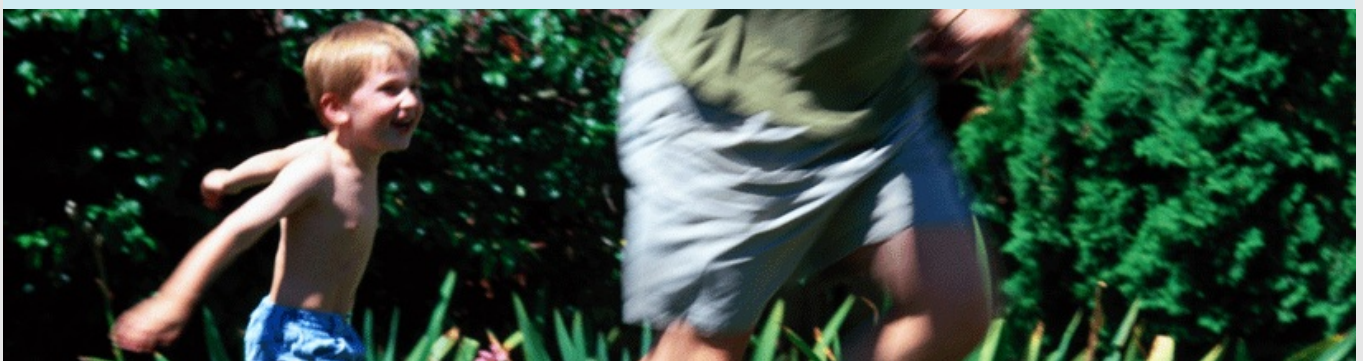




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## In this Issue

- ▶ NAF Board Member News
- ▶ Electrodiagnostic Services and Medicare
- ▶ Superfoods: Separating Fact from Fiction
- ▶ Takeda Presents Full Data Set from Phase 3 ADVANCE-CIDP 1 Clinical Trial Investigating HYQVIA® as a Maintenance Therapy for CIDP
- ▶ Have You Experienced Health Insurance Denials, Delays, Out of Network

## NAF Board Member News

**Dear Scott,**

On July 11 the American Osteopathic Association (AOA), the professional membership organization for the nation's more than 178,000 osteopathic physicians (DOs) and medical students, announced that after an extensive national search, its Board of Trustees has appointed Kathleen S. Creason, MBA, as Chief Executive Officer (CEO). Kathleen has served as the AOA's Interim CEO for the past six months and brings nearly two decades of leadership experience within the osteopathic profession to the role. Previously, she served as Executive Director of the American Osteopathic Information Association (AOIA) and prior to that as Executive Director of the Osteopathic Physicians & Surgeons of California.

As CEO, Creason will oversee strategic vision, operations, organizational growth and advocacy for the osteopathic profession. "We are absolutely thrilled to have someone with Ms. Creason's extensive experience and expertise assume the CEO role," said AOA President Ernest R. Gelb, DO. "She possesses a deep knowledge of the osteopathic profession and a keen business acumen, both of which will enable her to make a significant impact as our profession continues to grow and evolve into the future."

Kathleen is a Board Member of the Neuropathy Action Foundation (NAF) and currently serves as its Treasurer. "Kathleen has been involved with the NAF and the neuropathy community for over ten years and is one of the most committed, hardest working, authentic people I have ever had the pleasure of working with, said NAF Founder and President Dominick Spatafora. "Kathleen is a champion of patients, providers and the neuropathy community and I could not be more proud of her accomplishment."

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## Electrodiagnostic Services and Medicare

The *Electrodiagnostic Medicine Patient Protection and Fraud Elimination Act* has been reintroduced in the 118<sup>th</sup> Congress as H.R. 2639. The NAF not only supports the legislation, but recently joined numerous other provider and patient groups by signing a letter of support to leaders in Congress. Electrodiagnostic (EDX) medicine, which includes nerve conduction studies, needle electromyography, and similar procedures is used to diagnose and treat a variety of conditions. EDX testing may diagnose a common condition such as a pinched nerve or carpal tunnel, or rare diseases like ALS, muscular dystrophies, and neuropathies. Any delay in an accurate diagnosis could severely impact a patient's prognosis and alter their treatment or ability to access a clinical trial. Misdiagnosis can also drive unnecessary surgeries and inappropriate courses of therapy.

H.R. 2639 will improve patient care and eliminate fraud and abuse in EDX testing. This legislation seeks to ensure patients gets the right tests at the right time by creating a compliance mechanism for existing CMS rules governing EDX studies by requiring professionals performing the studies to

simply demonstrate that they have the correct equipment along with the correct training to perform/supervise the tests and make a diagnosis. Such an approach has been successful in other areas of patient care where quality was problematic and fraudulent testing was rampant, namely sleep labs and mobile mammography labs.

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## Superfoods: Separating Fact from Fiction

By: Emily Cooper, RDN

IG Living magazine

Trendy, nutrient-dense foods are all the rage, but is the hype (and the price tag) really worth it?

What comes to mind when you hear the term “superfood”? The Merriam-Webster dictionary defines a superfood as “a food (such as salmon, broccoli or blueberries) that is rich in compounds (such as antioxidants, fiber or fatty acids) considered beneficial to a person’s health.”

While today’s idea of a superfood may be trendy, the term has humble beginnings. In fact, the term “superfood” did not originate from a medical doctor, food scientist or dietitian, but rather came from a fruit company’s marketing campaign to promote bananas around World War I. It gained wild popularity in the late 2000s, and it remains fashionable today. In fact, it is still used in much the same way as it began — as a marketing tool to push particular foods. As of 2015, sales of foods promoted as a “superfood,” “superfruit” or “supergrain” were up 36 percent globally.

If you’re confused by or unsure about superfoods, you’re not alone. There are lots of misconceptions. Let’s dive a little deeper into the most common by separating fact from fiction.

Links to rest of article at:

[IG Living February-March 2023](#)

Page 38 is article

## Takeda Presents Full Data Set from Phase 3 ADVANCE-CIDP 1 Clinical Trial Investigating HYQVIA® as a Maintenance Therapy for CIDP

On June 20 Takeda announced full results from the pivotal Phase 3 ADVANCE-CIDP 1 clinical trial investigating HYQVIA® [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] as maintenance therapy in adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP). Results showed a clinically significant reduction in relapse rate with HYQVIA vs placebo (9.7% versus 31.4%, respectively;  $p = 0.0045$ ) and other analysis showed delayed time to relapse with HYQVIA vs. placebo. The company also observed favorable data across other endpoints from the study and favorable tolerability. These findings were presented at the 2023 Peripheral Nerve Society (PNS) Annual Meeting in Copenhagen, Denmark on June 20,

2023, and simultaneously published in the *Journal of the Peripheral Nervous System (JPNS)*.

CIDP is an acquired, immune-mediated condition affecting the peripheral nervous system that is characterized by progressive, symmetric weakness in distal and proximal limbs and impaired sensory function in extremities.<sup>1</sup> The role of immunoglobulin (IG) therapy for this rare, debilitating and slowly progressing or relapsing disease has been well-established.<sup>2</sup> IG is considered a standard of care for this complex and heterogeneous disease due to its broad immunomodulatory and anti-inflammatory effects. However, the high volume and frequency of treatment required to effectively manage this disease means that treatment can be a burden for patients and their health care providers.

“The results from the ADVANCE-CIDP 1 trial are encouraging for adults with CIDP who require maintenance treatment by offering the potential for a facilitated subcutaneous IG administration option with up to once-monthly dosing (every 2 to 4 weeks),” said Kristina Allikmets, senior vice president and head of Research & Development for Takeda’s Plasma-Derived Therapies Business Unit. “We are committed to expanding our portfolio of differentiated plasma therapies into new indications to further realize the tremendous therapeutic value of immunoglobulins in addressing the needs of patients with neuroimmunological disorders.”

ADVANCE-CIDP 1 is a Phase 3, prospective, randomized, double-blind, multicenter, placebo-controlled study in which adults with stable CIDP on intravenous immunoglobulin (IVIG) were randomized 1:1 to be switched to HYQVIA (n=62) or placebo (n=70) and received their assigned treatment for six months or until relapse or study withdrawal. The primary endpoint was proportion of participants who experienced a relapse defined as worsening of CIDP symptoms as measured by Inflammatory Neuropathy Cause and Treatment (INCAT). Secondary endpoints included patient proportion experiencing functional worsening, time to relapse, change from pre-subcutaneous treatment baseline in Rasch-built Overall Disability Scale (R-ODS) centile score and safety. Key findings showed:

- HYQVIA showed a clinically significant reduction in relapse rate compared to placebo, 9.7% (95% CI: 4.5%, 19.6%) and 31.4% (95% CI: 21.8%, 43.0%), respectively (p = 0.0045).
- HYQVIA showed a lower probability of functional worsening rates versus placebo (37.5% vs 54.4%) (95% CI –33.02%, 0.69%).
- Patients receiving HYQVIA experienced longer time to relapse compared to those receiving placebo, with the Kaplan–Meier curves separating early, at approximately Week 4.
- Change in R-ODS centile scores were lower in the HYQVIA group than the placebo group (least-squares mean difference [standard error] –6.1 [1.64] vs –0.9 [1.69], respectively).

The safety profile of HYQVIA in the ADVANCE-CIDP 1 trial was generally consistent with the existing EU Summary of Product Characteristics. Infusion characteristics were well-matched between HYQVIA (n = 600 infusions) and placebo (n = 647 infusions) groups, with <1% of all infusions affected by intolerability and/or AEs. In the HYQVIA (n=62) treatment arm, the most common causally-related local AEs (>5% of patients) included injection and infusion site pain and erythema, and infusion site edema and pruritus. The most common causally-related systemic AEs (>5% of patients) included headache, nausea, fatigue and pruritus.

“For patients with CIDP who need immunoglobulin treatment, the ADVANCE-CIDP 1 study results are encouraging,” said Dr. Robert Hadden, Consultant Neurologist, Dept. of Neurology, King’s

College Hospital, London. “If approved as a maintenance therapy for CIDP, this treatment may combine the ability to have subcutaneous treatment at home with less frequent infusions.”

The majority (88.7%) of patients receiving HYQVIA in the study received a four-week dosing interval and the mean time to deliver treatment was 125.9 minutes. The mean monthly dose equivalent was equal to 1.1 g/kg for patients receiving HYQVIA. The majority (86.3%) of patients received study treatment using two infusion sites per treatment, while 9.6% and 3.7% used one and three infusion sites, respectively.

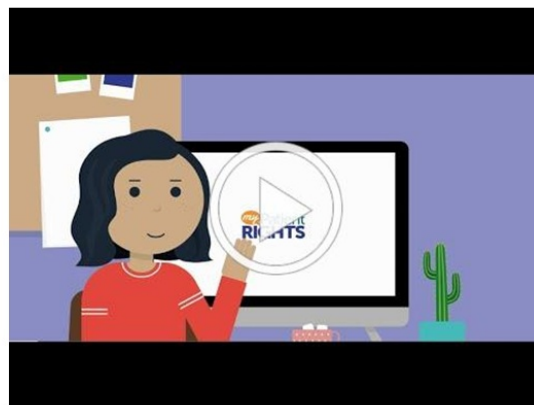
HYQVIA is currently under regulatory review in the U.S. and European Union for use as a maintenance therapy in adult patients with stable CIDP.

Further information about the ADVANCE-CIDP 1 clinical trial is available at ClinicalTrials.gov under study identifier [NCT02549170](https://clinicaltrials.gov/ct2/show/study/NCT02549170).



Need help with your health insurance?

Be sure to check out [mypatientrights.org](https://mypatientrights.org) !!



## Have You Experienced Health Insurance Denials, Delays, Out of Network Charges, Etc.?

My Patient Rights is a website inspired by actual patients who have experienced denials, delays, high out-of-pocket costs, out-of-network charges and other barriers to quality, affordable health care from their health plans. These patients want to make it easier for you to understand how to resolve issues with your health plan, reach the applicable government agencies, file a complaint and get the health care you deserve.

If your health plan has denied any health care services or prescriptions – or if you have experienced any other barriers with your health plan that leave you dissatisfied, My Patient Rights can help you resolve these problems. My Patient Rights is designed to help people who have been denied treatment or medicines, experienced delays or are dissatisfied with the decisions made by their health plan. It also serves as a platform for people to tell their health care stories so they can be learned from and shared to help increase accessibility, affordability, and quality of health care. If you need help or want to speak up please visit [MyPatientRights.org](https://MyPatientRights.org).

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