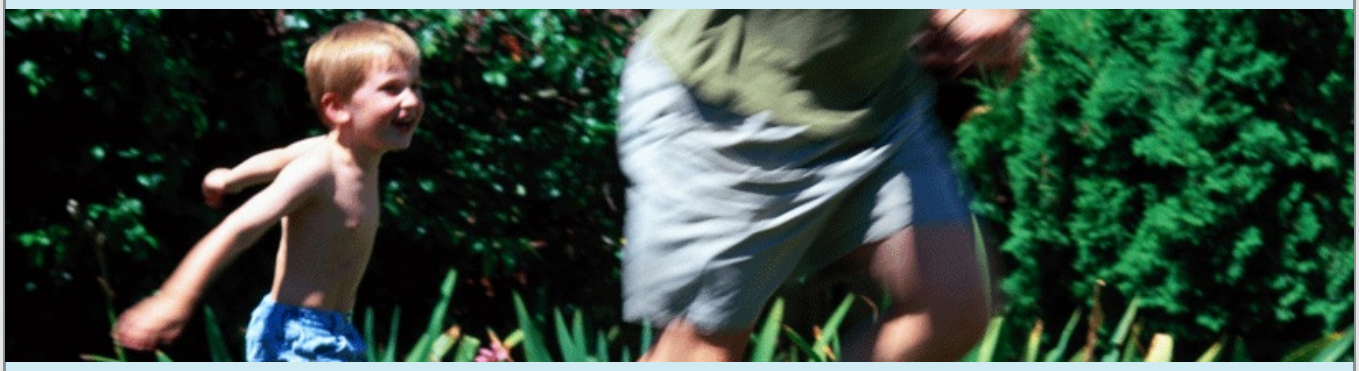
Neuropathy Action Foundation

Awareness ▪ Education ▪ Empowerment

Patient Voice - January 2025 Issue **Visit our Website**



In this Issue

NAF Calls for Increased Awareness of AI

Dear Member,

The NAF recently released a white paper titled "*The Promise and Potential Hazards of Artificial Intelligence (AI) for Neuropathy*." The white paper explores the ways in which AI can positively impact the lives of those living with neuropathy and their families and warns of potential pitfalls if AI in healthcare is not properly regulated. "Researchers and clinicians are already using artificial intelligence to revolutionize research and interventions for patients living with neuropathy, including to diagnose neuropathy earlier, predict disease progression, and to create personalized treatment regimens," said Dominick Spatafora, NAF board president.

In its white paper, the NAF lays out **six broad categories of AI applications** in neuropathy, including:

1. Early Detection and Diagnosis of Neuropathy
2. Predicting the Progression of Neuropathy
3. Managing and Monitoring Symptoms
4. Personalized Treatment Plans
5. Clinical Trials and Drug Discovery
6. Education and Training for Health Care Providers

"Despite its great promise, AI is not without potential pitfalls and risks for patients, including the potential for bias in AI modeling and the use of AI by health insurers to inform coverage determinations and possibly to deny claims. While these hazards could affect all patients, those patients living with neuropathy are more likely to confront diagnostic uncertainty, encounter limited or inadequate treatment options and grapple with barriers to access to care, such as step therapy requirements and claims denials," added Spatafora. "Ongoing awareness and advocacy by patients, families, providers, and policymakers will be necessary to balance the hopes and hazards of AI in the research, diagnosis, treatment, and management of neuropathy."

For patients with neuropathy, AI is increasingly being used in diagnosis, treatment, and management of the condition. To learn more and to access the full white paper please visit **www.neuropathyaction.org** or click on **AI for Neuropathy and Rare Diseases.pdf**.

Diabetic Clinical Trial for Diabetic Peripheral Neuropathy

A small startup in California that manufactures a medical device is hoping to make a

difference for those suffering from diabetic peripheral neuropathy.

The startup, CIONIC, and its product, the Cionic Neural Sleeve1, is a wearable neuroprosthetic designed to provide stimulation to muscles in the upper and lower leg of people with reduced mobility due to upper motor neuron disorders, neurological diseases, or injuries. The assistive technology was deemed safe and usable for impacted populations in a supervised and simulated home environment, evaluated for post market medical device surveillance, and has addressed gait deviations in people with foot drop2.

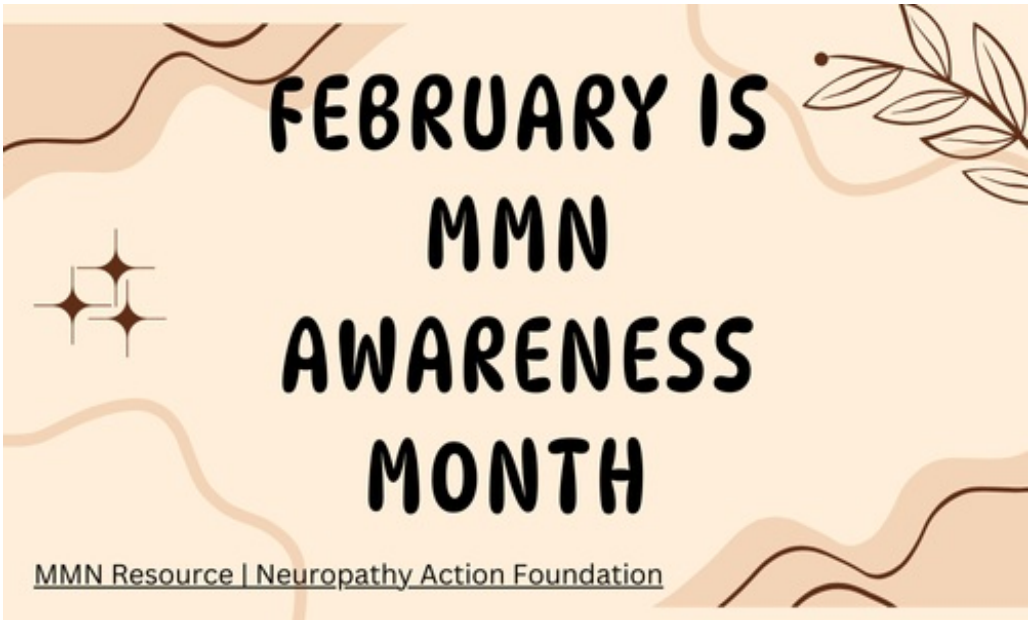
Foot drop, or difficulty lifting the front part of the foot as a result of dorsiflexor weakness, can be a symptom of another disorder, such as peripheral neuropathy3. The prevalence of peripheral neuropathy was estimated to be between 6% - 51% among adults with diabetes4, with painful symptoms typically affecting the feet and legs before it affects the upper limbs5. Treatment for diabetic peripheral neuropathy aims to relieve discomfort and prevent tissue damage, which may include regulating blood glucose levels, getting regular exercise, and taking care of the lower extremities6.

Electrical stimulation to the lower limbs was concluded as an effective therapy to improve symptoms of diabetic peripheral neuropathy7. Although the non-invasive electrotherapy offered by the Cionic Neural Sleeve corrected ankle dorsiflexion and inversion8, and improved quality of life measures9 for individuals with multiple sclerosis, CIONIC seeks to assess the usability of the device for the peripheral neuropathy population and focus on how patients interact and benefit from this novel technology. Thus, CIONIC is seeking volunteers with peripheral neuropathy to wear the Cionic Neural Sleeve and participate in a home use trial.

Ideal candidates are those who …

- Have been diagnosed with diabetic peripheral neuropathy
- Are an adult between the ages of 22 and 75
- Live in Southern California (LA, OC, IE, SD) or Northern California (Bay Area)
- Own a smart phone (iPhone or Android preferred)

If you or someone you care for is interested in getting involved, please contact **trials@cionic.com**.



NAF Encourages CMS to Safeguard Medicare Beneficiaries' Access to Care

The NAF along with nearly 40 other patient organizations sent a letter last month to the Centers for Medicare & Medicaid Services (CMS) to stress the importance that CMS take action to protect Medicare beneficiaries' access to needed therapies as reforms to the Part D program take effect for the upcoming Calendar Year (CY) 2025 and future plan years. The NAF remains concerned that absent further action by CMS, the forthcoming changes could have unintended consequences for the patients we represent.

As the Part D benefit design changes are implemented, plans will see a significant increase in their liability for drug expenditures in the catastrophic phase of coverage. Plans will now be responsible for 60% of costs in the catastrophic phase beginning next year, up from 15% in 2023. The higher level of cost sharing for prescription drug plan (PDP) creates incentives for plans to expand their use of utilization management (UM) tools such as step therapy, prior authorizations, refill limits, and changes in formularies. While these tools are intended to limit expenditures, the increased use of UM threatens to restrict patient access to therapies and increase out-of-pocket costs for beneficiaries.

Step therapy, for example, requires a patient to "fail first" on a less expensive treatment before being allowed to proceed to higher-cost therapies. Unfortunately, step therapy can lead to decreased access to the most appropriate therapies for a patient's medical needs, as well as delays in care that can lead to worse health outcomes and disease progression as an individual works through the "steps." Moreover, step therapy protocols may differ from clinical guidelines and decisions made between patients and their doctors. However, step therapy is but one example of a UM tool that may be utilized even more by plans going forward as the Part D benefit redesign goes into effect.

We appreciate that CMS has indicated it will monitor changes in formulary design and

acknowledged that plans, for most classes, may implement tools such as step therapy, prior authorization, and drug quantity limits; however, we believe more action is needed to protect beneficiaries' access to medically necessary therapies in 2025 and beyond. We urge the agency to take additional steps to support patients by increasing the transparency regarding the use of UM by PDPs, enhancing efforts to educate beneficiaries about potential changes to their plans related to UM, and providing additional details about what actions CMS is taking to ensure there is no inappropriate UM activity.

Congressional Spending Bill Falls Short on Home Infusion

The National Home Infusion Association (NHIA) expressed deep concern last month regarding the recently proposed government funding bill, which includes major changes to the qualifying criteria for drugs under Medicare's home infusion benefit but fails to address the underlying flaws that have plagued the program. Without fixing the structure of the benefit, Medicare beneficiaries in need of home infusions for treatment of a variety of medical conditions, including rare diseases, are unlikely to gain access to home-based care.

"The current home infusion benefit under Medicare is an outlier compared to the well-established commercial model and has failed to engage providers or patients. Expanding the list of eligible drugs without fixing these systemic barriers will result in less access than exists today," said Connie Sullivan, BSPharm, President and CEO of NHIA.

First launched in 2019, Medicare's home infusion therapy (HIT) services benefit has failed to achieve its promise of delivering patient access to home infusion. According to **CMS data**, several U.S. states haven't registered a single home infusion service visit. The same report found that less than 1,500 Medicare beneficiaries are receiving home infusion services each calendar quarter — and provider participation in the benefit has steadily declined since implementation. By contrast, passing the Preserving Patient Access to Home Infusion Act with changes proposed by NHIA could make home infusion available to hundreds of thousands of Medicare beneficiaries while significantly **reducing federal spending**.

NHIA is calling on Congress to urgently pass the Preserving Patient Access to Home Infusion Act, which would fix the broken home infusion benefit, reduce the cost of care, and broaden access. This bipartisan legislation — which enjoys support from **dozens of stakeholder organizations** (including the NAF) and was widely supported at a **hearing** in the House Ways & Means Committee this year — includes critical reforms that will ensure beneficiaries living in rural areas and those with disabilities who depend on home access can find a qualified provider.

FDA’s Neurology Drug Program

The American Brain Coalition (ABC) along with 99 other groups (including the NAF) requested that Congress provide $5 million as proposed by the Senate Appropriations Committee for FDA’s Neurology Drug Program. Funding at this level, an increase of $3 million, will help advance discoveries in all areas of brain health including neurodevelopmental, neurodegenerative, psychiatric, brain injuries, and more.

ABC sent the letter with 99 signatories to the Hill, and is pleased to report that 33 additional organizations signed-on following ABC’s October forum with FDA representatives. The NDP forum was a very well attended event where FDA shared updates on the NDP program and ABC members had the opportunity to ask about the NDP’s current and future plans. ABC is grateful to FDA for sharing these updates on their work across the neuroscience space and for engaging in discussion with ABC members.

A copy of the final letter can viewed at: **ABC’s FDA Neurology Drug Program (NDP) FY 2025 sign-on letter**.

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