in relapsing-remitting multiple sclerosis: secondary analysis of the WAVES Trial. Abstract PSY14. Consortium of Multiple Sclerosis Centers (CMSC) Annual Clinical Meeting 2023.

[7] Ghezzi L, Tosti V, Cantoni C, et al. Randomized clinical trial of intermittent calorie restriction in people with multiple sclerosis: effects on immunometabolic and cognitive measures. Abstract CE2.2. Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) 2023.

[8] Chase E, Lane MA, Srikanth P, et al. Randomized controlled trial of low-fat diet for fatigue in multiple sclerosis. Abstract DMX02. Consortium of Multiple Sclerosis Centers (CMSC) Annual Clinical Meeting 2023.

[9] Perlman J, Lehner-Gulotta D, Wetmore E, et al. Ketogenic diet intervention improves sleep in patients with relapsing multiple sclerosis. American Academy of Neurology 2023.

[10] Katz Sand I, Fitzgerald K, Sumowski J. Mediterranean Diet is associated with cognition in multiple sclerosis. American Academy of Neurology 2023.

[11] Alfredsson L, Olsson T, Hedstrom AK. Inverse association between Mediterranean diet and risk of multiple sclerosis. Abstract P185. Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) 2023.

In Summary

Identifying the diet plan that is best for you, and then working it into your daily life and following it over the long term, can be challenging. Fortunately, you do not have to "go it alone."

In fact, you should always talk with your primary care provider or neurologist before embarking on a new approach to your diet. In addition, for those with access to a registered dietitian or nutritionist, consulting one of these professionals along with your primary doctor and/or neurologist can provide you with a nutritional plan customized specifically for you.

We hope that our readers will find the details provided in this article to be informative and potentially spark interest in their own dietary regimen. For all communities, not just the MS community, eating in moderation and making informed food choices will result in a host of benefits to both short-term and long-term health outcomes. ■

Questions from Our Readers

By Dr. Barry Hendin
MSAA's Chief Medical Officer

Q: My MS is 24/7, and I experience problems with my legs, my hands, foot drop, balance, pain – you name it… every flare is always a bad flare. In looking at my paperwork from my doctor, it always says relapsing-remitting MS with "progressive features." I'm confused. Isn't this primary-progressive MS?

A: Unfortunately, too many people with MS experience problems "24/7." A lot of our attention as clinicians has been on disease-modifying therapies, which is vitally important, but this may result in our giving too little of our attention to day-to-day issues that affect quality of life.

Of course, there are wellness programs to improve quality of life and medications to address specific symptoms. An important element in fully addressing care for people with a heavy burden of disease should be a physiatry evaluation. A physiatrist can create a program that may include physical therapy, occupational therapy, or speech therapy to address specific problems of day-to-day function and well-being.

Feeling better today and protecting function for the future often involves a team rather than an individual. Depending on the circumstances, areas of treatment may also include pain management, psychiatry or psychology, and urology – in addition to seeing your neurologist.

The distinction between primary-progressive MS versus relapsing-remitting MS can be confusing. Relapsing-remitting MS generally begins with an acute event, such as a change in vision or sensation or motor function. Primary-progressive MS is usually more gradual in its onset. Relapsing forms of MS also have the hallmark feature of flare-ups – with periods of sudden and sometimes severe symptom worsening, followed later by a full or partial recovery. Progressive forms of MS can occasionally have a flare-up, but in general, progressive forms exhibit a slow but steady worsening of symptoms.

People with relapsing forms of MS may also experience progression. When the worsening is associated with an attack or relapse, we refer to it as relapse-associated worsening (RAW). When the progression is not associated with a relapse or acute inflammation, we refer to it as progression independent of relapse activity (PIRA). We are fortunate to now have a number of highly effective medications that reduce acute relapses, which in turn reduce

progressive disability caused by relapses, or RAW. Reducing progression independent of relapse activity, or PIRA, has been a more elusive problem. A great deal of research is being done at the present time to address this unmet need.

Q: What are the types of vision problems that can occur with MS and what is optic neuritis? How are these types of symptoms treated?

A: Vision problems are common in people with MS. The types of problems may relate to the optic nerve (optic neuritis) or to the control of eye movements (double vision and nystagmus).

Optic neuritis is one of the most common presenting symptoms of MS and it may occur in up to 50% of people with MS during their lifetime. The cause is inflammation and demyelination of the optic nerve. Symptoms vary but are often described as blurriness or a "spot in my vision."

Optic neuritis usually occurs in one eye but can occur in both. Often, but not always, optic neuritis can be associated with discomfort or pain with eye movement. The most common treatment is steroids, given over a three-to-five-day course. Once the inflammation has subsided, this usually results in a return to normal or near-normal vision.

MS can also cause abnormalities in the control of eye movements. If this affects an individual nerve or muscle, the result may be double vision. Alternatively, the problem with control of eye movement may cause an abnormal movement of the eye called nystagmus, and this can be associated with "jiggling" of the eye and a perception of movement or "jiggling" of the environment.

In some instances, double vision and nystagmus can occur simultaneously, producing a picture that we call intra-nuclear ophthalmoplegia. Acutely, these may also be treated with steroids, though these problems can sometimes resolve spontaneously over time. A referral to an ophthalmologist or neuro-ophthalmologist is sometimes needed for more specialized treatments, including special lenses to reduce double vision. ■

Please email questions for **Ask the Doctor** to **askdr@mymsaa.org**

Barry A. Hendin, MD, is a highly accomplished neurologist who specializes in MS. He is the chief medical officer for the Multiple Sclerosis Association of America (MSAA) and has spoken at several of MSAA's educational programs. After 45 years as a neurologist with Phoenix Neurological Associates, Ltd., Dr. Hendin is now director of the Arizona Integrated Neurology MS Center. He is also director of the Multiple Sclerosis Clinic at Banner University Medical Center and clinical professor of neurology at the University of Arizona Medical School.

Recent News and Study Updates in MS Research

By Susan Wells Courtney and Tom Garry

Reviewed by Dr. Barry A. Hendin
MSAA's Chief Medical Officer

Cell Therapy for Treatment-Resistant Progressive MS Receives FDA Fast Track Designation

In January 2024, the Food and Drug Administration (FDA) granted Fast Track designation to a cell therapy being evaluated for the treatment of refractory (treatment-resistant) progressive MS, among other disorders. The investigational medication, KYV-101, is a chimeric antigen receptor T-cell (CAR-T) therapy being developed by Kyverna Therapeutics.

CAR-T therapy is a sophisticated form of immunotherapy being used to treat many cancers and several autoimmune conditions. With these therapies, blood is taken from the patient so that their T cells, which are white blood cells that play a key role in the body's immune responses, can be isolated. A gene for a receptor – known as a chimeric antigen receptor, or CAR – is added to the T cells to enable them to attach to a specific cell antigen and thus better fight a particular condition. The treated T cells are then reintroduced to the patient through intravenous infusion.

KYV-101 is an autologous (meaning taken from the patient), fully human chimeric CAR-T therapy that targets CD19, a protein expressed on the surface of B cells. Like T cells, B cells are white blood cells that play a role in immune function. They have been implicated in the development of MS.

The FDA Fast Track designation was announced roughly two weeks after the FDA gave Kyverna Therapeutics clearance to evaluate KYV-101 in a Phase II trial that will enroll people with progressive forms of MS who are not responding satisfactorily to currently available treatments. Fast Track designation is an FDA program intended to facilitate and expedite the development and review of new drugs to address an unmet medical need in the treatment of a serious condition.

Ocrevus® Trial Exclusively Enrolling Black and Hispanic People Yields Encouraging Results

More than 94% of Black and Hispanic people with relapsing MS had no relapses during 48 weeks of treatment with the disease-modifying therapy (DMT) Ocrevus® (ocrelizumab), while no evidence of disease activity (NEDA) at Week 48 (the study's primary endpoint) was achieved by 46% of Black patients and 58% of Hispanic patients. These were the findings of the CHIMES study, the first clinical trial of a DMT

conducted exclusively in Black and Hispanic people with MS. CHIMES – which stands for characterization of ocrelizumab in minorities with multiple sclerosis – was a Phase IV trial, meaning that it was conducted following approval of the medication by the Food and Drug Administration (FDA).

The prospective, single-arm trial enrolled 182 Black or Hispanic people with relapsing MS who were 18 to 65 years old and who had an Expanded Disability Status Scale (EDSS) score of 0-5.5, indicating minimal to moderate MS disease burden. Researchers noted that the safety results of CHIMES were consistent with the findings of other trials of Ocrevus, with no new safety signals emerging.

"We are extremely excited about reporting data from CHIMES, the first Phase IV clinical trial focused on Black and Hispanic people living with MS," said Mitzi Joi Williams, MD, lead trial investigator, founding medical director at Joi Life Wellness MS Center in Atlanta, GA, and chairperson of MSAA's African American Advisory Board. Dr. Williams added, "We hope that the findings will not only improve the understanding of MS in minoritized groups, but also provide successful strategies to recruit and retain diverse populations in clinical trials on a larger scale."

Studies with Frexalimab Show Encouraging Results

Frexalimab is an investigational medication that takes a new approach to treating multiple sclerosis. This monoclonal antibody inhibits CD40L, a protein expressed by T-cells, which is a type of immune system cell that plays a role in MS. Frexalimab is thought to block T-cell interactions with two other types of immune system cells – B-cells and innate antigen presenting cells (APCs) – that also are involved in the MS disease process.

While T-cells express CD40L, B-cells and innate APCs express a similar protein, CD40. The CD40/CD40L costimulatory pathway regulates immune responses and has been implicated in both acute and chronic MS. Researchers say that frexalimab modulates T-cell and B-cell activation and innate immune cell function without depleting B-cells.

In the initial, 12-week portion of the Phase II study, participants with relapsing MS taking placebo and then switching to either a high or low dose of frexalimab, saw a significant decline of new gadolinium-enhancing T1 lesions after 12 weeks of treatment. In the open-label portion of the Phase II study, 96% of those taking a high dose of frexalimab developed no new gadolinium-enhancing lesions on Tesla 1 (T1) magnetic resonance imaging (MRI) over a 24-week period, and 91% had no new or enlarging lesions on Tesla 2 (T2) MRI. The results for those taking a lower dose were 80% and 74%, respectively.

These results are the first data to be generated by a Phase II trial of an anti-CD40L medication in multiple sclerosis. Researchers said that the findings support further investigation of frexalimab for the treatment of relapsing MS. ■

Collaborating to Create a Practice-Based Research Network

By Susan Wells Courtney

The Multiple Sclerosis Association of America (MSAA) and Novartis Pharmaceuticals Corporation have collaborated to develop the Multiple Sclerosis Implementation Network™ (MSIN™). This is an exciting and unique initiative to create a practice-based research network (PBRN) for medical professionals to best support individuals with MS.

MSIN is a patient-centric initiative, emphasizing the vital role of people living with MS and their involvement in this practice-based research network. MSIN will be guided by two advisory boards – one of which will be comprised of people living with MS and their care partners. The other advisory board will be comprised of healthcare professionals, research scientists, and advocacy partners.

According to MSAA's Chief Medical Officer Dr. Barry Hendin, learning what types of treatments and support work best for each patient will result in a better model of care and protocol for doctors across the country to follow. Dr. Hendin explains, "Certain health conditions have proven protocols for care. Hospitals and medical professionals have precise steps to follow when someone presents with symptoms of a certain condition, such as a stroke or heart attack. Evaluation and testing, immediate treatment, long-term therapies, symptom management, and lifestyle changes are well-established and result in a higher survival rate and better quality of life."

With MS, treatment protocols are not as firmly established. Highlighting the need for multidisciplinary MS Care Units, researchers in England published an article on the complexities of treating MS. They state, "Treatment of multiple sclerosis (MS) has become increasingly multifaceted and comprises not only a variety of disease-modifying drugs with different mechanism of action but also a wide range of symptomatic therapies. Today, it is not possible for the family physician or even many general neurologists to master the current treatment algorithm [precise instructions for treatment]."[1]

As a leading resource for the MS community, MSAA accomplishes our mission of improving lives today through vital services and support. Recognizing the need to have research inform MS practice, MSAA has embarked on this very exciting research program to improve patient outcomes and help ensure that patients are receiving the best MS care regardless of where they live.

MSAA is excited to announce the appointment of two principal investigators: **María E. Fernández, PhD** and **Leorah Freeman, MD, PhD.**

Dr. Fernández is Vice President of Population Health and Implementation Science at the University of Texas Health Science Center at UTHealth Houston and the founding Co-Director of their Institute for Implementation Science. Dr. Fernández is also the Lorne Bain Chair of Public Health and Medicine, Professor of Health Promotion and Behavioral Sciences, and Director of the UTHealth Houston Center for Health Promotion and Prevention Research (CHPPR).

Dr. Freeman is a neurologist who specializes in multiple sclerosis, neuromyelitis optica, and other neuroinflammatory conditions. At Dell Medical School at The University of Texas at Austin, she serves as Medical Director of the Multiple Sclerosis and Neuroimmunology Center and Fellowship Program Director. She also leads the Multiple Sclerosis Imaging and Outcomes Research Laboratory. Additionally, Dr. Freeman serves on MSAA's national Healthcare Advisory Council.

MSIN will serve as a model of innovation, improvement, and implementation of evidence-based care and best practices that connect participating healthcare professionals, spanning from MS comprehensive care centers to community-based neurologists. In sharing data and experiences, this PBRN enables participating centers to learn from each other while contributing to research to improve the quality of care and health outcomes for people with multiple sclerosis.

At the Annual Patient Engagement Open Forum (PEOF) Conference in Baveno, Italy, with more than 140 nominations from four continents, MSIN won the award as "Best Engagement Model" for a research initiative, based on its model of patient centricity.

MSAA is also pleased to partner with SEQSTER, a leading healthcare technology company, on this important initiative. SEQSTER is a pioneer in patient-centric healthcare data technology and patient management, specializing in patient enrollment, data collection, retention, and consent.

Together, the MSIN collaboration aims to: develop a research-driven data environment; use improvement and implementation approaches to improve care, experience, and outcomes; advocate for therapies and health interventions for all people living with MS, regardless of practice setting or location, helping to eliminate disparities; support the MS care workforce; and achieve optimal health outcomes for the entire MS community. To learn more about the Multiple Sclerosis Implementation Network, please visit **MSINresearch.org**. ■

1. Soelberg Sorensen P, Giovannoni G, Montalban X, Thalheim C, Zaratin P, Comi G. The Multiple Sclerosis Care Unit. *Mult Scler.* 2019 Apr;25(5):627-636. doi: 10.1177/1352458518807082. Epub 2018 Oct 23. PMID: 30351211; PMCID: PMC6439947.

Become an MSAA **Monthly Improver!**

MSAA Monthly Improvers are a generous group of donors making recurring, monthly gifts to improve the lives of people with MS.

Recurring donations make it easy for you to support MSAA's free programs and services – while also providing MSAA with a reliable stream of revenue each month.

Questions?
Contact Donor Relations at
(800) 532-7667, ext. 172, or
MonthlyGiving@mymsaa.org

SIGN UP TODAY!
engage.mymsaa.org/improver

$10/month ($120/yr)
quad canes for three individuals with MS

$15/month ($180/yr)
wide-grip utensil sets for eight individuals with MS

$25/month ($300/yr)
cooling vests for two individuals with MS

$65/month ($780/yr)
an MRI exam for an individual with MS

msaa *Improving Lives Today!®*
Multiple Sclerosis Association of America

The opportunities are endless!
Get involved with MSAA and create a DIY fundraiser around any occasion to benefit MSAA's free programs and services.

CREATE YOUR FUNDRAISER TODAY!
Learn more at **mymsaa.org/DIY**

MSAA's Improving Lives Benefit Recognizes Two Very Special Honorees

By Susan Wells Courtney

We are all greatly looking forward to Wednesday, May 15th, when MSAA's 10th Improving Lives Benefit will take place at the Barnes Foundation in Philadelphia and will be livestreamed, virtually connecting people across the country from the comfort of their homes. This vitally important event is not only inspirational, but also provides an opportunity to raise funds for MSAA's urgently needed programs and services, as well as to recognize two wonderful honorees for their critically important contributions to the MS community.

Each year, this event creates much excitement among the attendees as they learn about the impact of MSAA's programs and have an opportunity to hear encouraging messages from members of the MS community. Another exciting highlight of the evening is when we pay tribute to both our Mission Honoree and our Corporate Honoree. This year's very special and highly acclaimed Mission Honoree is Dr. Barry Hendin, MSAA's Chief Medical Officer, and our distinguished Corporate Honoree is Antidote Technologies, a digital patient engagement company. More details are provided on each of these esteemed honorees later in this column.

As mentioned earlier, MSAA will be livestreaming the Improving Lives Benefit, allowing everyone – regardless of location and circumstance – the opportunity to share in this uplifting and motivating experience. And whether you are attending in person or watching from the comfort and convenience of your own home… everyone will enjoy our amazing host, Tyler Campbell. An MS advocate and motivational speaker, Tyler is extremely passionate and has served as host of our Improving Lives Benefit for the past few years. His dynamic personality and profound personal experience as a person living with MS is sure to keep everyone inspired throughout the event. ■

Please visit MyMSAA.org/benefit for more details including: purchasing tickets, sponsorship information, and registering for the livestream.

Special Thanks to the Following Sponsors for MSAA's Improving Lives Benefit:

Presenting Sponsor:	**Novartis**
Silver Sponsors:	**EMD Serono ▪ Sandoz**
Corporate Partner Sponsors:	**Genentech ▪ TG Therapeutics Polar Products ▪ Viatris**

MSAA's Improving Lives Benefit 2024 Mission Honoree

This year's **Mission Honoree is Barry A. Hendin, MD, MSAA's Chief Medical Officer.**

At MSAA, we have been extremely fortunate to have such a highly accomplished neurologist and MS specialist serving as our Chief Medical Officer. Dr. Barry Hendin has been working with MSAA for many years, presenting and speaking at educational programs, and in June of 2019, he became MSAA's Chief Medical Officer. Dr. Hendin has continued to make tremendous contributions to MSAA's mission of Improving Lives Today.

As MSAA's Chief Medical Officer, Dr. Hendin provides valuable guidance on numerous initiatives and performs expert review of all medical information provided by MSAA to the MS community – often encompassing late-breaking news and intricate clinical trial findings. He has been a featured speaker for several of MSAA's informative webinars. Dr. Hendin has also played a major role in several vital initiatives, from MSAA's webinar series, "What You Need to Know About COVID-19 and MS," along with Dr. Carrie Hersh, to the development of MSAA's innovative digital tool, the Ultimate MS Treatment Guide. We are grateful for Dr. Hendin's decades of experience in the field of multiple sclerosis and greatly value his unwavering commitment to the care of individuals with MS.

In addition to his work at MSAA, Dr. Hendin currently serves as director of the Arizona Integrated Neurology MS Center, director of the Multiple Sclerosis Clinic at Banner University Medical Center, and clinical professor of neurology at the University of Arizona Medical School. He was previously a neurologist with Phoenix Neurological Associates, Ltd. for 45 years.

Dr. Hendin has been a great asset to MSAA and his list of achievements is extensive. To date, he has had more than 15 clinical appointments to various medical facilities, seven academic appointments, and served on nearly 30 councils, committees, board of directors, and a task force. In addition to his many honors and awards, Dr. Hendin has co-authored more than 30 medical articles and has been the principal investigator for more than 115 clinical trials.

Dr. Barry Hendin shared, "I am greatly honored to be recognized as MSAA's Mission Honoree for this year's Improving Lives Benefit. Receiving this award is a true compliment, and I am as humbled as I am grateful. I have been as enriched by the experience of working with MSAA, as I have been a contributor. My goal and the goal of MSAA remains the same: to improve the lives of people living with multiple sclerosis."

Above all is Dr. Hendin's unrelenting compassion to those in need and his enthusiasm to assist with any initiative that is of benefit to the MS community. We are

extremely appreciative of all of Dr. Hendin's work and admire his positive approach to the care of individuals affected by MS. It is with great pleasure that we recognize Dr. Hendin as our Mission Honoree at this year's Improving Lives Benefit. ■

MSAA's Improving Lives Benefit 2024 Corporate Honoree

Our **Corporate Honoree is Antidote Technologies**, a digital patient engagement company that offers online access to clinical trial information. For individuals looking to participate in the development of new treatments, Antidote provides the vital service of connecting patients to the appropriate clinical trials through an innovative and easy-to-use online resource.

MSAA first announced our partnership with Antidote Technologies in 2017, with the goals of increasing awareness of MS clinical trials and providing people with easy access to this important information. Through this partnership, we added the Antidote Match clinical trial search tool to our website, which can be accessed at **mymsaa.org/clinicaltrials**, allowing visitors to find trials that are right for them or their loved ones in minutes, just by answering a few questions.

According to Antidote, 80% of trials are delayed or closed due to the difficulty in finding patients to participate. This means that research is taking far longer than it should, while patients and care partners continue to wait for answers. Antidote strives to speed up the process through precision recruitment to help fill clinical trials faster, in conjunction with their Match tool developed to make the process of finding trials easier for patients.

Antidote also provides a number of resources on its website, including answers to frequently asked questions, educational webinars, detailed information on the different types and phases of clinical trials, questions to ask researchers, and patient stories.

We are grateful to have partnered with Antidote for the past several years in offering clinical trial information to the MS community and are thrilled to be able to continue this partnership. The resources Antidote provides are critical for the development of new treatments for MS and to evaluate the safety and effectiveness of current ones. We are extremely proud to partner with Antidote Technologies and to recognize them as this year's Improving Lives Benefit Corporate Honoree.

"Antidote is thrilled to be recognized as the 2024 Corporate Honoree at the MSAA Improving Lives Benefit," said Samantha Veeck, Antidote's co-CEO. "Over the past seven years, Antidote and MSAA have worked in partnership to connect the MS community with clinical trial opportunities and further our joint mission of advancing medical research. We are grateful for this opportunity and hopeful about what's next in the exciting multiple sclerosis research space." ■

Fluffy Ball of Cuteness: My Therapy Dog, Francesca

By Bob Becker

"That's not a dog, that's a fluffy ball of cuteness!" This perfect description of our Norwich terrier, Francesca, was uttered by a neighborhood boy as he and his family bicycled past my wife, Lesa, walking Francesca one day. Francesca attracts her fair share of attention, but she is more than just a pretty face.

To back up, in 1998, life was good. I worked as legal counsel for a corporation in Idaho, was married to a wonderful woman, and had two handsome young sons, Sam and Joe. It was April, and we had just returned from a fun-filled vacation to Disneyland. One morning, while I was showering, I noticed that I had numbness in my feet and parts of my chest. A few days later, I started experiencing pain in my feet.

I later received the multiple sclerosis diagnosis. I felt as though life was over for me. I became very sick, very quickly, and went on medical leave from work. I developed unrelenting burning pain in my feet, fatigue, balance and bladder problems, and a bout of optic neuritis that blinded me in one eye for six weeks. I began injections of one of only three medications then-approved for slowing down the progression of MS.

I was finally able to resume working, but had several relapses that resulted in a worsening of my MS. I went from being able to hike, backpack, ski, and undertake many home improvement projects, to being able to… just exist. None of the medications prescribed for my neuropathic pain was effective. So, I just had to bear it.

To help me cope, we got a Yorkie puppy that we named Buddy. Buddy was the sweetest little guy, not a mean bone in his body. For over 14 years, he provided me with love and affection when I needed it most.

In 2009, my MS-related disabilities became so overwhelming that I had to retire from my job. Buddy continued to provide me with solace until his passing in 2013. After Buddy passed, we traveled frequently, but we were not then ready for the challenges of getting another dog.

In October of 2019, we scaled back on our travel, as I was dealing with progressively more serious health issues related to my MS. Then, in March 2020, when the COVID-19 pandemic first hit, I suffered a heart attack and pulmonary embolism. I was hospitalized and underwent two invasive medical procedures. I came close to dying. After numerous other health issues and many tests, I was diagnosed with idiopathic peripheral neuropathy on top of my MS, causing several additional health problems. Overwhelmed, I felt hopeless.

Because of my mounting medical conditions, we decided to purchase a condo in Boise, Idaho, as a convenient place to stay for all my doctor appointments and medical needs. Our realtor friend invited us over to her home where we were greeted by her Norwich terrier, Teddy. He made a strong impression, showering us with gentle affection. We had never heard of a Norwich terrier, but decided that this breed would be a perfect fit for my wife and me.

Although we had to wait about a year, we were finally able to pick up our 2-lb. 10-oz. bundle of canine joy. We named her Francesca and immediately fell in love. On the way home, Francesca never looked back, settling into my lap as if she had been a member of our family forever.

Francesca is beautiful and very effusive. She is also hilarious, curious, quirky, attention-seeking, and endlessly charming. From her weird noises to her stout little legs – hopping around like a rabbit – she wins the heart of anyone around her.

Since I am unable to walk very far, I ride my motorized scooter on walks with Francesca and Lesa. As we encounter other people, Francesca strains on her leash to go up to them for some affection. No one can resist her.

The primary reason we got Francesca was to be my therapy dog. We have a morning and evening routine of mutual affection. When I am having a rough time, she somehow senses it. She will come up to me and lie down by my feet, ask to sit on my lap, or give me kisses on the neck. When she is up to her hat full of antics, my physical and mental burdens are relieved more effectively than from any medicine.

Bob Becker enjoys the companionship provided by his entertaining and charming therapy dog, Francesca.

I cannot imagine how I would cope with my health challenges if I did not have Francesca by my side. While I pray that someday my suffering will be lifted, for now, I take immense comfort in my wife Lesa's loving support and the unconditional love I receive from Francesca, my precious "fluffy ball of cuteness." ■

MSAA's Ultimate MS Treatment Guide

Make an Informed Choice That's Right For You!

This unique online tool helps individuals with MS and their care partners make an informed choice on treatment in conjunction with their physician:

- **Compare FDA-approved MS treatments and filter results**
- **View videos of experts and advocates discussing treatment information and their experiences**
- **Learn about treatment philosophy**

Find out more at MStreatmentguide.org

Connect with others and find support on

My MSAA Community

msaa *Improving Lives Today!®*
Multiple Sclerosis Association of America

Join more than 8,900 members who have similar experiences with multiple sclerosis in this online peer-to-peer forum.

- Get advice and support while connecting directly with people affected by MS
- Feel more confident managing one's own health or family's health
- Solve day-to-day challenges

Join My MSAA Community today:
healthunlocked.com/msaa

Do I feel confident discussing my MS management with my doctor?

An expert steering committee advised that people living with MS and care partners have a need for resources to help identify priorities and prepare for MS management discussions with their healthcare team.

My MS Workbook and My MS Checklist are free resources co-created by MSAA and Novartis in collaboration with the MS community to help meet this need.

Scan the QR code to access the My MS Workbook and My MS Checklist.

msaa Improving Lives Today!™
Multiple Sclerosis Association of America

NOVARTIS | Reimagining Medicine

2/24 407640

msaa Improving Lives Today!®
Multiple Sclerosis Association of America

Multiple Sclerosis Association of America
375 Kings Highway North, Suite B
Cherry Hill, NJ 08034 USA

CHANGE SERVICE REQUESTED

MSAA is very proud to present our 2024-2025

ART SHOWCASE

Each year, MSAA features the work of artists living with MS in the annual MSAA Art Showcase, highlighting one artist each month as our Artist of the Month.

We received many wonderful submissions from more than 70 artists across the country and are delighted to share their work and inspiring stories!

View the complete gallery at **mymsaa.org/artshowcase2024**