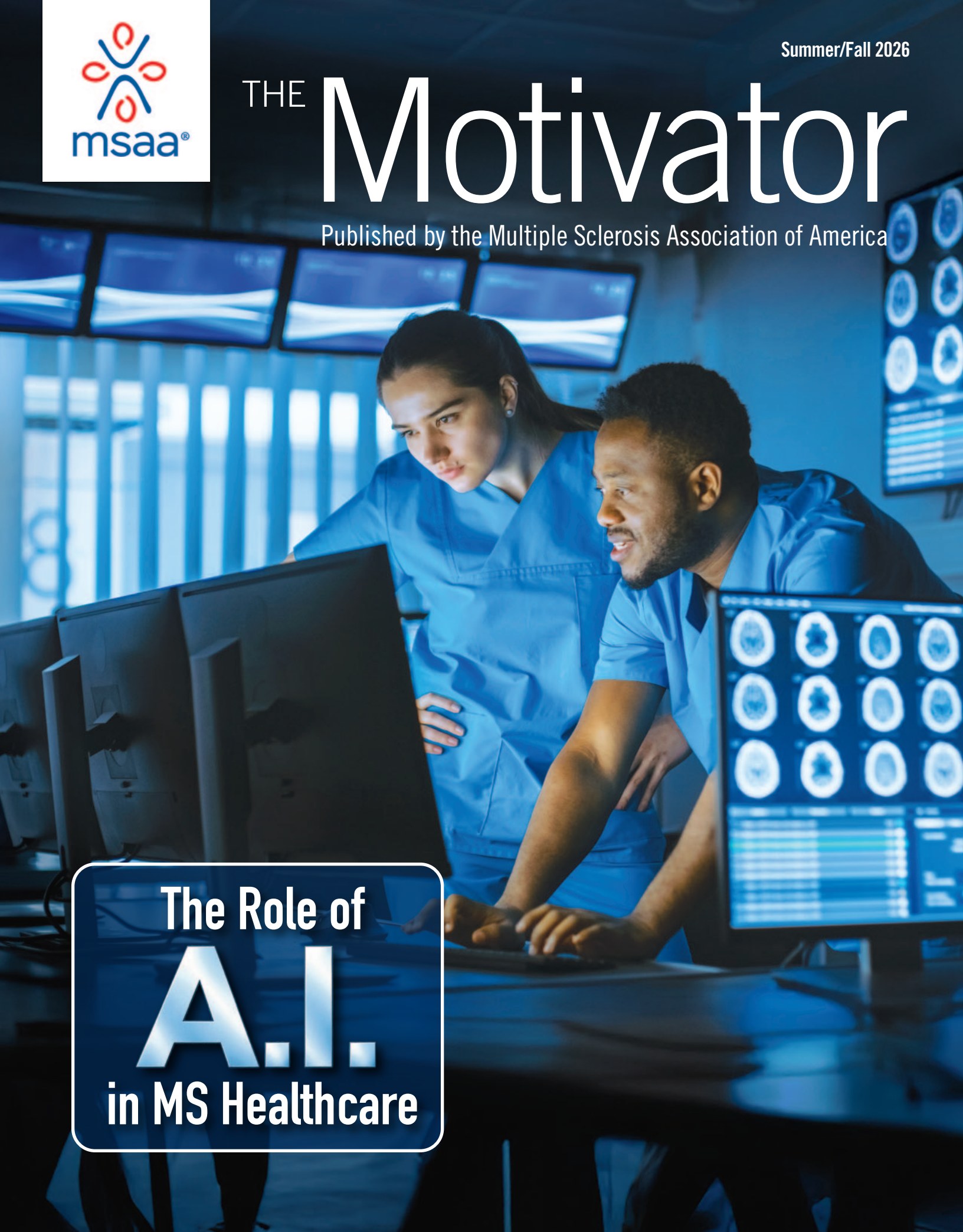
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THE Motivator

Published by the Multiple Sclerosis Association of America



The Role of A.I. in MS Healthcare

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VP of Communications & Marketing
Susan Wells Courtney
Senior Writer & Creative Director
Barry A. Hendin, MD, Chief Medical Officer
John Masino, Advertising Manager
Senior Director of Digital Communications

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

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The Multiple Sclerosis Association of America is the leading resource for the MS community, improving lives today by delivering vital services and compassionate support, while advancing access, research, and innovation to strengthen the MS community for tomorrow.

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Improving Lives, Creating Impact

By Amanda Montague, EdM
MSAA President and CEO

Every person who connects with MSAA becomes part of a community united by the belief that no one should face multiple sclerosis alone.

Some members of the MSAA family come to us seeking information after a new diagnosis. Others need help obtaining an MRI, cooling products, or guidance from a compassionate Helpline specialist. Some participate in our educational programs or have joined the Multiple Sclerosis Implementation Network® (MSIN®). Others volunteer, share our resources, tell their stories, or make a financial contribution so that someone they may never meet can receive the help they need. However you found your way to MSAA, you are part of our mission and we are so grateful that you are here.

As we approach the end of the year, I especially want to thank those who have supported MSAA financially. Whether you made your first gift this year, have given for many years, or contributed at a time when you were able, please know that your generosity has mattered. It matters deeply to MSAA, but even more importantly, it matters to the people and families we serve.

In this issue of *The Motivator*, you will see examples of what our extended MSAA family is making possible. We are deeply grateful for the generosity of the Veyl family, whose support is helping us launch the next phase of our MRI Access Program, which will incorporate advanced AI MRI technology, providing participating individuals and their healthcare professionals with more detailed information from their MRI scans. Our pilot program with Claimable will explore a new way to help people navigate access challenges. And the Multiple Sclerosis Implementation Network®, or MSIN®, is reaching an important milestone with its first study involving Octave's MSDA biomarker test.

Also in this issue, our cover story takes a closer look at artificial intelligence (AI) and its growing role in MS healthcare. AI may create new opportunities to improve diagnosis, personalize care, and accelerate research, but it also raises important questions about privacy, bias, equity, and access. MSAA has an essential role to play in these conversations, helping ensure that innovation is guided by the voices and experiences of people affected by MS.

You will also meet MSAA Board Members Terrie and Kevin in our Thoughts About Giving column. Terrie and Kevin are both

extraordinary people who happen to be living with MS. Their stories reflect the personal reasons people choose to support MSAA and demonstrate how individual acts of generosity can become a powerful collective force.

If you have supported MSAA in the past, thank you. You have helped make MSAA a trusted source of help and hope, and we never take your generosity for granted. If you are considering a year-end gift, I hope you will choose to invest in our mission again. Every gift, at every level, strengthens our ability to improve lives today while creating greater possibilities for tomorrow.

And if this is your first introduction to MSAA, I warmly invite you to join us. There is a place for you in this family: as a donor, advocate, volunteer, partner, or friend. Together, we can ensure that everyone affected by MS feels supported, empowered, and never alone. ■



MSAA Webinars and Videos

MSAA offers a variety of educational webinars and videos covering a wide range of vital topics. Several are also available in Spanish.
Please visit **mymsaa.org/videos** to learn more.

Amanda Montague, EdM is the President & CEO for the Multiple Sclerosis Association of America (MSAA). Ms. Montague has been a dedicated member of MSAA's senior management team and a vital part of MSAA for more than 20 years. In her previous role as Chief Mission Officer at MSAA, Ms. Montague led all programmatic and educational initiatives, as well as partnerships with stakeholders and relationships with the MS healthcare professional community. In addition to her work at MSAA, Ms. Montague also serves as a Stakeholder Reviewer for the Patient Centered Outcomes Research Institute (PCORI) in Washington, DC, has served as a member of the American Academy of Neurology's (AAN) MS Quality Measure Review Panel, and has published and presented research in major journals and at national and international conferences.

Amanda has a BA in Economics from Smith College, an EdM in Risk & Prevention from Harvard Graduate School of Education, and an MA in International Patient Advocacy Management from Catholic University of the Sacred Heart in Rome, Italy.

The Role of A.I. in MS Healthcare



By Tom Garry
Edited by Susan Wells Courtney
Reviewed by Barry A. Hendin, MD

Introduction

Each day brings new reports on the promise and perils of artificial intelligence (AI) – milestones achieved, concerns uncovered, rosy predictions, and apocalyptic warnings.

While elected officials, tech moguls, and media commentators wrestle with the broad implications of AI, from the economic to the existential, multiple sclerosis researchers are pursuing more-focused questions, examining whether artificial intelligence can:

- identify people likely to develop MS years before their first demyelinating event
- improve the speed and accuracy of diagnosis
- better predict the course of each person's MS and how each will respond to specific disease-modifying therapies (DMTs)
- enhance how people with MS move and communicate
- speed the development of new therapies

It's what Michael G. Dwyer, PhD, calls "narrow AI." A neuroimaging specialist, Dr. Dwyer uses that term to distinguish how the work that he and other MS researchers are doing, differs from the endeavors, often the subject of debate, of companies like OpenAI and Anthropic.

Dr. Dwyer serves as director of the Neuroinformatics Development Lab at the Buffalo Neuroimaging Analysis Center of Buffalo General Medical Center in upstate New York. He explains that teams around the world are employing AI tools in virtually all aspects of MS care.

In some cases, according to Dr. Dwyer,

artificial intelligence is upgrading existing capabilities, such as increasing the prognostic information that a sophisticated software program can derive from analyzing magnetic resonance imaging (MRI) scans. He adds that in other instances, AI is blazing a trail in uncharted territory.

"Researchers and clinicians have been slowly employing early AI methods over the last decade or so," states Dr. Dwyer. "For example, MRI scanner manufacturers have been including artificial intelligence tools to speed up scan times or improve the quality of scans, but there's been a turning point in the last five years where the capabilities have started improving exponentially. We're now able to employ AI approaches much more quickly because there's a large ecosystem of AI tools across medicine and society."

As part of the next phase of MSAA's MRI Access Program, we are partnering with icometrix, a global leader in AI-driven neuroimaging, to conduct advanced AI-powered MRI analysis on the MRI scans performed. This research initiative is designed to generate standardized, de-identified data that will help researchers better understand patterns of healthcare access, care navigation, patient engagement, and financial burden among people living with MS.

This article will examine the many ways, both incremental and incredible, that AI already is reshaping multiple sclerosis care and may affect everyday life with MS in the years ahead.

Persistent Challenges in MS Diagnosis and Treatment

There's no such thing as an "easy" disease, but that doesn't mean some aren't harder to manage than others. And, says MSAA's Chief Medical Officer Barry Hendin, MD, multiple sclerosis falls toward the far end of the difficulty spectrum.

"The challenges begin with diagnosis and extend through predicting the likely course of a person's MS, to choosing initial and subsequent treatments, and deciding whether and when to stop therapy," says Dr. Hendin, a neurologist and MS specialist in Phoenix, Arizona. He adds that while recent years have seen considerable advances on all of those fronts, further progress is needed – progress that AI may help deliver.

Starting with the first challenge he cited – diagnosis – Dr. Hendin explains that the timely and accurate identification of multiple sclerosis can be complicated because many MS symptoms could be attributable to numerous neurological or musculoskeletal issues, as well as other conditions. Is a woman's fatigue the result of anemia, a persistent virus, depression, MS, or any one of a dozen other causes? Is a pinched spinal nerve, MS, or some other issue causing a man's left foot to drag?

The difficulty in distinguishing MS from other conditions has led to reported rates of misdiagnosis ranging from 5% to 18%.[1] In one study involving 428 people with multiple sclerosis, 40% reported misdiagnosis of symptoms that eventually were attributed to

MS.[2] Dr. Hendin notes that updates in 2024 to the McDonald Criteria employed to identify MS have improved matters. In fact, in a study that compared the performance of the 2024 criteria to the prior version, issued in 2017, the newer guidelines reduced the median time from symptom onset to diagnosis from 84 days to 40 days and correctly identified 93% of people who actually had MS.[3]

"These are noteworthy gains, but they still leave room for improvement," says Dr. Hendin, explaining that a particularly intriguing possibility is that AI's data-crunching prowess may enable it to identify people at high risk for MS years before they have a presenting symptom such as optic neuritis and numbness in a limb. Such a capability would, in turn, raise the question of whether pre-symptom intervention could delay, modulate, or even prevent MS onset.

Turning to treatment, Dr. Hendin says that one of the main challenges clinicians face today can be considered a "good problem" to have. He explains, "Thirty years ago, we had three approved disease-modifying therapies, or DMTs, two of which had essentially the same means of working. Now, we have more than 25 approved brands of DMTs for relapsing forms of MS. Those medications work in a variety of ways, range from moderate to high efficacy, and have important differences in terms of the nature and frequency of their side effects."

As a result, Dr. Hendin adds, clinicians and newly diagnosed patients face a daunting task when they sit down to weigh the advantages and disadvantages of various treatments. He explains that physicians traditionally have been taught to "start low and go slow," to try to find the least-potent dose of a medication that will adequately control a patient's condition, and to move to more-powerful therapies only if needed.

The thinking behind this approach is that less potency will mean fewer side effects. However, he says, recent studies suggest that there is benefit in initiating treatment with high-efficacy DMTs, even allowing for the greater potential for adverse effects, because there may be a window of opportunity in the early stages of MS when introduction of these potent agents can silence inflammation, favorably impacting outcomes over the long-term.

Dr. Hendin's hope is that by analyzing millions of data points on hundreds of thousands of people with MS, AI will provide insights on the likely course of each patient's MS and each individual's expected response to a particular therapy, allowing for truly individualized decision-making. Dr. Hendin adds that AI may also be of considerable help at the other end of the treatment journey, as clinicians and patients grapple with the question of whether, after several years without disease activity, it is safe to stop a DMT. "Again, the idea is that artificial intelligence would look at a whole host of patient characteristics and similar factors and offer a data-validated prediction of whether discontinuing treatment would lead to a relapse or disability progression," he says.

Artificial intelligence is already providing Dr. Hendin with information crucial to the treatment plans he formulates for his patients. In this case, however, the information isn't coming from analyzing a massive database. Rather, it is generated by an AI tool that acts as a silent listener in the exam room.

Dr. Hendin explains that several months ago, the academic medical center where he practices deployed AI "scribes" to take notes and generate summaries during patient visits. "I expected that the technology would provide a passable note that I would need to spend considerable time refining. Instead, I have been very pleasantly surprised by the quality of AI-generated reports.

"There is a level of judgment, if you will, that the technology exercises in screening out casual conversation and homing in on what matters, such as the patient's history and workup findings. Of course, I still have to edit the report and add my conclusions, but the technology definitely has saved me time overall and, most importantly, enables me to be fully focused on the patient and to have a truly in-depth discussion with each individual."

The ability of such AI tools to help clinicians reduce their administrative burdens and devote more attention to patient care is critical at a time when the United States is facing a shortfall of more than 21,000 neurologists and high burnout rates among physicians in the specialty.[4,5]

So, there are plenty of aspects of patient care where AI might be able to lend a helping hand. But what role is AI playing in those areas currently, and how might it drive future advances, not only in direct patient care but also in developing new therapies and making life better for people with MS? That's what we'll look at next.

AI and MS Diagnosis and Monitoring: Current Status and Future Directions

"I wonder if that was an early sign that I had MS."

Many people newly diagnosed with multiple sclerosis will look back over past years and remember some unusual symptom or event that, in retrospect, might have been the first indication that they had a neurological condition. Not the episode of optic neuritis or loss of sensation in a limb that sent them to the doctor and led to the diagnosis, but some subtle sensation or problem that occurred five, 10, or even 15 years earlier.

It's easy to dismiss such thoughts as to what psychologists term "recall bias" – a tendency to view past events inaccurately or to invest them with undue significance based on current knowledge. However, a recent study involving more than 12,000 people showed that as early as 15 years before diagnosis, people ultimately diagnosed with MS had patterns of seeking healthcare that differed significantly from those of people with similar demographic characteristics.[6]

Researchers drew on data from the

government health system in British Columbia, Canada, to identify 2,038 people with multiple sclerosis. They then matched each of those people with up to five people of the same sex, birth year, and postal code who did not have MS. In comparing the two groups, they found that people in the MS cohort had more doctor's visits for:



- ill-defined symptoms and mental health issues starting 14 to 15 years before onset of the symptoms that led to an MS diagnosis
- neurologic and vision issues eight to nine years before MS symptom onset
- musculoskeletal, sensory, and/or nervous system issues four to eight years before onset of MS symptoms

The study's authors wrote that their findings "suggest that MS may begin much earlier than previously recognized" and indicated that there were "opportunities for earlier identification and intervention."

In analyzing 25 years of data for 12,220 people, those researchers used two highly sophisticated software programs. However, neither program was AI-powered. So, if conventional computer software can identify tell-tale trends in healthcare utilization a decade or more before an MS diagnosis, how much more precision can artificial intelligence models bring to that task?

A great deal more, according to a team of investigators at the University of California, San Francisco (UCSF). They developed SPOKE, which they describe as a "knowledge graph," or a structured database that presents information as a network of interconnected relationships and entities. SPOKE links information from more than 30 databases, allowing AI analysis of millions of pieces of information on symptoms, physician visits, treatments, patient demographics, and other key factors. In a study published in 2022, the SPOKE model predicted the disease status of 5,752 people three years before they were diagnosed with MS.[7]

Beyond predicting who may develop MS, AI is also playing an important role in determining who has developed MS. A recent analysis of 28 studies involving 4,350 people with either MS or a closely related

condition, neuromyelitis optica (NMO), found that MRI-based AI models outperformed other neuroimaging modalities, particularly when it came to recognizing early-stage MS and NMO. Across the studies assessed, AI-powered imaging technologies correctly identified the presence of MS in 89% of cases and correctly ruled out the disease in 91% of cases.[8]

Recent updates to the McDonald Criteria for diagnosing MS provide additional impetus to tap into AI's capabilities. Dr. Dwyer explains that the 2024 revisions to the criteria added two MRI findings – the central vein sign and paramagnetic rim lesions* – to the list of factors to be considered in diagnosing MS. "Those can be difficult markers to read clinically, so I think we're going to see AI-based tools coming out that will help operationalize and standardize identification of those imaging biomarkers," he adds.

**Please note the following definitions: The central vein sign is a small vein running through the center of a brain lesion. This indicates inflammation and demyelination, and supports an MS diagnosis.*

Paramagnetic rim lesions are MS lesions that are encircled by a thin, dark rim of iron-rich cells. These types of lesions are markers of increased risk for disability progression and brain atrophy.

Beyond aiding in the initial diagnosis of MS, AI-powered analysis of MRI scans is providing researchers with a treasure trove of previously inaccessible information that may help predict disease course and guide treatment plans.

Dr. Dwyer has been a leader in one such effort. He and colleagues at the University of Buffalo, where he serves as Associate Professor of Neurology and Biomedical Informatics at the Jacobs School of Medicine and Biomedical Sciences, partnered with researchers in the Netherlands and the biopharmaceutical industry. Together they developed an AI tool that can detect lesions that essentially have been invisible to conventional imaging technologies.

A neuroimaging specialist, Dr. Dwyer explains that scientists have long known that the grey matter of the brain, which accounts for roughly half of total brain volume and includes the cortex, is involved with MS progression, including cognitive decline. However, standard magnetic resonance imaging typically cannot identify cortical lesions – even though these lesions are routinely found when pathologists conduct postmortem autopsies on people who had MS. While some advanced imaging techniques have had a limited degree of success in spotting the lesions, these markers of MS disease activity and damage remain as "terra incognito" (or "unknown territory") in most cases.

To obtain a better picture – literally – of what was going on in the cortex of people with MS, Dr. Dwyer and his colleagues developed an imaging-processing approach called "multimodal cortical lesion enhancement," or MMCLE. Applying that technique and others, they were able to

assess multiple scans and, by looking at the relationships between findings on the different imaging studies, identify lesions that weren't apparent on any single scan.[9]

The researchers then tested their approach by analyzing thousands of MRI scans obtained from more than 700 people with MS who participated in the Phase III ORATORIO trial that led to FDA approval of the DMT Ocrevus® (ocrelizumab). The results were startling.

Dr. Dwyer explains that while the original scans generally didn't show any cortical lesions, enhanced imaging processing showed that patients often had 15 to 20 such lesions. He adds, "When a patient has an MRI, the scan is often performed to answer a yes-or-no question, such as, 'Does the person have any new gadolinium-enhancing lesions?' However, when you obtain a scan, you're acquiring a huge amount of data about what's going on in the individual's brain."

He continues, "The challenge has been to pull all that raw data together in a way that transforms it into clinically meaningful information. Our study highlighted one way of doing that, and other research efforts are applying AI techniques to increase the information yield of imaging in other ways." Collectively, he adds, those approaches have significant potential to give people with MS and their clinicians a much more complete, reliable sense of the likely course of the person's disease, enabling them to make better-informed decisions.

AI and MS Care: Current Status and Future Directions

To give an example, let's say that you aren't responding well to your current DMT, so your clinician recommends switching to a medication that is highly effective in most people, but that carries a small risk for a potentially life-threatening side effect.

Before you're willing to take on that risk, you have an important question: "You said the medication is effective for 'most people.' What is the likelihood that it will be effective for me?"

"Unfortunately," your clinician explains, "there isn't enough evidence to provide a reliable answer to that question."

That is the discussion that often follows a recommendation to start Tysabri® (natalizumab), or other monoclonal antibody medication that carries the same risk. Tysabri is a high-efficacy DMT, but it increases risk for progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability.[10] Although rare, clinicians work to mitigate that risk through three steps: testing for the presence of an antibody that elevates the chances of PML, limiting duration of treatment, and closely monitoring patients. However, the danger cannot be eliminated altogether.

But what if clinicians could predict with 90% accuracy whether you would respond well to the medication? People not likely to benefit from the treatment could move on to

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other options, while those with a high probability of responding would have a key new datapoint to consider as they made their decision.

Thanks to a team of French and Brazilian researchers' innovative use of AI, such information soon may be available to people considering treatment with Tysabri. Those researchers employed artificial intelligence to analyze several characteristics of white blood cells in people with MS and healthy volunteers. They found that the morphology – or structure and shape – of T cells, which play an important role in immune function, could help predict response to the medication in about 90% of cases.[11]

"Being able to base our treatment recommendations on these sorts of sophisticated analyses made possible by AI is a huge step forward in the effort to provide highly individualized care," says Dr. Hendin.

That effort also may benefit from AI-driven research into developing biology-based frameworks for categorizing and treating MS. Traditionally, people have been diagnosed as having relapsing-remitting, secondary-progressive, or primary-progressive MS. While that framework is useful, experts long have felt that it doesn't adequately account for the wide variety of ways in which MS manifests itself initially and behaves subsequently.

Late last year, scientists at University College London and other institutions published research suggesting that people with MS can be divided into two subtypes based on MRI findings and blood levels of a protein called serum neurofilament light chain, or sNfl.[12] When brain or spinal cord nerve cells are damaged due to injury or inflammation, they release sNfl, which eventually enters the bloodstream. As a result, serum levels of the protein can be a marker of recent MS disease activity.

In a study that used a form of AI called "machine learning" to assess data from 634 people with MS, the researchers found that people who had high blood levels of sNfl early in the course of their condition as well as MRI evidence of damage to the corpus callosum – a region located deep in the brain – tended to develop new lesions quickly and to have an aggressive disease course from the outset. Conversely, study participants who had lower levels of sNfl initially and early imaging evidence of reduced volume in the cortical region and deep grey matter of the brain typically had a slower-progressing form of MS.

Another study published last year – this one analyzing data on roughly 8,000 people with MS, 118,000 doctor visits, and more than 35,000 MRI scans, used AI to identify eight proposed clinical states of multiple

sclerosis, ranging from early/mild/evolving through asymptomatic radiological MS activity and relapse to advanced.[13]

Noting that their findings "are more compatible with the view of MS as a disease continuum than with the traditional view of distinct phenotypes," the researchers concluded that their classification approach could help improve patient management and drive the discovery of new medications. (A "disease continuum" refers to the gradual development and progression of a disease rather than distinct stages over time. Early intervention as well as intervention at any time along this continuum can lead to better long-term outcomes.)

While researchers are using specialized artificial intelligence tools to reshape the future of multiple sclerosis care, studies show that commonly available AI platforms can help enhance the management of MS right at this moment.

For example, Spanish investigators asked the AI program, "ChatGPT-4o," and 290 neurologists, how they would manage 20 hypothetical cases of multiple sclerosis or a related condition, neuromyelitis optica spectrum disorder (NMOSD). In 73% of cases, ChatGPT recommended a treatment plan that is consistent with the latest MS guidelines. The neurologists only met that mark in 67% of cases, a statistically significant difference from the AI platform's performance. Further, when ChatGPT was explicitly directed to formulate a treatment plan that reflected the guidelines, it did so 81% of the time.[14]

The researchers noted that ChatGPT was more likely than the neurologists to follow evidence-based guidelines both in initiating treatment and intensifying therapy, as needed. They added that their findings showed: "AI's potential to support timely treatment decisions. Incorporating such tools into practice and training may accelerate best-practice adoption and improve patient outcomes."

In addition to helping clinicians make optimal choices regarding currently available medications, researchers see AI having great potential to speed the development of new therapies.

Fewer than 12% of investigational medications evaluated in Phase I clinical trials ultimately win approval from the Food and Drug Administration (FDA). And those that are approved typically take 10 to 15 years to develop.[15] Early indications suggest that AI can cut clinical trial timelines by one third to one half by helping to develop efficient study designs, assess which patients are good candidates for a particular trial, and drive recruitment.[16] Researchers also see AI playing a valuable role in evaluating whether medications already approved to treat other conditions, such as statins used to lower cholesterol levels, may have efficacy in treating multiple sclerosis.

Of course, MS management entails more than medications. Assistive devices play a large role in preserving functionality and quality of life. Biomedical engineers have developed a number of AI-based technologies to facilitate movement and communication. A representative sample of items is shown on the next page.

- **Cionic® Neural Sleeve 2:** An FDA-cleared wearable sleeve that employs smart sensors and AI algorithms to analyze movement, predict gait patterns, and deliver synchronized electrical stimulation to four major leg muscle groups to improve walking and relax muscle spasms.
- **Motus Hand Device:** A robotic rehabilitation tool for the upper limbs that uses AI-driven therapy to automatically adjust resistance and movement patterns based on a user's changing coordination and strength.
- **Robotic Exoskeletons and Arms:** Motorized exoskeletons have onboard sensors and software to assist with walking and posture training, while assistive robotic arms mount to wheelchairs to help with everyday grasping tasks.
- **Spoken:** An augmentative communication app that uses predictive AI to learn a user's unique speech patterns and accurately forecast words to help build sentences quickly.
- **Dragon® Home:** Voice-recognition software that transcribes spoken words into text with high accuracy, assisting individuals who experience hand fatigue or difficulty typing.

Beyond technologies designed specifically for people with neurological needs, general AI tools such as ChatGPT, Gemini, and Microsoft Copilot can help with cognitive symptoms, such as "brain fog," by summarizing long email threads, organizing daily schedules, or drafting correspondence.

Defining AI – and Its Potential Downside in MS Care

Who better to define AI than AI itself? Here's how Google's Gemini AI service responded when asked to describe artificial intelligence in two sentences:

"Artificial intelligence (AI) refers to computer systems designed to simulate human cognitive functions, such as learning, reasoning, problem-solving, and decision-making. By analyzing vast amounts of data to recognize patterns, AI enables technologies to perform complex tasks like understanding language, generating content, and making autonomous decisions."

Those capabilities were imaginable to only the most far-sighted of visionaries when mathematicians and computer scientists gathered on the campus of Dartmouth College one summer 70 years ago for a conference where the phrase "artificial intelligence" was coined. Six years earlier, English mathematician and logician Alan Turing had unveiled his "Turing Test," a means of measuring machine intelligence that was a noteworthy event in the development of AI.

After some early successes, the AI field stagnated for much of the 1970s and 1980s, largely due to the limitations of the computers then available. Things got back on track in the late 1980s and early 1990s

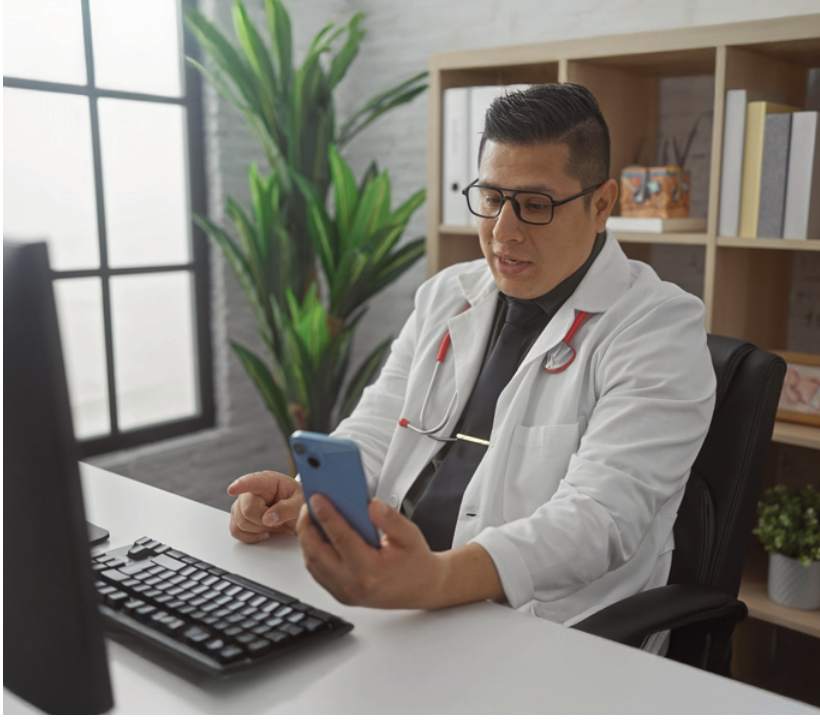
as “machine learning” (ML) came into the forefront. This AI modality employs statistical techniques to recognize patterns and then make predictions or decisions by analyzing data, rather than by following explicit programming instructions.

To use a very rough analogy, ML is equivalent to a student learning by reading an entire book, absorbing its contents, and coming to one’s own conclusions about the lessons it offers, rather than by having a teacher assign specific chapters to be read and explaining the significance of each.

By 1997, artificial intelligence had advanced to the point that IBM’s Deep Blue AI model defeated world chess champion Garry Kasparov, capturing headlines around the world by checkmating Kasparov’s king.

The arrival of the 21st Century brought dramatic increases in computing power thanks to technologies such as graphics processing units (GPUs), the availability of large data sets that are the lifeblood of AI, and the development of artificial neural network architecture. Computer scientists explain that these neural networks mimic the structure of the human brain by having interconnected nodes (think neurons) organized in layers to process input data and generate signal outputs.

While machine learning typically relies on inputs that have been structured by humans – such as a uniform set or type of data – neural networks can learn autonomously by drawing on diverse, unstructured sources, such as audio, images, and human speech, as well as print. So-called “deep learning” uses multi-layered neural networks to identity patterns by processing vast amounts of data.



Meanwhile, large language models (LLMs) are specialized deep neural networks designed to understand natural language. LLMs acquire this knowledge by training on multi-billion-word data sets to learn the statistical relationships between different words and phrases, enabling them to understand, summarize, and generate human language.

Simple, right?

If not, here’s an AI-facilitated analogy that may help.

Remember our student who took the initiative and read the book on his own?

What if he were to read not just one book but every book in the school library? Further, what if he could remember the entire contents of each, recognize patterns and trends across the full collection, resolve apparent contradictions, and draw on the full breadth of his knowledge to instantly provide his 25 classmates with detailed answers to different questions they posed about a

variety of subjects?

That would make the young man a genius (and a very popular classmate), but he still couldn't hold a candle to the most basic of current AI tools.

So we've covered the benefits AI may offer people with multiple sclerosis, but what about downsides specific to MS care?

Dr. Dwyer says one of the main potential pitfalls has less to do with AI's behavior than human behavior. He says, "AI tools are amazing. They are wonderful things, but people still have to wonder about them – wonder if an AI-generated result is correct, wonder if the information really is applicable to your question or your patient. When you interact with humans, you usually can tell when they don't really know what they're talking about, but when you interact with ChatGPT or a similar AI app, it is optimized to provide plausible answers even if they are not the right answers."

He adds that much of the work AI performs takes place in a figurative black box, preventing humans from seeing if the correct processes are being employed. Dr. Dwyer explains, "There's a lot of great research going on to try to open that black box and peer into how an AI model is thinking, but until we have insight into that process, it's important to verify information rather than being lulled into a false sense of security."

A neuroimaging specialist, Dr. Dwyer notes that this concern with vigilance prompted more than 70 radiologists and other imaging specialists, AI scientists, medical journal editors, statisticians, and others to develop the Checklist for Artificial Intelligence in Medical Imaging, or CLAIM, to promote consistent, complete reporting of AI science as it pertains to medical imaging.

Dr. Hendin says that people with multiple sclerosis and their care partners should exercise comparable caution rather than accept AI-generated answers about MS care at face value. "AI is an excellent tool for developing questions and summarizing concerns that you want to share with your clinician, but it should not intrude on or displace the patient-clinician relationship when it comes to decision-making," he adds.

Other concerns related to AI and MS care are amplified versions of long-standing worries about the uses and abuses of data. These include the potential for AI to inherit biases from the material it trains on, insurers' use of data-driven algorithms to unfairly deny claims, and threats to patient privacy.

Making AI Stand for "Absolute Individualization"

Dr. Hendin says that while concerns about the potential adverse impact of AI on MS are important and must be addressed, the potential benefits of the technology also must be pursued.

He looks forward to a day, perhaps not far off, when a clinician and patient can sit down together to review an AI-generated synthesis of the person's history and symptoms, MRI findings, genetic information, biomarker

results, comorbidities, and several other factors, along with projections of the likely course of the person's MS and treatment recommendations tailored to one's unique situation.

"When we get to that level of specificity, we'll be able to truly practice precision medicine and achieve the outcomes that such an individualized approach offers," he says.

Multiple sclerosis is a disease of a human being's neural networks. Based on early, promising indications, it appears that treating the disease in agreement with the insights provided by artificial neural networks may be just what the doctor ordered. ■

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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 an active hepatitis B virus (HBV) infection.
- Have had an allergic reaction to ofatumumab or life-threatening injection-related reaction to KESIMPTA.

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East Hanover, New Jersey 07936-1080

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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 a history of liver problems.
- 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. There are two kinds of reactions:
  - **At or near the injection site:** redness of the skin, swelling, itching, and pain. Talk to your HCP if you have any of these signs and symptoms.
  - **That may happen when certain substances are released in your body:** fever, headache, pain in the muscles, chills, tiredness, rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue and throat, and feeling faint, or chest tightness. Contact your HCP right away if you experience any of these signs and symptoms, especially if they become worse or you have new severe signs of reactions after subsequent injections. It could be a sign of an allergic reaction, which can be serious.
- **Low immunoglobulins.** KESIMPTA may cause a decrease in some types of antibodies. Your HCP will do blood tests to check your blood immunoglobulin levels.
- **Liver damage.** KESIMPTA may cause liver damage. Your HCP will do blood tests to check your liver before you start KESIMPTA and while you take KESIMPTA if needed. Tell your HCP right away if you have any symptoms of liver damage such as:
  - yellowing of the skin and eyes (jaundice)
  - nausea
  - vomiting
  - unusual darkening of the urine
  - feeling tired or weak

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.
- Have had an allergic reaction to ofatumumab or life-threatening injection-related reaction to KESIMPTA.

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 a history of liver problems.
- 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.
  - **Pregnancy Registry:** There is a registry for women who become pregnant during treatment with KESIMPTA. If you become pregnant while taking KESIMPTA, tell your healthcare provider right away. Talk to your health care provider about registering with the MotherToBaby Pregnancy Study in Multiple Sclerosis. The purpose of the registry is to collect information about your health and your baby's health. For more information or to register, contact MotherToBaby by calling 1-877-311-8972, by sending an email to MotherToBaby@health.ucsd.edu, or go to www.mothertobaby.org/join-study.
- 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.

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 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. There are two kinds of reactions:
  - **at or near the injection site:** redness of the skin, swelling, itching and pain. Talk with your health care provider if you have any of these signs or symptoms.
  - **that may happen when certain substances are released in your body:** fever, headache, pain in the muscles, chills, tiredness, rash, hives, trouble breathing, swelling of the face, eyelids, lips, mouth, tongue and throat, and feeling faint, or chest tightness. Contact your health care provider right away if you experience any of these signs or symptoms, especially if they become worse or you have new severe signs of reactions after subsequent injections. It could be a sign of an allergic reaction, which can be serious.
- **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.
- **Liver damage.** KESIMPTA may cause liver damage. Your HCP will do blood tests to check your liver before you start KESIMPTA and while you take KESIMPTA if needed. Tell your HCP right away if you have any symptoms of liver damage, such as:
  - yellowing of the skin and eyes (jaundice)
  - nausea
  - vomiting
  - unusual darkening of the urine
  - feeling tired or weak

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.



Questions from Our Readers

By Dr. Barry Hendin
MSAA's Chief Medical Officer

Q: MSAA recently featured the cover story, "In Search of MS Biomarkers," in its Summer/Fall 2025 issue of *The Motivator.* In the article, you note that in MS, biomarkers are either found via imaging or via bodily fluids, including blood or cerebrospinal fluid. I wanted to ask how often most neurologists might be looking at such biomarkers and if testing of bodily fluids is done routinely, or if much of this has yet to become a part of day-to-day practice per the changes as noted in the recent update?

A: As you point out, biomarkers include MRI imaging, and humeral biomarkers, derived from bodily fluids, such as blood and spinal fluid.

MRIs are our most frequently used biomarker for risks of acute inflammation and MS progression. More sophisticated MRI techniques are now being employed to predict prognosis for MS progression.

Currently, the most commonly used humeral biomarkers are spinal fluid oligoclonal bands for MS diagnosis. Other biomarkers include aquaporin-4 antibodies for the diagnosis of NMOSD (neuromyelitis optica spectrum disorder), and MOG (myelin oligodendrocyte glycoprotein) antibodies for MOGAD (myelin oligodendrocyte glycoprotein antibody-associated disease) diagnosis. Both NMOSD and MOGAD are autoimmune disorders of the central nervous system that may mimic multiple sclerosis, but are separate diseases.

The two most commonly used serum-derived humeral biomarkers are neuro filament light and GFAP (glial fibrillary acidic protein). Neuro filament light is a marker for acute inflammation such as a relapse, while GFAP has been a marker for MS progression. An 18-protein array, which measures the proteins' biochemical activities, has been developed by Octave with the hopes of serving as a marker for acute inflammation and progression.

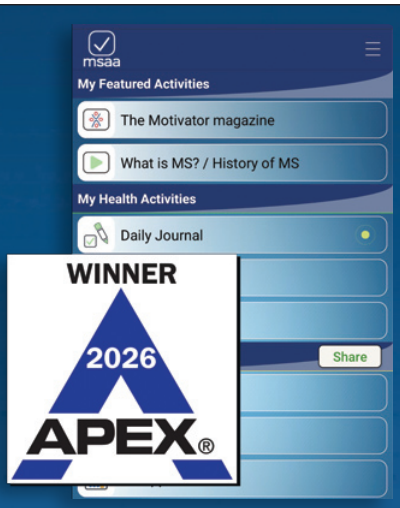
These biomarkers are evolving. Some clinicians are using them as part of regular practice, and some neurologists are not using them regularly. There is an active research program to assess their best role and usage in clinical practice. Stay tuned!

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

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Q: I am a 75-year-old female retired nurse anesthetist and was diagnosed with MS in 2001 at the age of 51. I've been taking a disease-modifying therapy, but my neurologist has diagnosed me with "smoldering MS" and feels that I should not take any disease-modifying therapy due to my advanced age.

Not knowing if I had aged out of treatment, we agreed to follow my B cells, and when they rose above zero, treatment would be resumed. My treatment schedule is now every nine months.

Do you agree with this treatment plan or do you indeed feel that someone my age does not benefit from further treatment? Is my immune system so dampened by my age that any progression would be minimal?

A: A choice regarding when to stop disease-modifying therapies (DMTs) is always going to be a shared decision between you and your clinician. But there are biological facts and guiding principles that may help with that decision-making.

The guiding principle for stopping or starting disease-modifying therapies is based on the ratio between the potential risk and the benefit of that treatment. The benefit should always exceed the risk.

The biology of aging includes immuno-senescence, which refers to the natural aging of the immune system. Immunosenescence reduces the power of autoimmunity and therefore the likelihood of relapses as people with MS age. Our DMTs exert their greatest

power by reducing relapses. And if the risk of relapse is less than the power or benefit of the DMT, treatment becomes less necessary. The benefit therefore is less. As we age, the risk of our immunotherapies remains the same or increases. Therefore, the risk benefit ratio changes. We know that in different populations, this shift can begin as early as a person's 50s or 60s.

For the clinician and for the person with MS, assessing risk in an individual is more difficult. We can use biomarkers such as MRI and humeral biomarkers (please see earlier discussion of biomarkers on page 22). Despite our improvement in technology, there remains uncertainty regarding any individual patient. In clinical practice, there is a wide variation as to when the discussion begins and the outcome of those discussions with regard to stopping medications. Some clinicians and some patients choose to stop earlier and some wait longer, but as I said at the beginning of this answer, it's ultimately a decision between the patient and the clinician.

In my own practice, we have these discussions as my patients age. I encourage considering the discontinuation of DMTs as people progressively age, particularly in their late 60s and 70s. Not surprisingly, some of my patients discontinue in their 50s, while others choose to wait and delay discontinuation until they are older.

Need an MRI?

Are you in need of an MRI, but unable to afford one? If so, MSAA may be able to help!

For more than two decades, MSAA has been assisting individuals who do not have medical insurance or cannot afford their insurance costs for an MRI, to help determine a diagnosis of MS or to evaluate MS disease activity.

For more information, please visit **mymsaa.org/mri**

The MRI Access Program is made possible with support from EMD Serono, Genentech, and the Veyl Family.



Please note that the MRI Access Program will soon be expanding to a new and innovative program that is supplemented with an AI-driven imaging report in addition to your free MRI to better understand current disease activity and predict future disease progression. Stay tuned for more details coming soon!

Q: I am experiencing overwhelming fatigue, and I know that many people with MS suffer from this symptom. I am trying to plan ahead, avoid overheating, and conserve my energy. Do you have any other specific recommendations, and are any specific medications for fatigue safe and effective?

A: You are correct that many people with multiple sclerosis suffer from fatigue – it is probably the most common symptom of MS.

Your strategy for dealing with fatigue is also basically correct. It's a combination of conserving energy and also of using energy as efficiently as possible.

My general recommendations center around wellness. We want to make sure that people with MS are getting sufficient sleep, exercising regularly (but not beyond what can be comfortably tolerated), and eating a healthy diet, such as a Mediterranean diet.

We want to make sure that they are attending to their mental health and particularly any associated anxiety and depression. Anxiety and depression increase fatigue, so it's reassuring to know that these mental health issues are treatable by the appropriate mental health specialist, and often with medications. It's helpful to have a good primary care physician to monitor any comorbidities (other conditions), because medical problems often affect energy and fatigue.

Using your available energy efficiently is important. That means setting priorities for the activities that are the most important to you, and taking breaks when necessary, i.e., listening to your body. Because people with MS are so often sensitive to overheating, we encourage strategies to avoid overheating, which include a few different strategies, such as drinking a cold or frozen (non-alcoholic) drink, taking a cool shower, and the use of cooling products. For people with mobility issues, we encourage using assistive equipment to allow for more efficient mobility. Please note that MSAA offers free cooling products plus safety and mobility equipment to individuals meeting financial eligibility requirements.

Most people can manage fatigue with a combination of behavioral and wellness strategies, but sometimes medications are helpful. Although there are currently no FDA-approved medications specifically for MS fatigue, amantadine (previously Symmetrel®) and Provigil® (modafinil) are widely used off-label to treat MS fatigue. The good news is that there are multiple strategies for dealing with the fatigue of MS. ■

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 Tom Garry and Susan Wells Courtney
Reviewed by Dr. Barry A. Hendin
MSAA Chief Medical Officer

Remibrutinib Shows Positive Results from Two Phase III Studies

On September 1, 2026, positive results were announced from two Phase III studies of the investigational medication, remibrutinib, in individuals with relapsing forms of MS. These two international Phase III trials, REMODEL-1 and REMODEL-2, were identical in design and together enrolled approximately 2,000 adult participants.[1]

These studies were multicenter, randomized, and double-blinded – comparing the effectiveness and safety of remibrutinib to teriflunomide (Aubagio®) – for a period of up to 30 months (two-and-a half years). After the 30-month period was complete, the studies continued as open-label extensions for up to five years. To clarify, in a double-blind study, neither the participants nor the medical team know who is receiving the medication and who is receiving the placebo. In an open-label study, both the participants and the medical team are aware of what each individual is receiving.

Remibrutinib is an experimental oral disease-modifying therapy (DMT) belonging to a class of medications known as Bruton's tyrosine kinase inhibitors, or BTKi's. These medications modulate both B-cells and myeloid cells – such as microglia and macrophages – which play important roles in immune function and can contribute to the development of MS. BTKi medications cross the blood-brain barrier, enabling them to impact chronic inflammation within the central nervous system (CNS). The CNS is comprised of the brain, spinal cord, and optic nerves.

In both studies, compared to teriflunomide, remibrutinib significantly reduced annualized relapse rate (ARR), which was a primary endpoint. Remibrutinib also showed positive results in all of the secondary endpoints, which included: a delay in confirmed disability progression at both three and six months; a reduction in CNS lesions as shown on magnetic resonance imaging (MRI); lower serum neurofilament light chain concentrations, indicating less CNS nerve damage; and a higher proportion of participants with no evidence of disease activity (NEDA).

The US Food and Drug Administration (FDA) approved remibrutinib (with the brand name, "Rhapsido®") in September 2025 for the treatment of chronic spontaneous urticaria (CSU), a condition exhibiting chronic hives with no known external trigger. In the REMODEL-1 and REMODEL-2 Phase III trials for individuals with relapsing MS, the safety profile was positive, consistent with remibrutinib in CSU, with no liver safety signal. ■

FDA Approves Ocrevus® for Pediatric Relapsing-Remitting MS

In May 2026, the Food and Drug Administration (FDA) approved Ocrevus® (ocrelizumab) for the treatment of relapsing-remitting MS in children and adolescents age 10 and older who weigh 55 pounds or more.[2] The approval makes the intravenously infused medication only the second disease-modifying therapy (DMT) with an FDA-sanctioned indication for use in pediatric patients.

In 2018, the FDA approved Gilenya® (fingolimod) for use in children and adolescents ages 10 to 17 years who have relapsing forms of MS.

In the Phase III OPERETTA 2 study, ocrelizumab cut annualized relapse rate 48% vs fingolimod (0.07 vs 0.14). Ocrelizumab also reduced new or enlarging T2 lesions (48% reduction vs fingolimod) and gadolinium-enhancing T1 lesions (87% reduction vs fingolimod). In addition, safety in children was similar to the safety in adults, with infrequent serious adverse events and infections, and no discontinuations resulting from adverse events. ■

Studies Demonstrate Favorable Outcomes with Fenebrutinib for Both Relapsing and Primary-Progressive MS

Fenebrutinib is an investigational, oral disease-modifying therapy (DMT) belonging to a class of medications known as Bruton's tyrosine kinase inhibitors, or BTKi's. As noted earlier, these medications modulate both B-cells and myeloid cells – such as microglia and macrophages – which play important roles in immune function and can contribute to the development of MS. BTKi medications cross the blood-brain barrier, enabling them to impact chronic inflammation in the central nervous system.

Involving almost 1,500 people with relapsing MS,[3] FENhance 1 and FENhance 2 are similarly designed Phase III studies being conducted to evaluate the safety and efficacy of fenebrutinib versus Aubagio® (teriflunomide) in people with relapsing MS. In these two studies, the relapse rate for those taking fenebrutinib was between 40% and 50% lower than for those taking Aubagio. In addition, significant relative reductions in T1 gadolinium-enhancing lesions and new or enlarging T2 lesions were seen on MRI with fenebrutinib compared to Aubagio.

Moving from relapsing MS to primary-progressive MS (PPMS), the Phase III FENtrepid trial assessed the efficacy and safety of fenebrutinib compared to Ocrevus® (ocrelizumab) in 985 people with PPMS. Ocrevus is an intravenously infused medication that is currently the only disease-modifying therapy (DMT) approved for the

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Expanding Access, Advancing Equity, and Shaping the Future of MS Care

By Claude Pinnock MD, MPH
MSAA Chief Operating & Health Officer

Providing Access to MRIs

For people living with multiple sclerosis (MS), access to care involves much more than receiving a diagnosis or treatment. Ongoing disease monitoring, navigating healthcare systems, overcoming financial challenges, and participating in research, all play important roles in achieving the best possible outcomes. While advances in treatment have transformed the MS landscape, barriers to care continue to affect many individuals and families.

At the Multiple Sclerosis Association of America (MSAA), we are committed to identifying and addressing these challenges. Through innovative partnerships, research initiatives, and patient-centered programs, MSAA is working to expand access, advance equity, and create new opportunities for people living with MS.

One of the most critical components of MS care is access to magnetic resonance imaging (MRI). MRI remains an essential tool for monitoring disease activity, evaluating treatment effectiveness, and supporting clinical decision-making. Yet many individuals face barriers to obtaining recommended imaging, including financial constraints, insurance challenges, and other socioeconomic factors.

To better understand these challenges and their impact on health outcomes, MSAA recently partnered with icometrix to establish a second phase of our MRI Access Program. This research initiative is designed to generate standardized, de-identified data that will help researchers better understand patterns of healthcare access, care navigation, patient engagement, and financial burden among people living with MS.

MRI scans included in the program will receive AI-enabled quantitative analysis, providing insight into subtle disease activity and progression. This new initiative will combine this data with patient-reported outcomes and demographic information, to create a unique dataset. This combined information bridges measures of disease burden with the real-world experiences of individuals receiving MS care.

The initiative received Institutional Review Board (IRB) approval in May 2026, with recruitment expected to begin later this year.

Addressing Insurance Denials to Expand Access

MSAA is also exploring innovative approaches to help individuals overcome barriers to accessing care. This includes our partnership with Claimable to help people with MS appeal insurance denials for MRI scans. MRI is central to both diagnosing MS and tracking disease activity, yet coverage is frequently delayed or denied for reasons that

have little to do with clinical need.

Claimable is a physician-led team of clinicians, data scientists, and healthcare and insurance experts on a mission to overturn wrongful insurance denials. Denials are reversed far more often than most people expect, yet fewer than 1% are ever appealed, often because the process is time-consuming and unfamiliar. Claimable's appeals platform makes it possible for more people to appeal and get the care they need.

While still in its early stages, this initiative reflects our commitment to identifying practical solutions that can support people living with MS as they navigate complex healthcare systems. As the pilot program develops, MSAA looks forward to evaluating how technology-enabled appeal support may help with access to MRI scans, disease-modifying therapies, and other supportive services.

Multiple Sclerosis Implementation Network® (MSIN®)

Finally, in addition to improving access to care, MSAA continues to expand opportunities for meaningful participation in research. The Multiple Sclerosis Implementation Network® (MSIN®), previously featured in *The Motivator*, continues to make significant progress as a patient-centered research network designed to bridge scientific innovation and real-world clinical practice.

Since its launch, MSIN has brought together healthcare professionals, researchers, and people living with MS to build the infrastructure necessary to support collaborative research that reflects the realities of MS care. With over 2,000 individuals with MS enrolled, a major milestone is now approaching with the imminent launch of the network's first study.

The upcoming study will evaluate the adoption of the Multiple Sclerosis Disease Activity (MSDA) biomarker test and its effectiveness in supporting clinical decision-making and improving outcomes. Biomarker-based tools hold promise for providing clinicians with additional information that may help guide treatment decisions and monitor disease activity. Through this study, MSIN will generate valuable real-world evidence regarding how these tools can be incorporated into routine clinical practice.

Translating Innovation into Meaningful Benefits

Together, these three initiatives demonstrate MSAA's comprehensive approach to addressing barriers across the MS care continuum. Our MRI initiative seeks to better understand the factors that influence access to care and disease monitoring. Our Claimable pilot program explores new ways to help individuals navigate those challenges. MSIN is creating opportunities for individuals living with MS to participate in research that may shape the future of MS care.

As the MS landscape continues to evolve, MSAA remains committed to ensuring that innovation translates into meaningful benefits for the people we serve. By advancing research, expanding access, and fostering collaboration, we are helping to build a future in which every person living with MS has the opportunity to receive the care, support, and resources they need to live their best life. ■

Inspired to Support Our Mission

By Scott Fremont, Vice President of Development and Susan Wells Courtney, Senior Writer & Creative Director

MSAA is guided by a Board of Directors that brings together unique and diverse backgrounds to its leadership role in helping MSAA continue to provide needed support for the MS community. One of the board's primary goals is to support MSAA's work to strategically target emerging areas of need.

In this issue's "Thoughts About Giving" column, we feature two members of MSAA's Board of Directors, Dr. Terrie Livingston and Kevin Stockton. Each has a very special connection to MSAA and both are enthusiastic in sharing their perspectives on MSAA and how it makes a positive impact on the MS community.

Dr. Terrie Livingston is the Vice President of Medical Affairs at Octave Bioscience with more than 25 years of experience in the pharmaceutical and biotech industries. Diagnosed with multiple sclerosis in 2006, Terrie's professional dedication is deeply intertwined with her personal journey.

"Twenty years ago, my life changed forever when I received my MS diagnosis... but my path to that diagnosis wasn't immediate," Terrie notes. "As a minority patient, it took a painful, three-year diagnostic journey just to get answers. That period of uncertainty sparked a fire in me to change the narrative of this disease. I have dedicated my career in Medical Affairs to pushing the boundaries of biotech and pharma, striving to advance the research that will define our future."



MSAA's Board Member Dr. Terrie Livingston

Kevin Stockton is a strategy, marketing, and sales executive with 25 years of leadership experience. Most recently, Kevin served as Senior Vice President and Head of Strategy, Business Development, and Cybersecurity for the Americas at Siemens Healthineers. Kevin was diagnosed with MS in 2014, and due to his professional background, knew MSAA through our MRI program.

Kevin explains, “Helping people get the critical, but very expensive, diagnostic imaging they need, especially if they are uninsured or poorly insured, was near and dear to my heart. My decision to join MSAA’s Board of Directors came at a good time in my life, as I was looking for ways to give back to the MS community, given that I have had MS for over a decade now. MSAA's patient focus truly resonates with me. MSAA is an organization without equal when it comes to providing services and support for the MS community."

Sharing the Unique Ways in which MSAA Serves the MS Community

“I did not initially realize the breadth and depth of the programs offered by MSAA, and now that I do, I find it to be amazing,” Kevin shares. “MSAA truly understands what individuals with MS need at the time they need those services. MS is a long road and it can be very different for each individual, so having a comprehensive array of programs and support available at different points of one’s journey is critical.”

Terrie concurs, "What stands out to me is how deeply MSAA understands that the MS journey is never a straight line… it is a path of unique challenges and quiet victories. I’ve seen firsthand how MSAA acts as a beacon of hope for the nearly one million people living with MS in the United States, actively working to bridge gaps in care. MSAA focuses on reclaiming the quality of life that people with MS deserve right now, even as we work toward future clinical breakthroughs."



MSAA’s Board Member Kevin Stockton

Encouraging Others to Become Involved with MSAA

"Our community is at its strongest when we stand together,” states Terrie. “Looking out at the MS community, I don't just see individuals facing a diagnosis – instead, I see a powerful, resilient village. Getting involved with MSAA connects you to a collective force that is actively shifting the narrative of this disease. Your voice, your story, and your presence add to our shared strength. Together, we ensure that no one has to navigate these complexities alone."

Kevin adds, “Individuals can get involved as much or as little as they wish. Regardless of where you are in your MS journey, having a community to support you – and for you to

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support the community – will make your life and the management of your disease better. While there is no substitute for one's clinical care team, there is a tremendous amount of collective wisdom from within the MS community… and I really believe that MSAA is one of the best sources to tap into that collective wisdom."

Support from the MS Community Helps Fund Urgent Programs and Services

"All of MSAA's programs and services can only happen through the generous support of our donors," Kevin emphasizes. "Money enables the mission. It is critical to receive any support we can – big or small from our donors – to not only keep MSAA's vital programs and services in place, but to also expand what MSAA can do in the future."

Terrie explains, "Donor generosity is the literal fuel for MSAA's mission. As a clinician and researcher, I look at clinical progress, but as a board member, I see how donor support is the direct link to improving daily lives. Your support is the reason a newly diagnosed individual can find clarity instead of fear. It directly funds the free programs, critical MRIs, and vital safety equipment that allow people to reclaim their independence. When you support MSAA, you are directly investing in someone's ability to live their life to the fullest today." ■

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treatment of PPMS. In the study, fenebrutinib had a 12% reduction in risk of disability progression compared to Ocrevus.[4]

On September 29, 2026, the company developing fenebrutinib announced that the US Food and Drug Administration (FDA) has accepted their New Drug Application (NDA) under priority review of fenebrutinib for the treatment of both relapsing and primary-progressive forms of MS. ■

Medical details and study results provided in MSAA's published materials are for informational purposes only and are not to be considered as treatment advice or recommendations. Readers are encouraged to consult a healthcare professional before making any changes to their current treatment regimen.

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A Blessing in Disguise

By Aranzazu "Zazu" M. Calzado

Nearly a decade ago I first realized something wasn't quite right with my left leg. At first, I blamed long walks. I was carrying extra weight back then, so I convinced myself my knees were simply protesting. It seemed like the most logical explanation.

Life went on, and so did I. Little by little, strange symptoms appeared. My torso became numb. My body would suddenly vibrate for no apparent reason. My left leg started having electric-like spasms. I even remember laughing with my mother about the vibrations because they seemed so bizarre.

Of course, I did what almost everyone does: I searched online and every result seemed to point to multiple sclerosis. I immediately dismissed the idea. I thought I was probably overthinking things.

My doctor referred me to a neurologist, who ordered an MRI of my lumbar spine. The results showed no lesions, and I was told my symptoms were likely related to my weight and the strain on my knees.

So, I followed the advice. I lost 120 pounds. I always joke that I finally got rid of the "twin" I'd been carrying around for years. I expected everything to improve. Instead, my symptoms continued to progress.

A few years later, my left leg began dragging. My walk became slower and uneven. Looking back, it was obvious something wasn't right, but I was still functioning. I could walk long distances, climb stairs, work full-time, travel, and live independently. So, I kept pushing forward.

Then, in 2021, I sought another opinion. It felt as though every possible test was ordered – MRIs, blood work, procedures. By then, I felt like a human pincushion.

Finally, on December 15, 2021, I heard the words that changed my life: *"You have multiple sclerosis."*

And not just multiple sclerosis, but primary-progressive multiple sclerosis. I remember staring at my neurologist, thinking, *"Not me. Are you sure?"*

But there it was and just a few days before Christmas. I often joke that while everyone else received presents that year, I got MS instead of charcoal. At the time, it felt like the cruelest Christmas gift imaginable.

But with time, something unexpected happened. That diagnosis slowly transformed from what I believed was life's greatest curse into one of its greatest blessings. MS forced me to slow down.

It taught me to notice the little moments I used to rush past. It showed me that we spend so much energy worrying about things that will never matter while overlooking the things that truly do.

One of the things that truly matters to me is my love of photography, and I submitted three of my works, along with my bio, to this year's

MSAA Art Showcase. In my bio, I note, “My journey with photography began in childhood, inspired by the vivid colors, traditions, and everyday moments of my homeland [Spain]. From an early age, my camera became a way to observe, understand, and connect with the world around me.”

I've learned that life becomes lighter when we stop measuring ourselves by what we've lost and start celebrating what remains. MS has made me stronger than I ever imagined. It has made me more grateful, more compassionate, more patient, and more present.

Most importantly, it revealed something I may never have fully appreciated otherwise – the incredible people surrounding me. My family and friends didn’t disappear when life became difficult. On the contrary, they stepped closer.

They became my strength when I felt weak, my hope when I felt discouraged, and my light during some of my darkest days. Whenever I begin to lose confidence, they gently remind me that I am capable of far more than I believe. Their love has carried me through countless difficult moments.



A photography enthusiast, Aranzazu “Zazu” Calzado poses with her camera while on a trip to Chile. Inset: Zazu’s still-life photo, “Quiet Harvest,” is featured in MSAA’s Art Showcase.

Nearly five years after my diagnosis, I still have hard days. I still wish I could run, hike without thinking about every step, or simply walk without wondering whether my leg will cooperate. But I no longer ask, *"Why me?"* Instead, I ask, *"What is this teaching me today?"*

And every day, the answer is the same… Slow down… Love deeper… Appreciate more… And find joy.

It also deepened my faith, giving me the strength to face each new day with hope, courage, and peace. Looking back now, I realize that although multiple sclerosis changed my body, it also transformed my heart. The Christmas of 2021 brought me a diagnosis I never wanted. But it also gave me a new way of seeing life.

Sometimes the greatest blessings don't arrive wrapped in beautiful paper. Sometimes they arrive disguised as the very thing we would never have chosen for ourselves.

For me, the Christmas I received MS became the Christmas I discovered gratitude, resilience, stronger faith, and a deeper appreciation for life. And that is a gift no disease can ever take away. ■

MSAA Receives National Awards



Several of MSAA's free programs and educational resources have received awards from both the **Digital Health Awards®** and **APEX Awards for Publication Excellence**! This year's awards include:



MSAA's podcast episode, "Family Planning – Motherhood and MS"



The Summer/Fall 2025 issue of MSAA's magazine, *The Motivator*



MSAA's educational article series, "What's New in MS Research"



MSAA's Ask the Expert series on our MS Conversations blog



My MS Manager – MSAA's free mobile app for iOS and Android devices

For more information, please visit **mymsaa.org/2026awards**

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Art Showcase



River Tapestry – by Sally MacAllister

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For guidelines, visit **mymsaa.org/artshowcase**

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MSAA welcomes paintings in oil, watercolor, and acrylic, as well as pastels and drawings in pencil and ink. MSAA also accepts digital artwork, including graphic design and photography. All submissions must be sent electronically.

MSAA will accept **3 pieces** of artwork per artist. Artwork will only be accepted from individuals who have MS and are 18 years of age or older.

Submissions will be featured on MSAA's website beginning March 2027, in recognition of MS Awareness Month. MSAA will also highlight 12 artists and their artwork throughout the year.

For more information, please contact:
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