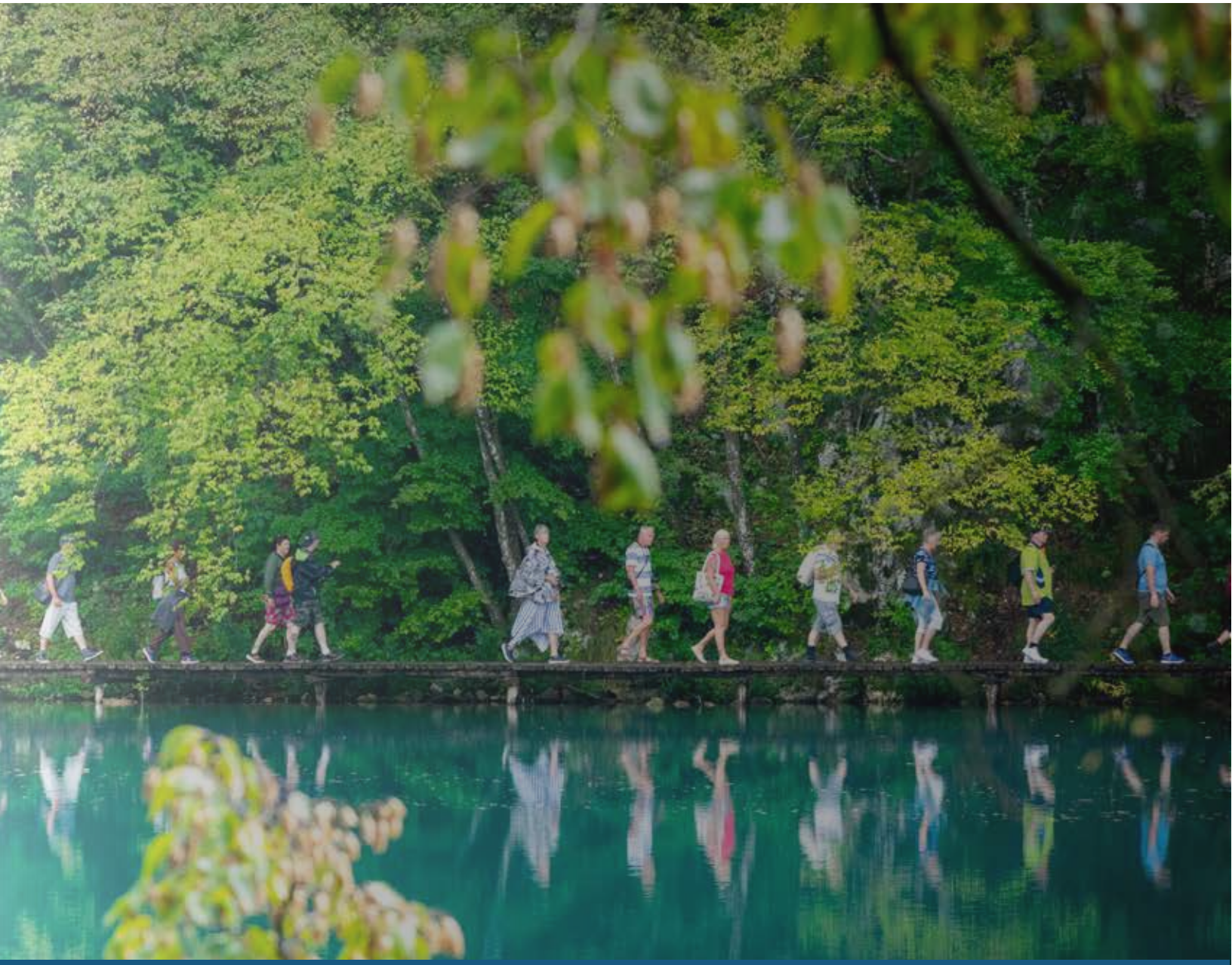
Neuropathy Action Foundation

Awareness • Education • Empowerment



IVIG for Neuropathy

Michelle Greer, RN, IgCN

Jonothan S. Katz, MD

The Neuropathy Acton Foundation (NAF), a 501(c)(3) non-profit, is dedicated to ensuring neuropathy patents obtain the necessary resources, information and tools to access individualized treatment to improve their quality of life. The NAF increases awareness among physicians, appropriate institutions, the general public and public policy officials that neuropathy can potentially be a serious, widespread and disabling condition, which may be treatable when appropriate medical care is provided.

Our Vision

The Neuropathy Action Foundation (NAF) will be a premiere patient advocacy organization ensuring that neuropathy patients have access to individualized medications, IVIG and other treatments through patient empowerment and advocacy.

Our Goals

Patient Empowerment: The NAF educates and assists neuropathy patients on how to become informed advocates for their healthcare.

Public Awareness and Physician Education: The NAF actively supports programs that create public and physician awareness of neuropathy, the use of IVIG and other remedies to improve patient care through NAF activities and services.

IVIG stands for intravenous immune globulin. Immune globulins are antibodies, a key component of the immune system. IVIG is made from donated human blood plasma. There are many brands manufactured by various companies, and although in general they possess similar attributes, specific manufacturing processes makes each product unique.

IVIG treats many different diseases where there is either a deficiency of antibodies or if there is an "autoantibody" where the body starts to attack itself. IVIg is used to treat certain neuropathies that fall into the category of being "autoimmune". Although there are many types of neuropathy, only a small percentage are the result of an autoimmune condition. Depending on the type, treatment can be short term, long term or for life.

People who receive IVIG should notice an improvement in symptoms. Neuropathy patients get IVIg to suppress the attack on oneself. This turns off the autoimmunity and leads to improvement in the weakness, sensory loss, and loss of function that are part of neuropathy. If you are receiving IVIG and do not notice any improvement over time, you should discuss this with the prescribing physician.

IVIG can be given in a hospital outpatient setting, a physician's office or at home. You should speak with your physician about which site of care is best for you. Although this is a complex infusion, it is very commonly and successfully administered in the home setting, where is may offer a level of comfort and convenience.

When IVIG is ordered and the decision is made where it will be given, the infusion team typically ensures that health insurance will cover the product. Payers have different sets of criteria for how IVIG is covered. There is a prior authorization process in almost all cases and it is sometimes challenging to obtain approval. In general, payers want to know that the diagnosis and medical necessity for treatment have been clearly documented. Documentation from clinical appointments and testing are submitted to the insurance, who decide if treatment is approved or denied. Denials can occur when documentation does not clearly show a diagnosis that requires treatment with IVIG. The challenge for the authorization process relates to the many forms of neuropathy that can

have similar findings and the expertise that is often needed in this area of medicine. In most cases, with the right documentation, authorization can be successful.

Once prior auth is obtained, the infusions are scheduled. Patients should receive education to set expectations about side effects and how to mitigate them. Infusion-related side effects may include flu-like symptoms: headache, nausea, vomiting, chills, fever, body aches and dizziness. Blood pressure changes can also occur. Most infusion protocols include premedication with acetaminophen and diphenhydramine that can help offset these reactions. Some physicians add additional pre-therapies based on their preferences, or they may add some medications based on the person's prior medical history. For example, if the person has a history of migraines, they might be asked to take migraine medication as part of the premedication protocol. These medications may also be repeated during and after the infusion as needed.

Neuropathy patients get IVIg to suppress the attack on oneself. This turns off the autoimmunity and leads to improvement in the weakness, sensory loss, and loss of function that are part of neuropathy.

Hydration is also very important while on IVIG. Some physicians will suggest intravenous fluids as a part of the premedication protocol to ensure adequate hydration. Unless there is an usual circumstance where increased fluids would be contraindicated, you should try to drink up to 6-8 glasses of water daily while on therapy.

Less common side effects include:

Anaphylaxis – a severe allergic reaction to IVIG. Regardless of site of care, access to medications given for anaphylaxis must be readily available in the event this occurs.

Renal dysfunction or failure – this is a black box warning on the prescribing information for IVIG. This is due to this reaction occurring originally to a sucrose stabilizer in an IVIG formulation no longer available. Some products contain a sugar-derivative to stabilize the solution. Most on the market these days are sugar-free. If there is a history of renal issues or if there is a history of diabetes, a sugar-free product should be used. Additional, blood tests to monitor renal function will be done.

Thrombosis – this is another black box warning and can occur as a clot in the peripheral veins or in an organ such as the lungs, brain or heart. If there is a history of thrombosis or there are risk factors associated with a potential for this to occur, additional premeds might be necessary. It doesn't mean IVIG cannot be successfully implemented. Extra precautions may be needed.

Aseptic meningitis syndrome (AMS) – this is an inflammation in the lining of the brain that occurs in the absence of some sort of bacteria or virus. The person can experience severe headache accompanied by neck stiffness, nausea and vomiting and light sensitivity. Some studies have shown that people with a history of migraines may be at a higher risk for this adverse reaction.

All of these side effects are best managed simply by ensuring that IVIg infusions run at a rate the patient tolerates. Although prescribing information always contains suggested maximum infusion rates, it is always best to start slowly to assess tolerability. Rates can be gradually increased at predetermined intervals to allow the body to adjust to the antibodies, up to some predetermined maximum infusion rate.

There is no set dosing for IVIG for any of the conditions. Dosing depends on a combination of factors including MD preference, suggestions in literature and product inserts, patient health and responses to prior treatment with IVIG. Exact dosing is based on the person's weight and may be adjusted to an ideal body weight. Sometimes dosages are slightly refined to fit with IVIG vial sizes and insurance reimbursement. In the end, the infusions may take several hours per day, and may be done between one and five days per week and repeated in cycles. Depending on response, these cycles may occur weekly, every other week, every three weeks or monthly. It is all up to the MD and dispensing pharmacy to make the exact recommendations for each individual.

In summary, IVIG can be a life altering therapy. Most people tolerate the infusions with few side effects, while the physical improvements allow them to live their lives to the fullest.

MICHELLE GREER, RN, IgCN, is senior vice president of sales for Nufactor, a Specialty Infusion Company.

(800) 323-6832 | www.nufactor.com

JONATHAN S. KATZ, MD is the director of neuromuscular disease program at the Forbes Norris ALS/MDA Center in San Francisco.

(415) 600-3604 | www.sutterhealth.org

Neuropathy Action Foundation

Awareness ▪ Education ▪ Empowerment

1950 Old Tustin Avenue
Santa Ana, CA 92705

(877) 512-7262
info@neuropathyaction.org

nufactor®

A SPECIALTY INFUSION COMPANY

44900 Winchester Road
Temecula, CA 92590

(800) 323-6832
nxinfo@nufactor.com