April-May 2024

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PI & Aging

How to Stay Socially Active

A Guide to Traveling with IG Therapy

IG Therapy for Neuropathy: An Individualized Approach

Medical Hypnosis: Hope for Patients

Treatments for MMN

FOR PATIENTS WITH PRIMARY HUMORAL IMMUNODEFICIENCY (PI)

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Important Safety Information for ASCENIV™

WARNING: RISK OF BLOOD CLOTS (THROMBOSIS), POOR KIDNEY FUNCTION, AND INABILITY TO FILTER WASTE FROM KIDNEYS. BLOOD CLOTS MAY OCCUR WITH INTRAVENOUS IMMUNE GLOBULIN PRODUCTS, INCLUDING ASCENIV.

Before taking ASCENIV, talk to your doctor if you:

- Are of advanced age
- Are unusually sedentary (long periods of sitting down or inactive)
- Are taking estrogen-containing medicines (birth control pills, hormone replacement therapy)
- Have a permanent intravenous (IV) catheter
- Have hyperviscosity of the blood (diseases such as multiple myeloma or other causes of elevated proteins in the blood)
- Have cardiovascular (heart) problems or previous history of stroke

Thrombosis may occur even if you do not have any risk factors.

Serious kidney problems and death can also happen in certain patients who receive such products.

If you are at high risk of thrombosis or kidney problems, your doctor should adjust the dose of ASCENIV and will monitor you for signs and symptoms of thrombosis and viscosity, as well as kidney function.

What is ASCENIV (immune globulin intravenous, human)?
ASCENIV (immune globulin intravenous, human) is a prescription medicine to help adults and adolescents (12 to 17 years old) with primary immunodeficiency fight and prevent infections.

ASCENIV is for intravenous administration only. ASCENIV is made from healthy human blood/plasma.

Who should not use ASCENIV?
ASCENIV should not be used if you had a severe allergic reaction to human immune globulin or if you have been told by a doctor that you are immunoglobulin A (IgA)-deficient and have developed antibodies to IgA and hypersensitivity after exposure to a previous plasma product.

What are possible warnings and precautions with taking ASCENIV?
Hypersensitivity. Severe allergic reactions may occur with immune globulin products, including ASCENIV. If you have a severe allergic reaction, stop the infusion immediately and get medical attention. ASCENIV contains IgA. If you have known antibodies to IgA, you may have a greater risk of developing potentially severe allergic reactions.

If you take ASCENIV or a similar immune globulin product, you could experience a serious and life-threatening blood clot (thromboembolism). This may include pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness, or weakness on one side of the body. If you are at risk, your doctor may decide to adjust the dose of ASCENIV. Your doctor will monitor you for any signs or symptoms of blood clots or poor blood flow in your arteries.

Always tell your doctor immediately if your medical history is similar to what is described here, and especially if you experience any of these symptoms while taking ASCENIV.

Kidney problems or failure. Kidney problems, kidney failure, and death may occur with use of human immune globulin products, especially those containing sucrose (sugar). ASCENIV does not contain sucrose.

If you have kidney disease or diseases with kidney involvement, your doctor should perform a blood test to assess your hydration level and kidney function before beginning immune globulin treatment and at appropriate intervals thereafter. If your doctor determines that kidney function is worsening, they may discontinue treatment. If your doctor determines you to be at risk, they may start your dose of ASCENIV at a safe level.

People taking human immune globulin products, including ASCENIV, may experience hyperproteinemia (high levels of protein in the blood), hyponatremia (low levels of sodium in the blood), and hyperviscosity (poor blood flow). Your doctor may perform certain blood tests and monitor you to minimize any of the above risks.

Aseptic meningitis syndrome (AMS). Aseptic meningitis is a non-infectious inflammation of the membranes that cover the brain. It causes a severe headache, which may occur with human immune globulin treatment, including ASCENIV. AMS usually happens within a few hours to 2 days after treatment. AMS is more commonly associated with higher doses of treatment and/or after rapid infusion. Your doctor may perform a neurological exam, including spinal tap (sampling fluid which surrounds the spinal cord) to evaluate your condition and to rule out other causes of meningitis.

Hemolysis. Hemolysis refers to the destruction of red blood cells. Immune globulin products, including ASCENIV, may contain certain antibodies that can result in the rupturing of red blood cells. Your doctor should monitor you for signs and symptoms of hemolysis, which may include additional confirmation tests.

Taking intravenous human immune globulin products may cause a build up of fluid in the lungs (pulmonary edema) that is unrelated to heart problems. Your doctor should monitor you for lung-related side effects and may conduct appropriate tests that can detect the presence of certain white blood cells (anti-neutrophils) in the drug or your blood. If needed, your doctor may decide to use oxygen or other respiratory methods to help your breathing.

Transmissible infectious agents. Because ASCENIV is made from human blood, it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. Your doctor will report to the manufacturer any cases of suspected infections spread by the product.

Interference with lab tests. Because ASCENIV contains a variety of antibodies that are infused into your body, blood tests to determine antibody levels may provide misleading interpretations. Be sure to always tell your doctor, nurse, or lab technician of any medicines you are taking and that you are using ASCENIV.

Interactions with medicines. ASCENIV can make vaccines (like measles, mumps, rubella, and chicken pox vaccines) less effective in your body. Before you get any vaccines, tell your healthcare provider that you take ASCENIV.

What are other possible side effects of ASCENIV?
In clinical studies of ASCENIV, some patients experienced the following:

- Headache
- Sinus inflammation (sinusitis)
- Diarrhea
- Intestinal lining inflammation caused by virus (gastroenteritis)
- Common cold (nasopharyngitis)
- Upper respiratory tract infection
- Bronchitis
- Nausea

These are not all the possible side effects of ASCENIV. Talk to your healthcare provider about any side effect that bothers you or that does not go away.

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.

For additional safety information about ASCENIV, please see full Prescribing Information at www.asceniv.com

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Features

Up Front

Columns

Sources

Departments

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About IG Living
IG Living magazine brings together patients, advocates and caregivers in the immune globulin (IG) community.

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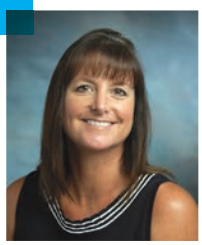
Engaging in Life for Improved Outcomes



LIVING WITH a chronic illness can sometimes feel as though there are insurmountable challenges. It can be isolating, frustrating and scary. But rather than passively accepting the hand you are dealt, it is possible to instead engage in life by focusing on the things you can control such as obtaining social support, traveling and embracing therapies that may provide additional relief for your symptoms.

Staying socially active with a primary immunodeficiency (PI), especially when getting older, can be difficult. No doubt, the spread of the "big three" respiratory viruses — COVID-19, influenza and respiratory syncytial virus — may make you hesitant to be around others for fear of getting sick. But, as we explain in our article "Staying Socially Active with PI — Especially When Aging" (p.20), while the last thing you want to do is expose yourself to something that could make you seriously ill, it's important to understand that over time, social isolation and loneliness can make you sick, too, putting you at higher risk for a number of illnesses such as high blood pressure, heart disease, a weakened immune system, anxiety, depression and more. And, getting older doesn't help! It's a fact that as people age, their social circles get smaller. Therefore, we offer 10 suggestions for how to keep socially active that can be vitally important to your overall health.

It's easy to just be content with staying home to avoid getting sick and/or hassling with the worry about getting needed treatment, but living with a chronic condition shouldn't keep you from getting together with family and friends, exploring new destinations and making new memories. So, if travel is something you've put on the back burner because you are worried about transporting your immune globulin (IG) supplies, we outline steps to minimize stress and maximize confidence for your next travel adventure in our article "Planes, Trains and Automobiles: Traveling with IG Therapy" (p.28). Whether you want to fly, ride or drive to your destination, planning and preparation can help you travel with confidence.

While IG therapy is a miracle drug — especially for those with PI, autoimmune conditions and neuropathies — there are also other treatments that may provide relief for symptoms of these conditions. Hypnosis is often an underutilized therapy; many consider it contrived, but it actually can be an effective treatment for chronic pain and other symptoms of chronic illness. In our article "Medical Hypnosis: Evidence-Based Therapy for Chronic Pain and More" (p.32), we explain how hypnosis works and how research validates its effectiveness.

As always, we hope you enjoy these articles, as well as the many more educational and insightful topics presented in this issue of *IG Living*.

Ronale Tucker Rhodes

Ronale Tucker Rhodes, MS

IGLiving

Our mission is to support the IG community through education, communication and advocacy

A community service from FFF Enterprises, Inc.

Publisher **Patrick M. Schmidt**
Editor **Ronale Tucker Rhodes, MS**
Associate Editor **Rachel Maier, MS**
Art Director **Allan Bean**

Contributing Writers

Wendie Chadd
Abbie Cornett, MBA
Michelle Greer, RN, IgCN
Terry O. Harville, MD, PhD
Suze Kopynec, MPAS, PA, ASCH
Jessica Leigh Johnson
Mairead McConnell, PhD
Beth McNeal, OTRL, CHT
Trudie Mitschang
Surayyah Morris, PharmD
Megan Ryan
Michelle Searle

Navigating the Ethical Landscape of AI in Medicine

By Abbie Cornett, MBA

IN LESS than a century, the trajectory of technological advancement has been nothing short of astonishing. I recall conversations with my great grandmother, who was born in the 1880s, who vividly described the transition from riding a horse to school to witnessing Neil Armstrong's historic moonwalk in 1969. I never anticipated I would one day experience a similar sense of awe, reflecting on the rapid strides technology has made since those conversations.

The shift from horse-drawn carriages to the marvel of rockets my grandmother saw was astounding, but the progress of the last 50 years has been unparalleled. Scientific breakthroughs since then have propelled us from rotary phones to the ubiquity of cell phones, and from rudimentary word processors to laptops boasting capabilities surpassing the banks of computers that facilitated Armstrong's moonwalk.

The journey of medical discovery during this period has been equally remarkable. It began with a budding understanding of deoxyribonucleic acid (DNA) and the cloning of Dolly the sheep in 1996, which evolved into the revolutionary realm of DNA editing and CRISPR technology (short for "clustered regularly interspaced short palindromic repeats") that can be programmed to target specific stretches of genetic code and edit DNA at precise locations. From there, it moved on to allow scientists to quickly create cell and animal models that can be used to accelerate research into diseases such as cancer and other genetic disorders, and now it is embarking into the latest frontier: artificial intelligence (AI).

AI, which refers to the simulation of human intelligence by software-coded heuristics, holds immense promise, particularly in the field of medicine. From diagnostics to treatment, the technology offers potentially unprecedented precision and efficiency. Yet, this marvel also raises ethical concerns and potential challenges in its implementation, especially for patients.

Some of the most pressing concerns for patients center on data security and privacy. The vast amount of sensitive patient data processed by AI systems raises concerns about data breaches and unauthorized access. Therefore, safeguarding patient privacy must be a paramount consideration in the integration of AI into medical practices.

Moreover, a significant concern arises regarding AI's ethical application in the healthcare decision-making processes. Despite the capability of AI systems to swiftly and accurately evaluate and treat patients by processing extensive medical data, there is a potential risk. While AI can enhance diagnostic accuracy and provide optimal treatment recommendations much faster than human physicians, there is a concern about overreliance on algorithmic outputs, which could sideline the human touch in healthcare.

And, while the loss of the human touch is significant for all patients, the risks of using AI for patients with rare or chronic illnesses are more pressing. Each rare disease is is linked only to a small number of patients whose disease tends to present in the same or similar ways. That makes it hard to collect the data AI needs to accurately predict diseases and outcomes, especially for atypical cases. However, machine learning algorithms are being developed to leverage existing electronic health records to identify patterns and predict the likelihood of specific rare diseases. Analyzing large datasets provides a valuable tool for early detection and intervention, potentially improving outcomes for patients with rare conditions. As AI algorithms continue to learn and refine themselves, there is optimism that they can overcome some of the limitations associated with data scarcity and contribute to advancements in rare disease diagnosis and treatment.

Navigating the shift from horse-drawn carriages to AI-driven medical breakthroughs underscores the swift pace of technological evolution. But, as we observe the remarkable progress of AI in medicine, it's crucial to acknowledge the potential drawbacks of its rapid growth. Collaborative efforts among scientists, policymakers and the public are vital for the responsible development and deployment of AI in this field. Strict regulations, transparent guidelines and continuous ethical discussions are imperative to ensure a positive trajectory.

References

1. National Human Genome Research Institute. Deoxyribonucleic Acid. Accessed at www.genome.gov/genetics-glossary/Deoxyribonucleic-Acid.
2. Dolly the Sheep Becomes First Successfully Cloned Mammal. History, July 5, 2023. Accessed at www.history.com/this-day-in-history/first-successful-cloning-of-a-mammal.
3. Broad Institute. Questions and Answers About CRISPR. Accessed at www.broadinstitute.org/what-broad/areas-focus/project-spotlight/questions-and-answers-about-crispr.
4. Frankenfield, J. Artificial Intelligence (AI): What It Is and How It Is Used. Investopedia, Dec. 4, 2023. Accessed at www.investopedia.com/terms/a/artificial-intelligence-ai.asp.
5. Krishnan, G, Singh, S, Pathania, M, et al. Artificial Intelligence in Clinical Medicine: Catalyzing a Sustainable Global Healthcare Paradigm. *Frontiers in Artificial Intelligence*, 2023;6:1227091. Accessed at www.ncbi.nlm.nih.gov/pmc/articles/PMC10497111.
6. Khan, B, Fatima, H, Qureshi, A, et al. Drawbacks of Artificial Intelligence and Their Potential Solutions in the Healthcare Sector. *Biomedical Materials & Devices*, 2023 Feb 8:1–8. Accessed at www.ncbi.nlm.nih.gov/pmc/articles/PMC9908503.

ABBIE CORNETT, MBA, is the patient advocate for *IG Living* magazine. She can be reached at patient advocate@igliving.com or (800) 843-7477 x1366.

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What Types of Medicare Policies Cover Hizentra in the Home for CIDP?

I was diagnosed with chronic inflammatory demyelinating polyneuropathy (CIDP) in 2015, and I am retiring at the end of this month (I am a primary care physician) and transitioning to Medicare. I am in the 10 percent of patients who still require "booster" infusions of intravenous immune globulin (IVIG) approximately every 10 weeks, even though I transitioned to self-administered weekly subcutaneous IG (SCIG; Hizentra) in 2019.

I have worked with a consultant who states the IVIG infusions will be much better covered at an infusion center billed through Parts B and C rather than trying to have it covered as a home infusion through Part D. Additionally, Hizentra is also covered by Parts B and C, but are the associated supplies for this diagnosis covered as well?

Abbie: I spoke with Leslie Vaughan, RPh, CSP, IgCP, chief operations officer at Nufactor, a specialty infusion company, who said periodic IVIG infusions for CIDP will not be covered by Medicare Part B in the home setting. They may be covered by Part D or via Medicare Advantage with prior authorization, and a Part D drug copayment may apply. Nursing and supplies might be covered with a Medicare Advantage plan, but there is no coverage for nursing or supplies with a stand-alone Part D plan. The periodic IVIG infusions, nursing and supplies would be covered by Medicare Part B if administered in a hospital or an outpatient infusion center that has a Medicare prescriber on site. In this case, Part B would pay for 80 percent, and a supplemental plan would pay for the remaining 20 percent. If you don't have a supplemental plan, you would be responsible for the remaining 20 percent.

Hizentra is covered by Medicare Part B in the home setting for CIDP when administered via an external infusion pump and the provider has a Medicare DME/POS provider number. Part B also provides payment for the pump and supplies. If nursing is required, there is coverage via Part B, but only if the provider has a home infusion therapy Medicare provider number. Similar to Part B in the infusion center, Medicare will pay for 80 percent, with the remaining 20 percent being covered by a supplemental plan or the patient. If you have a Medicare Advantage plan, coverage varies by plan, but does require prior authorization. Talk with your current provider about your options as you transition to Medicare.

What Do I Need to Know About My Infusion Medication When Traveling Abroad?

I am scared to travel abroad because I get sick often. What do I need to know if I travel abroad with my infusion medication? And, is it easy for Americans to get healthcare in an emergency?

Abbie: Traveling abroad with infusion medication can be a daunting prospect, particularly if you have concerns about your health. To ensure success, research the regulations of the destination country regarding medication importation, carry a translated copy of your medication information, and contact the U.S. embassy for local healthcare information. Obtain a doctor's note detailing your medical condition and the necessity of infusion medications, and consider purchasing international health insurance for emergency medical coverage. Familiarize yourself with local emergency services and hospitals, and always travel with extra medication to account for unforeseen delays. In case of a medical emergency abroad, seek treatment at the nearest hospital, as many countries provide emergency care to all individuals. However, be aware of potential up-front payment for medical services, and keep all receipts for potential reimbursement. Prioritize thorough preparation and consultation with healthcare professionals to alleviate concerns and ensure a safe and enjoyable international travel experience.

For more information about traveling with immune globulin medication and supplies, see the article "Planes, Trains and Automobiles: Traveling with IG Therapy" on page 28.

» Have a question? Email us at editor@IGLiving.com.
Your information will remain confidential unless permission is given.

ABBIE CORNETT, MBA, is the patient advocate for *IG Living* magazine. She can be reached at patient advocate@igliving.com or (800) 843-7477 x1366.

Making Friendships in Adulthood

By Mairead McConnell, PhD

TODAY, WHEN human beings are more technologically connected than ever before, loneliness has become an epidemic. Research shows that more than three in five Americans report feeling lonely and lacking companionship. Loneliness not only feels unpleasant, but a lack of social relationships and support is associated with a higher risk of both physical and mental health problems.[1]

As humans, we are social creatures, and we all need social connection to survive and thrive. However, making friends in adulthood isn't necessarily easy, and you may face real barriers such as illness, low energy, financial stressors or shyness. Perhaps, like many people, you became disconnected from friends during the pandemic. Perhaps it is challenging to continue to navigate social interactions and illness risk. Or, maybe you have decided that you don't need friendships in your life. Even if these are true for you, the fact remains that increasing your social connectedness can improve not only your health, but your overall quality of life.

Consider implementing these tips to create new friendships or reignite old ones!

1) Challenge the stories you are telling yourself. The number one reason I hear that people don't try to make friends is that they believe everyone else already has friends and/or they are too busy. This couldn't be further from the truth. The reality is that most people are likely also in need of friendship and would appreciate you reaching out. Notice if there are other stories holding you back. Maybe you think you don't have enough to offer, or that you don't need friends anyway. Sometimes our mind tells us stories to protect us from taking a risk, but these stories aren't always true; you don't have to believe everything your mind tells you.

2) Come out and say it. "I'm interested in making new friends. Would you like to get lunch sometime?" When it comes to making friends, there is no need to hide your intentions. It's perfectly OK to state it outright. This can feel vulnerable, of course, but letting people know your intention will help them understand your expectations and connect you to those who want the same thing.

3) Reach out to old friends. Over the course of our lives, we lose touch with people, even if nothing went wrong. If there are friends you wish to reconnect with, consider reaching out to them with a message, letter or phone call. More often than not, they are also in need of connection and would appreciate hearing from you.

4) Propose events that you would enjoy. If you invite a potential friend to an event or activity, choose something you would enjoy or that you are comfortable with; being in your element will allow you to be more authentic. Plus, even if the friendship doesn't blossom, you still spent time doing something you enjoy.

5) Give and take. Building friendships is just as much about accepting invitations as it is about initiating them. If you often find yourself turning down invitations, consider making a counterproposal instead. If you struggle with energy later in the day, suggest a morning meet-up. If indoor events pose too much illness risk, propose meeting outside for a walk or on a restaurant patio. With the warmer weather comes more opportunities to connect in safe and comfortable ways.

6) Attend community events. You'd be surprised how many groups are organized around hobbies and activities such as crafting, hiking, painting, bowling, book clubs, walking, etc. Through some online searches, you can find events that interest you. Choose one and check it out!

7) Keep trying. Building friendships and community is a process that requires time and effort. Don't give up if you don't find your people immediately. Give yourself time and kindness, and know that whoever you are, you are worthy of friends and deserve supportive people in your life. IG

Reference

1. Demarinis, S. Loneliness at Epidemic Levels in America. *Explore*, 2020;16(5), 278–279. Accessed at doi.org/10.1016/j.explore.2020.06.008.

MAIREAD MCCONNELL, PhD, is a clinical psychologist and assistant professor at Banner University Medical Center in Tucson, Ariz. She specializes in health psychology and is passionate about helping patients live well while navigating the challenges of chronic illness.

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Important Safety Information

Hizentra®, Immune Globulin Subcutaneous (Human), 20% Liquid, is a prescription medicine used to treat:

- Primary immune deficiency (PI) in patients 2 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults

WARNING: Thrombosis (blood clots) can occur with immune globulin products, including Hizentra. Risk factors can include: advanced age, prolonged immobilization, a history of blood clotting or hyperviscosity (blood thickness), use of estrogens, installed vascular catheters, and cardiovascular risk factors.

If you are at high risk of blood clots, your doctor will prescribe Hizentra at the minimum dose and infusion rate practicable and will monitor for signs of clotting events and hyperviscosity. Always drink sufficient fluids before infusing Hizentra.

See your doctor for a full explanation, and the full prescribing information for complete boxed warning.

Treatment with Hizentra might not be possible if your doctor determines you have hyperprolinemia (too much proline in the blood), or are IgA-deficient with antibodies to IgA and a history of hypersensitivity. Tell your doctor if you have previously had a severe allergic reaction (including anaphylaxis) to the administration of human immune globulin. Tell your doctor right away or go to the emergency room if you have hives, trouble breathing, wheezing, dizziness, or fainting. These could be signs of a bad allergic reaction.

Inform your doctor of any medications you are taking, as well as any medical conditions you may have had, especially if you have a history of diseases related to the heart or blood vessels, or have been immobile for some time. Inform your physician if you are pregnant or nursing, or plan to become pregnant.

Infuse Hizentra under your skin *only*; do not inject into a blood vessel. Self-administer Hizentra only after having been taught to do so by your doctor or other healthcare professional, and having received dosing instructions for treating your condition.

Please see Brief Summary of full Prescribing Information on reverse.

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"I am very grateful for the simplicity that prefilled syringes provide, even for someone like me who has limited strength in their hands."

—**Angela**, patient advocate on Hizentra*

Learn more about Hizentra prefilled syringes at **Hizentra.com/elevate**

*Patient advocates are not healthcare professionals or medical experts. For medical questions, please contact your physician. Patient advocates are compensated by CSL Behring LLC for their time and/or expenses.

Ig=immune globulin.

Immediately report to your physician any of the following symptoms, which could be signs of serious adverse reactions to Hizentra:

- Reduced urination, sudden weight gain, or swelling in your legs (possible signs of a kidney problem).
- Pain and/or swelling or discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, or numbness/weakness on one side of the body (possible signs of a blood clot).
- Bad headache with nausea; vomiting; stiff neck; fever; and sensitivity to light (possible signs of meningitis).
- Brown or red urine; rapid heart rate; yellowing of the skin or eyes; chest pains or breathing trouble; fever over 100°F (possible symptoms of other conditions that require prompt treatment).

Hizentra is made from human blood. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

The most common side effects in the clinical trials for Hizentra include redness, swelling, itching, and/or bruising at the infusion site; headache; chest, joint or back pain; diarrhea; tiredness; cough; rash; itching; fever, nausea, and vomiting. These are not the only side effects possible. Tell your doctor about any side effect that bothers you or does not go away.

Before receiving any vaccine, tell immunizing physician if you have had recent therapy with Hizentra, as effectiveness of the vaccine could be compromised.

Please see full prescribing information for Hizentra, including boxed warning and the patient product information.

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.

You can also report side effects to CSL Behring's Pharmacovigilance Department at 1-866-915-6958.

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*In an online survey, at least 32 of 33 people who self-infused Ig in prefilled syringes were very/somewhat satisfied on all measures mentioned.

HIZENTRA®, Immune Globulin Subcutaneous (Human), 20% Liquid
Initial US Approval: 2010

BRIEF SUMMARY OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use HIZENTRA safely and effectively. Please see full prescribing information for HIZENTRA, which has a section with information directed specifically to patients.

What is HIZENTRA?
HIZENTRA is a prescription medicine used to treat primary immune deficiency (PI) and chronic inflammatory demyelinating polyneuropathy (CIDP). Infuse HIZENTRA only after you have been trained by your doctor or healthcare professional. HIZENTRA is to be infused under your skin only. DO NOT inject HIZENTRA into a blood vessel (vein or artery).

Who should NOT take HIZENTRA?
Do not take HIZENTRA if you have too much proline in your blood (called "hyperprolinemia") or if you have had reactions to polysorbate 80. Tell your doctor if you have had a serious reaction to other immune globulin medicines or have been told that you have a deficiency of the immunoglobulin called IgA.

Tell your doctor if you have a history of heart or blood vessel disease or blood clots, have thick blood, or have been immobile for some time. These things may increase your risk of having a blood clot after using HIZENTRA. Also tell your doctor what drugs you are using, as some drugs, such as those that contain the hormone estrogen (for example, birth control pills), may increase your risk of developing a blood clot.

What are possible side effects of HIZENTRA?
The most common side effects with HIZENTRA are:

- Redness, swelling, itching, and/or bruising at the infusion site
- Headache/migraine
- Nausea and/or vomiting
- Pain (including pain in the chest, back, joints, arms, legs)
- Fatigue
- Diarrhea
- Stomach ache/bloating
- Cough, cold or flu symptoms
- Rash (including hives)
- Itching
- Fever and/or chills
- Shortness of breath
- Dizziness
- Fall
- Runny or stuffy nose

Tell your doctor right away or go to the emergency room if you have hives, trouble breathing, wheezing, dizziness, or fainting. These could be signs of a bad allergic reaction.

Tell your doctor right away if you have any of the following symptoms. They could be signs of a serious problem.

- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain and/or swelling of an arm or leg with warmth over the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body. These could be signs of a blood clot.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of a brain swelling called meningitis.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a blood problem.
- Chest pains or trouble breathing.
- Fever over 100°F. This could be a sign of an infection.

Tell your doctor about any side effects that concern you. You can ask your doctor to give you more information that is available to healthcare professionals.

Please see full prescribing information, including full boxed warning and FDA-approved patient product information. For more information, visit Hizentra.com.

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.

You can also report side effects to CSL Behring's Pharmacovigilance Department at 1-866-915-6958.

Based on April 2023 version.

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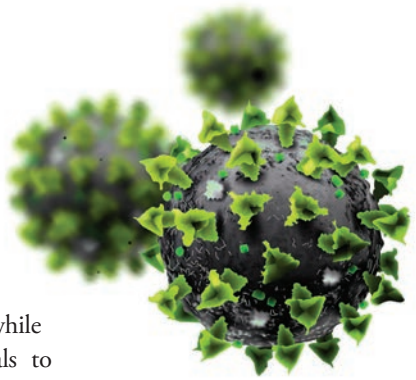
CSL Behring

SARS-CoV-2 and COVID-19

By Terry O. Harville, MD, PhD



SINCE EARLY 2020, I think it is safe to say that everyone has heard of SARS-CoV-2 and COVID-19. Even though the worst seems to have passed, and some have declared the pandemic over, approximately 1,500 Americans are still dying from COVID-19 each week, indicating the pandemic is not truly over.[1] Further, we have been dealing with two other concurrent respiratory viruses, influenza and respiratory syncitial virus (RSV), making this a triple-threat, especially for patients who are immunocompromised or have immunodeficiency. In the next several columns, I will be discussing the origins of the SARS-CoV-2 virus and the pandemic, how it affects the immune system, how appropriately or inappropriately the immune system responds, and how vaccination deals with acute infection and post-infection chronic disease (PASC, post-acute sequelae of COVID-19, also known as long COVID).

The initial "SARS" (severe acute respiratory syndrome) was present in China in late 2002, and it was recognized by the World Health Organization by February 2003, posing a concern for a potential worldwide pandemic. Fortunately, early recognition and quarantine methods limited the spread by July 2003, with no further significant infections found. SARS was determined to be a coronavirus, similar to what was known to be endemic in bats. Bats were thought to have infected civet cats, with further mutations allowing for infection in humans. In 2012, MERS (Middle East respiratory virus) was reported in Saudi Arabia. It, too, was determined to be a coronavirus similar to SARS, but it was endemic in camels, from which it spread to humans. Fortunately, too, MERS was controlled without widespread infections. This may have been because while MERS could spread from animals to humans, human-to-human transmission appeared to be limited. Viruses that spread from animals to humans are called zoonotic viruses. SARS-CoV-2 was named after the original SARS, with additional information included: severe acute respiratory syndrome coronavirus 2. (Some now name the original SARS as SARS-CoV-1.) COVID-19 (coronavirus disease 2019) is the term used for having infection with the virus named SARS-CoV-2. Frequently, people just refer to it as COVID.

In January 2020, I became very worried about SARS-CoV-2 because this virus uses a protein known as ACE2 (angiotensin-converting enzyme 2) found on the surfaces of cells throughout the body as its point of entry into the cells. ACE2 has a major role in cleaving angiotensin 2 to produce angiotensin 1-7. The former causes a rise in blood pressure, and the latter a decrease in blood pressure. Affecting this could result in dysregulation of blood pressure control that results in dysautonomia (a nervous system disorder that disrupts autonomic body processes). ACE2 also helps to reduce inflammation in the body, and affecting its function could result in increased inflammation. Since the receptor binding domain (RBD) of the spike protein of SARS-CoV-2 binds to ACE2 to enter cells, I had concern about adverse effects directed against ACE2.

When our immune system makes an antibody, this is a new protein for which the immune system will also make an antibody against. This initial antibody is defined as an idiotype, and the secondary antibody directed against it is called an anti-idiotype. This was first reported by Niels Jerne, MD, in 1974 as the Network Theory Hypothesis.[2] My concern was that when people make antibodies to the RBD of the spike protein, they would make an anti-idiotypic antibody directed against ACE2. So, we performed a study and determined this to be true.[3,4] We believe this has an adverse role in COVID-19 and post-COVID disease (PASC or long COVID).

In the next column, I will discuss the origins of SARS-CoV-2 and COVID-19, with particular regard to why the immune system struggles with this virus. IG

References

1. Centers for Disease Control and Prevention. Covid Data Tracker, Jan. 15, 2024. Accessed at covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.
2. Jerne, NK. Towards a Network Theory of the Immune System. *Annals of Allergy, Asthma and Immunology*, 1974 Jan;125C(1-2):373-89. Accessed at pubmed.ncbi.nlm.nih.gov/4142565.
3. Arthur, JM, Forrest, JC, Boehme, KW, Kennedy, JL, Owens, S, Herzog, C, Liu, J, and Harville, TO. Development of ACE2 Autoantibodies After SARS-CoV-2 Infection. *PLoSONE*, 16(9):e0257016. Accessed at journals.plos.org/plosone/article?id=10.1371/journal.pone.0257016.
4. Harville, O, and Arthur, JM. Anti-Idiotypic Antibodies in SARS-CoV-2 Infection and Vaccination. *New England Journal of Medicine*, 386(5):February 2, 2022 DOI: 10.1056/NEJMc2119443.

TERRY O. HARVILLE, MD, PhD, is medical director of the Special Immunology Laboratory at the University of Arkansas for Medical Sciences and a consultant for immunodeficiencies, autoimmunities and transplantation.

Is Pain Its Own Disease?

By Michelle Greer, RN, IgCN

PAIN IS subjective, takes many forms and types, and varies from person to person. It can be acute or chronic, and it can range from very minimal to quite severe. There is a lot to consider when assessing pain, identifying its potential causes and deciding on an individualized treatment plan. But is pain a symptom of disease, or a disease in its own right?

What Is Pain?

The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage."[1] Since its adoption in 1979, this definition has become accepted widely by healthcare professionals and researchers in the pain field, and it was adopted by several professional, governmental and nongovernmental organizations, including the World Health Organization.[2]

It is generally believed that chronic pain is neuropathological in nature, but researchers aren't classifying it as a brain disease just yet.

In 2018, a task force was formed to expand on this definition, and in 2020, the following was added to the original definition:[1]

- Pain is always a personal experience that is influenced to varying degrees by biological, psychological and social factors.
- The experience of pain and the perception of pain (nociception) are different phenomena: Pain cannot be inferred solely from activity in sensory neurons.
- A person's report of an experience as pain should be respected.
- Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being.
- Verbal description is only one of several behaviors used to express pain; inability to communicate does not negate the possibility that a human experiences pain.

Classifying Pain

There are many ways to break down and classify pain.

- Nociceptive pain can be either somatic (related to the body) or visceral (related to deep inward feelings). This kind of pain is caused by injury, swelling or inflammation. Somatic pain is often described as sharp, aching or throbbing at the site of the pain's origin.[5] Visceral pain may be felt in an area farther away from its origin, a phenomenon known as referred pain.[5]
- Neuropathic pain is caused by nerve damage. It is often described as shooting, burning or numb.[6]
- Psychogenic pain is caused by psychological factors. Psychogenic pain can start with and/or accompany physical pain.
- Acute pain is temporary. It comes on suddenly and is treatable with or without medication.
- Chronic pain lasts longer. It can be more challenging to manage.
- Pain can be located anywhere in the body, and in some cases, be or feel generalized.

Describing Pain

When someone is experiencing pain, there are many things for healthcare practitioners to assess to determine treatment. Patients should be given the opportunity to explain and describe the pain from their perspective, and to describe pain in many ways:[1] sharp, dull or cramping; stabbing, tender or throbbing; burning, shooting or aching; or stinging, sore or stiff. Things to clarify and explore include location, onset and duration; things that aggravate it; things that are more difficult because of the pain; things that have relieved the pain; and descriptive words.

Further, the degree to which a patient experiences pain should be assessed. One common practice is the use of a pain scale. There are several types of pain scales, but the numeric pain scale is one of the most common, with 0 equaling no pain and 10 equaling the most severe pain. For children, a scale with faces where 0 is happy and 10 is crying can also be used.

Treatment

A treatment plan is based on a thorough pain assessment, including determination of acute versus chronic, type and patient preference. Treatments may be non-pharmacological or pharmacological. Non-pharmacological measures include rest, ice, heat, massage, acupuncture, exercise, yoga, aromatherapy and other alternative medicine practices. Pharmacological measures include non-prescription/over-the-counter and/or prescription medications that may be oral, topical, injectable or infusible. They may be specific for pain relief and/or include medications for inflammation, muscle relaxation and/or anxiety and any other symptom that contributes to the pain.

A pain treatment plan, whether it is acute or chronic, almost always includes a combination of both non-pharmacological and pharmacological interventions. If a patient is interested in alternative medicines, these should be considered by the prescribing practitioner. Clinicians are urged to learn about these approaches to pain treatment not only because of their therapeutic promise, but also because many patients use complementary and alternative medicine, raising the possibility of interactions with conventional treatments.[4]

Quality of Life

Pain, when it is ongoing and uncontrolled, has a detrimental, deteriorative effect on virtually every aspect of patients' lives. It produces anxiety and emotional distress, undermines well-being, interferes with functional capacity and hinders the ability to fulfill family, social and vocational roles. Not treating pain properly can lead to impaired sleep, an inability to complete normal activities of daily living, a decreased quality of life, a negative impact on personal finances due to an inability to work, and anxiety and depression. The impact on healthcare spend is also tremendous. With such broad-based effects, it is apparent that chronic pain diminishes quality of life.[3]

Pain vs. Disease

Acute pain (i.e., pain you feel when you stub your toe) generally resolves quickly, and doesn't fit the description of a disease state the same way chronic pain does. Unlike acute pain, chronic pain not only interrupts and impairs normal functioning, but it also lasts longer than pain caused by an acute injury or illness, and it recurs for months or even years.[7] But is chronic pain a symptom of disease or a disease itself?

Experts began to explore this question in the mid-20th century, when John J. Bonica, MD, known as the founding father of the discipline of pain medicine, observed that pain is indicative of a disease when it persists, loses its biologic damage signaling function and becomes destructive and difficult to manage with traditional therapies.[7] Later discussions during the 1980s posited that chronic pain is what's left over after the "real" disease resolved, but in the 1990s, the idea that there must be a link between disease and the endogenous pain system gained traction and furthered the notion that pain is its own disease.[7] By 2004, John D. Loeser, MD, professor emeritus of neurological surgery, anesthesiology and pain medicine at the University of Washington, argued that according to the Encyclopedia Britannica's definition of disease — an impairment of the normal state of an organism that interrupts or modifies its vital functions — chronic pain should be recognized as a disease in its own right.[7]

Debate Continues

Today, while there is agreement that acute pain is a symptom and not a disease, there is not yet an international consensus whether or not chronic pain is itself a disease. It is generally believed that chronic pain is neuropathological in nature, but researchers aren't classifying it as a brain disease just yet. The etiology of chronic pain conditions continues to be studied.

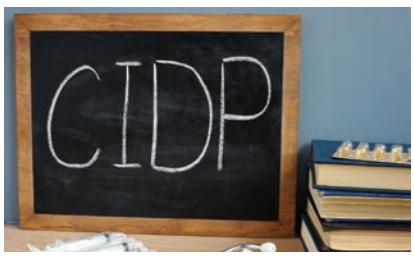
Sources

1. International Association for the Study of Pain. IASP Announces Revised Definition of Pain, July 16, 2020. Accessed at www.iasp-pain.org/publications/iasp-news/iasp-announces-revised-definition-of-pain.
2. Raja, SN, Carr, DB, Cohen, M, et al. The Revised International Association for the Study of Pain Definition of Pain: Concepts, Challenges, and Compromises. *Pain*, 2020 Sept. 1;161(9):1976-1982. Accessed at pubmed.ncbi.nlm.nih.gov/32694387.
3. Jacques, E. The Phases, Treatment and Types of Nociceptive Pain. Verywellhealth, Dec. 29, 2023. Accessed at www.verywellhealth.com/what-is-nociceptive-pain-2564615.
4. Nonciceptive Pain. Healthline, updated Sept. 18, 2018. Accessed at www.healthline.com/health/nociceptive-pain#treatment.
5. Simpson, CA. Complementary Medicine in Chronic Pain Treatment. *Physical Medicine and Rehabilitation Clinics of North America*, 2006;17(2):451–472. Accessed at pubmed.ncbi.nlm.nih.gov/25952068.
6. Katz, N. The Impact of Pain Management on Quality of Life. *Journal of Pain and Symptom Management*, 2002;24(1):S38-S47. Accessed at www.ncbi.nlm.nih.gov/pmc/articles/PMC5573040.
7. Raffaeli, W, and Arnaudo, E. Pain as a Disease: An Overview. *Journal of Pain Research*, 2017;10:2003-2008. Accessed at www.ncbi.nlm.nih.gov/pmc/articles/PMC5573040/#b6-jpr-10-2003.

MICHELLE GREER, RN, IgCN, is senior vice president of sales at Nufactor, a specialty infusion company.

MEDICINES

GAMMAGARD LIQUID Approved to Treat CIDP



Takeda's GAMMAGARD LIQUID [immune globulin infusion (human) 10% solution] has been approved by the U.S. Food and Drug Administration (FDA) as an intravenous immune globulin (IVIG) therapy to improve neuromuscular disability and impairment in adults with chronic inflammatory demyelinating polyneuropathy (CIDP). It can be used as induction therapy, which includes an induction dose followed by maintenance doses. However, for treatment of CIDP, GAMMAGARD LIQUID has not been studied in immunoglobulin-naive patients nor as maintenance therapy for periods longer than six months.

Approval is based on results from a prospective, open-label, single-arm, multicenter clinical study (ADVANCE-CIDP 2) that evaluated the efficacy and safety of GAMMAGARD LIQUID in adults with CIDP who developed a relapse in the randomized, double-blinded, placebo-controlled study evaluating efficacy, safety and tolerability of HYQVIA (ADVANCE-CIDP 1) in adults with CIDP. Efficacy in ADVANCE-CIDP 2 was based on responder rate, where a responder was defined as a subject who demonstrated an improvement of functional disability. The responder rate was 94.4 percent (N=18, 95% CI: 74.2% to 99.0%). Improvement in grip strength and change in Rasch-built Overall Disability Scale (R-ODS) score were recorded across participants.

The most common adverse reactions observed in greater than or equal to 5 percent of clinical study patients were headache, pyrexia, anemia, leukopenia, neutropenia, illness, blood creatinine increase, dizziness, migraine, somnolence, tremor, nasal dryness, upper abdominal pain, vomiting, chills, nasopharyngitis and pain in extremity.

"The approval of GAMMAGARD LIQUID for treatment of CIDP is an encouraging validation of our decades-long commitment to advancing plasma-derived therapies on behalf of people living with rare neuromuscular disorders and bringing our portfolio of differentiated IG therapies to these patients," said Richard Ascroft, senior vice president and head of Takeda's U.S. plasma-derived therapies business unit. "Together with the recent HYQVIA approval in the U.S., we can now offer induction and maintenance therapy options to adults living with CIDP that may accommodate their personal treatment needs."

GAMMAGARD LIQUID is the only IVIG with multiple neuromuscular disorder indications in the U.S. since it is now approved for CIDP, and it is the only FDA-approved IVIG to treat multifocal motor neuropathy as a maintenance therapy to improve muscle strength and disability in adults. It is also indicated in the U.S. as a replacement therapy for people 2 years of age or older living with primary immunodeficiency.

Takeda's GAMMAGARD LIQUID® Approved by U.S. FDA for Adults with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Takeda press release, Jan. 29, 2024. Accessed at www.takeda.com/newsroom/newsreleases/2024/Takedas-GAMMAGARD-LIQUID-Approved-for-Adults-with-CIDP-in-United-States..

MEDICINES

Hizentra 10 Gram Prefilled Syringe Now Available

In January, CSL Behring added a 10 gram prefilled syringe for Hizentra (immune globulin subcutaneous [human] 20% liquid) for the treatment of primary immunodeficiency (PI) and chronic inflammatory demyelinating polyneuropathy (CIDP). The prefilled 10 gram syringe is in addition to the already available 1 gram, 2 gram and 5 gram syringes.

"The availability of the 10 gram prefilled syringe is CSL Behring's latest development in helping the rare disease community effectively manage PI and CIDP, as some patients may require treatment at a higher volume," said Bob Lojewski, senior vice president and general manager of CSL Behring North America. "We understand how important flexibility and convenience are in treatment options for people managing these lifelong conditions, and milestones such as this continue to reinforce our promise to address the unmet needs of people living with rare diseases."

CSL Behring Announces Availability of Hizentra® (Immune Globulin Subcutaneous [Human] 20% Liquid) 10g Prefilled Syringe. CSL Behring press release, Jan. 3, 2024. Accessed at www.prnewswire.com/news-releases/csl-behring-announces-availability-of-hizentra-immune-globulin-subcutaneous-human-20-liquid-10g-prefilled-syringe-302024891.html.

MEDICINES

FDA Approves New IVIG Product to Treat PI

The U.S. Food and Drug Administration (FDA) has approved ALYGLO (immune globulin intravenous [IVIG], human-stwk) 10% liquid, formerly referred to as "GC5107," for the treatment of adult patients aged 17 years and older with primary humoral immunodeficiency (PI).

Approval was based on results of a Phase III prospective, open-label, single-arm, historically controlled, multicenter study that assessed the efficacy and safety of GC5107B in patients with a confirmed diagnosis of PI in the United States and Canada. Key findings from the trial for patients aged 17 years and older include the following: a primary efficacy end point of 0.03 acute serious bacterial infections (aSBIs) per patient-year, which met the FDA efficacy requirement of less than one aSBI per patient-year, and the proportion of infusions with temporally associated adverse events occurring during or within 72 hours after infusion was 0.22, which met the FDA-required prespecified end point of less than 0.40. Secondary analyses were annual rate or days of other infections, antibiotic use, days out of work/school/day care or unable to perform normal activities due to infection, and days of hospitalization due to infection.

ALYGLO uses the company's novel cation exchange chromatography (CEX) in the manufacturing process for removing coagulation factor XIa (FXIa) to undetectable levels. The presence of residual activated FXIa in some commercial IVIG products has been identified as the root cause of a small number of thromboembolic events in patients receiving IG infusions.

GC Biopharma Announces US FDA Approval for ALYGLO™ (Immune Globulin Intravenous, Human-stwk) 10% Liquid for Adults with Primary Humoral Immunodeficiency (PI). GC Biopharma press release, Dec. 18, 2023. Accessed at www.biospace.com/article/releases/gc-biopharma-announces-us-fda-approval-for-alyglo-immune-globulin-intravenous-human-stwk-10-percent-liquid-for-adults-with-primary-humoral-immunodeficiency-pi-.

MEDICINES

FDA Expands BIVIGAM Indication to Patients 2 Years and Older

ADMA Biologics' supplemental biologics license application to revise BIVIGAM's (immune globulin intravenous [IVIG]) prescribing information to expand the primary humoral immunodeficiency (PI) indication to pediatric patients 2 years of age and older has been approved by the U.S. Food and Drug Administration (FDA).

Approval was based on a pediatric-only prospective, open-label, multicenter trial with 16 children and adolescents with PI who received IVIG, ranging from 300 to 800 mg/kg every three weeks or four weeks, for approximately five months. All individuals were male and 80 percent were white. The study showed that 25 percent of individuals experienced adverse reactions occurring during or within 72 hours after end of infusion. Reactions were mild or moderate in severity, with no infusion site reactions in the study. For the pediatric study, reactions included fatigue, headache, nausea and rash.

The efficacy analysis was based on the incidence of serious bacterial infections (SBIs), including bacteremia or sepsis, bacterial meningitis, osteomyelitis or septic arthritis, bacterial pneumonia or visceral abscess. There were no SBIs in the cohort during the mean observation period (152 days), and there were no other serious infections or hospitalizations due to infection in the study. Further, no individuals in the study needed intravenous antibiotics during the study.

Additionally, investigators reported that the trough total immunoglobulin G (IgG) levels were maintained above 500 mg/dL in all individuals throughout the study, with no apparent difference in total IgG before the first and last infusion.

In the study, the safety and efficacy were established based on the findings, demonstrating the effects were similar to those in adults. There were no specific dose requirements necessary to achieve the targeted IgG levels for pediatrics.

"We are pleased to announce that BIVIGAM has received FDA approval for treating PI in patients aged 2 years and older. Previously, the indication for BIVIGAM was restricted to PI patients aged 12 years and older," said Adam Grossman, president and chief executive officer of ADMA. "This expanded label for BIVIGAM allows ADMA to actively address the treatment needs of younger PI patients earlier in their treatment journey. In the periods ahead, we look forward to offering BIVIGAM as an FDA-approved treatment option for these pediatric PI patients."

Gallagher, A. FDA Approves IVIG for Pediatric Patients Aged 2 and Older with Primary Humoral Immunodeficiency. *Pharmacy Times*, Dec. 13, 2023. Accessed at www.pharmacytimes.com/view/fda-approves-ivig-for-pediatric-patients-aged-2-and-older-with-primary-humoral-immunodeficiency.

MEDICINES

HYQVIA Now Approved as Maintenance Therapy for CIDP

The U.S. Food and Drug Administration (FDA) has approved HYQVIA [immune globulin infusion 10% (human) with recombinant human hyaluronidase] for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent the relapse of neuromuscular disability and impairment in adults. HYQVIA first received approval in the U.S. in 2014 for the treatment of primary immunodeficiency in adults, which has since been expanded to include children 2 to 16 years old.

Approval is based on results from a randomized, double-blinded, placebo-controlled study (ADVANCE-CIDP 1) and a single-arm, open-label, extension study (ADVANCE-CIDP 3) that evaluated the efficacy and safety of HYQVIA as a maintenance therapy in adults with CIDP. The efficacy evaluation included 122 adults from ADVANCE-CIDP 1 with a confirmed diagnosis of CIDP and who had remained on a stable dosing regimen of intravenous immune globulin (IVIG) therapy for at least three months prior to screening. The analysis of the primary endpoint demonstrated a statistically significant difference between the relapse rates in the HYQVIA group (N=57, 14.0 percent) compared to the placebo group (N=65, 32.3 percent) (p=0.0314). The treatment difference of -18.3 percent (two-sided 95 percent CI: -32.1 percent, -3.1 percent) indicated that HYQVIA demonstrated superiority over placebo in preventing relapse of CIDP.

The safety of HYQVIA in adults with CIDP was evaluated across ADVANCE-CIDP 1 (N=62) and ADVANCE-CIDP 3 (N=79). The most common adverse reactions observed in greater than 5 percent of study subjects in clinical studies of HYQVIA for CIDP were local reactions, headache, pyrexia, nausea, fatigue, erythema, pruritus, increased lipase, abdominal pain, back pain and pain in extremity.

For adults with CIDP, HYQVIA can be infused up to once monthly (every two, three or four weeks) due to the hyaluronidase component, which facilitates the dispersion and absorption of large IG volumes in the subcutaneous space between the skin and the muscle. Because it is delivered subcutaneously, HYQVIA can be administered by a healthcare professional in a medical office, infusion center or at a patient's home. In addition, it can be self-administered after appropriate patient or caregiver training.

U.S. FDA Approves Takeda's HYQVIA® as Maintenance Therapy in Adults with Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Takeda press release, Jan. 16. 2024. Accessed at www.businesswire.com/news/home/20240115984065/en/U.S.-FDA-Approves-Takeda's-HYQVIA®-as-Maintenance-Therapy-in-Adults-with-Chronic-Inflammatory-Demyelinating-Polyneuropathy-CIDP.

Autoimmune Corner

MEDICINES

Complement C5 Inhibitor Zilucoplan Is Approved by FDA to Treat MG

A recent study from Osaka University discovered that small changes in specific immune cell populations may indicate the presence of autoimmune disease. CD4+ T cells are known to have a crucial role in the onset and progression of many autoimmune diseases.

The research team used single-cell RNA sequencing and an analytical approach known as non-negative matrix factorization to analyze the gene expression profiles of CD4+ T cells in healthy individuals and patients with autoimmune diseases. This analysis identified 18 different types of CD4+ T cells and 12 distinct gene programs. These were then used as a reference to analyze nearly two million CD4+ T cells from almost 1,000 people with 20 different autoimmune diseases. Shimon Sakaguchi, MD, PhD, senior author of the paper, explained: "We found that characteristic changes in CD4+ T cells defined by the 18 categories and 12 gene programs were associated with specific autoimmune diseases, suggesting that these conditions have a detectable 'signature.'"

Also, the researchers found notable changes in CD4+ T cell categories and gene programs that were linked to two factors understood to influence the risk of developing an autoimmune disorder: aging and sex. Genetic factors that promote disease development accumulated in CD4+ T cells exhibiting specific gene programs. "Our study presents a comprehensive catalogue of the CD4+ T cell changes that are seen in 20 different autoimmune diseases, providing an invaluable resource for researchers," said lead author and PhD student Yoshiaki Yasumizu.

This catalogue could lead the way for precision medicine, as it may be used to detect autoimmune disease in patients by simply taking a blood sample and analyzing the CD4+ T cell features.

Changes in CD4+ T Cells Associated with Autoimmune Diseases. Drug Target Review, Jan. 12, 2024. Accessed at www.drugtargetreview.com/news/113623/changes-in-cd4-t-cells-associated-with-autoimmune-diseases.

RESEARCH

Study Suggests Two-Way Link Between Autoimmune Disease and PND

Women with autoimmune diseases are more likely to experience perinatal depression (PND). However, findings from a new Swedish study suggest that the reverse is also true: Women with a history of PND are at higher risk of developing an autoimmune disease. According to the study, a significant positive bidirectional link was found for autoimmune thyroid disease, psoriasis, multiple sclerosis, ulcerative colitis and celiac disease.

Led by Emma Bränn, PhD, a team of researchers from the Karolinska Institutet in Stockholm, Sweden, identified all women who had given birth in Sweden between 2001 and 2013, a total of 815,000 women and 1.3 million pregnancies. Of those women, just more than 55,000 were diagnosed with depression while pregnant or within a year of delivery. Controlling for factors including genetic makeup and childhood environment, researchers then compared the incidence of 41 autoimmune diseases in women who had and did not have PND. Results showed that women with autoimmune diseases were 30 percent more likely to have PND, and women with PND were 30 percent more likely than women without PND to develop an autoimmune disease.

According to Dr. Bränn, the research team wanted to conduct the study because previous research has shown involvement of the immune system in depression, with similarities in both symptoms of the immune system — activated diseases and depression and the molecular pathways activated by the immune system. "Adding on top of the tremendous changes in the immune system that we see in the body of the women during the perinatal period, we hypothesized that autoimmune diseases could be associated to perinatal depression," said Dr. Bränn. "This had also been shown in some previous literature but not to the extent as what we have investigated in this paper."

According to Dr. Bränn, the results help make a case for counseling women at several points during healthcare interactions before and after conception and childbirth, as well as during rheumatology visits, to inform women with autoimmune diseases who are contemplating motherhood of the association with developing PND. And, the results may also demonstrate a need for monitoring women in these groups for depression or autoimmune disease.

Researchers say they will continue to examine long-term effects of depression during pregnancy and in the year after childbirth. "Depression during this sensitive period can have serious consequences for both the mother and the baby. We hope that our results will help decision-makers to steer funding toward maternal healthcare so that more women can get help and support in time," said Dr. Bränn. IG

Fellick, M. Two-Way Link Between Autoimmune Disease/Perinatal Depression. Medscape, Jan. 15, 2024. Accessed at www.medscape.com/viewarticle/two-way-link-between-autoimmune-disease-perinatal-depression-2024a10000wj?form=fpf.

RESEARCH

FDA Clears Kyverna Therapeutics to Start Clinical Trial for Scleroderma Cell Therapy

The United States Food and Drug Administration (FDA) cleared Kyverna Therapeutics to begin human trials of its autologous CAR T-cell therapy KYV-101 as a potential treatment for scleroderma.

Kyverna will initiate a Phase I/II open-label, multicenter trial, dubbed KYSA-5, to evaluate KYV-101 in adults with diffuse cutaneous systemic sclerosis, a rare and chronic autoimmune disease, also known as scleroderma.

KYV-101 is designed to modify a patient's own T cells to target CD19, a protein expressed on the surface of B cells; CD19 is a critical component of the immune system that can become overactive in autoimmune diseases. By targeting CD19, Kyverna hopes its cell therapy will enable T cells to recognize and deplete B cells in a patient's body.

"We are keen to initiate our KYSA-5 trial in this new patient population and generate data to support our KYV-101 design goals," Kyverna CEO Peter Maag said in a statement. "With the deep B-cell depletion from KYV-101 treatment, patients with scleroderma may have a full reset of their immune system to stop the vicious cycle of their overactive immune system." IG

Kyverna Therapeutics Gets FDA Clearance to Start Clinical Trial for Scleroderma Cell Therapy. Precision Medicine Online, Oct. 12, 2023. Accessed at www.precisionmedicineonline.com/regulatory-news-fda-approvals/kyverna-therapeutics-gets-fda-clearance-start-clinical-trial.

Staying Socially Active with PI — Especially While Aging

Illness and age are no doubt obstacles to a satisfying social life, but cultivating meaningful social connections is vitally important to your health. Here are our top tips for building a life you love.

By Rachel Maier, MS

DO YOU feel an ache for social connection? I bet you do. Humans are made for it!

But cultivating healthy social connections is easier said than done, especially when you're aging, dealing with a chronic disease such as primary immune deficiency (PI) — or both. The things that used to fill your social calendar might not work for you anymore.

Maybe you are retired and miss daily interactions with co-workers and colleagues; your kids are grown, so little league games are a thing of your past, and you find yourself missing sideline chats with fellow parents; or you lost your spouse, a friend or even the ability to drive; or your aging body makes things you used to enjoy more difficult or impossible. If you also have a PI, things are even more complicated, and you may find yourself unsure of how to cultivate a fulfilling social life since there is risk involved with being around other people.

Life certainly gets lonelier when your social circle shrinks, and yet prioritizing social activity becomes more and more important as the years wear on. Social connections suffer when activity levels decline, and it's a struggle to know what to do about it. But whatever your hiccup or hinderance — even if it's PI — finding ways to have an active social life is vitally important to aging well and staying healthy.

The Importance of Social Connectedness

If you feel socially stuck, you're not alone. Many aging adults experience social isolation, which is lack of

relationships with others and limited social support or contact. So many things contribute to social isolation, which can cause loneliness and serious health problems.

In January 2023, results from the National Poll on Healthy Aging (NPHA) showed that about one in three adults (34 percent) ages 50 to 80 report feelings of social isolation, and 51 percent of those who have a disability or health condition that they say limits their activity also report they experience a lack of companionship.[1]

We asked Cheyenne Crawford, the wellness director at Cedar Lake Village in Johnson County, Kan., to help us understand why social isolation is such a problem for aging adults. According to Crawford, social isolation comes down to feeling discouraged by uncontrollable changes, both physically and socially, that limit people's ability to live the way they really want to live. The details of their life change — they retire, their relationships change, their body does funny things — and their social circle naturally gets smaller.

"As we age, it can become more difficult to have consistent social interactions," explains Crawford. "Getting to social activities outside of the house becomes more and more difficult. Bodily changes such as hearing loss even cause a whole new feeling of isolation: Not being able to hear conversations or things going on around you may be embarrassing or frustrating and may cause a pullback in socializing. Vision loss is the same: If someone is used to playing card games with a group of friends or is in a book club, they may feel like they are unable to attend those events. Pain and other common health problems can be very discouraging to seniors, too. For example, if they are having trouble sleeping at night, they may not have the energy to go to an activity that they would normally be able to attend."

But despite the hardship or inconvenience, Crawford emphasizes staying socially active is vitally important to overall health: "Socializing is one of the most important factors for seniors' lives. It can affect both mental and physical aspects of health, along with quality of life."

Unlike social isolation, social connectedness is healthy and important for mental well-being, and by extension, physical health, too. It combats loneliness by giving people a sense of belonging and being cared for, valued and supported.[2] People who are socially connected and have stable, supportive relationships are more likely to make healthy choices, have better mental and physical health outcomes and are better able to cope with hard times, stress, anxiety and depression.[2]

Indeed, research shows social connectedness dramatically improves the health of older adults. In fact, socially isolated and/or lonely older adults are at a higher risk for heart disease, depression and cognitive decline, but making new social connections later in life helps older adults boost their self-esteem, reduce their feelings of loneliness and increase physical activity. When people find activities that are meaningful to them, they tend to live longer, be in better moods and live with a sense of purpose.[3]

Socializing is one of the most important factors for seniors' lives. It can affect both mental and physical aspects of health, along with quality of life.

The Problem of PI

But there is an elephant in the room when it comes to cultivating a healthy social life: How can people with compromised immune systems stay socially active — and safe? (After all, those with PIs were social distancing before it was even a thing.) Spending time with other people carries an inherent risk. If you're someone with a compromised immune system, understandably the last thing you want to do is expose yourself to pathogens that could make you seriously ill.

Perhaps not surprisingly, people with chronic illnesses are more apt to feel socially isolated. "Those living with chronic illness are the most prone to social isolation. Being in constant pain really discourages someone from participating in activities. Another concern is worry about catching an illness from others at social activities," adds Crawford.

However, have you considered this startling statistic? Nearly one in three people with a long-term physical health condition also has a mental health problem, most often depression or anxiety.[4] What's more, people with chronic diseases such as PI are especially prone to mental health problems. And, people with PI are 91 percent more likely to

HyQvia

[Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

What is HyQvia®?

HyQvia [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] is a liquid medicine that is given under the skin (subcutaneously) to treat primary immunodeficiency (PI) in people 2 years and older.

IMPORTANT SAFETY INFORMATION

What is the most important information that I should know about HyQvia?

- HyQvia can cause blood clots.
- Call your healthcare professional (HCP) if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.
- Your HCP may perform blood tests regularly to check your IgG level.
- Do not infuse HyQvia into or around an infected or red swollen area because it can cause infection to spread.

Who should not take HyQvia?

Do not take HyQvia if you:

- Are allergic to IgG, hyaluronidase, other blood products, or any ingredient in HyQvia.

What should I avoid while taking HyQvia?

- HyQvia can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your HCP that you take HyQvia.

What should I tell my HCP before I start using or while using HyQvia?

Tell your HCP if you:

- Have or had any kidney, liver, or heart problems or history of blood clots because HyQvia can make these problems worse.
- Have IgA deficiency or a history of severe allergic reactions to IgG or other blood products.
- Are pregnant, trying to become pregnant or are breast feeding. It is not known whether HyQvia can harm the unborn baby or breastfed infant.

What are the possible or reasonably likely side effects of HyQvia?

HyQvia can cause serious side effects. If any of the following problems occur after starting HyQvia, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.

Meet the only monthly* subQ IG treatment and say hy to more of what you love.

0.025 infections per year

This is equivalent to 25 acute serious bacterial infections (ASBIs) out of 1,000 patients over the course of the 12-month study period.

The FDA standard for efficacy—that is, if an immunoglobulin works—is less than 1 ASBI per year. In the clinical trial, people taking HyQvia experienced significantly less than that.

0 days in the hospital per year

There was a mean of 0.037 days spent in the hospital due to infection during the study.

<4 days off work or school per year

On average, patients taking HyQvia missed 3.31 days of work or school due to an infection.

- HyQvia was studied in a clinical trial of 83 people with PI, with the main goal of measuring how many acute serious bacterial infections (ASBIs) they experienced over the course of 1 year
- ASBIs are short-term but serious infections caused by bacteria that require immediate medical care
- ASBIs included 2 episodes of pneumonia, both treated as outpatients with oral antibiotics. An additional episode of pneumonia requiring hospitalization occurred during the ramp-up
- The most common general (systemic) side effects were headache, antibody formation against hyaluronidase (Hy), fatigue, nausea, fever, and vomiting. The most common side effects at the infusion site (local) were pain, redness, swelling, and itching

*Between infusions, based on administration every 3 or 4 weeks.
subQ IG=subcutaneous immune globulin.

IMPORTANT SAFETY INFORMATION (continued)

- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.

After HyQvia infusion a temporary, soft swelling may occur around the infusion site, which may last 1 to 3 days, due to the volume of fluid infused. The following possible side effects may occur at the site of infusion and generally go away within a few hours, and are less likely after the first few infusions.

- Mild or moderate pain
- Redness
- Swelling
- Itching

The most common side effects of HyQvia are:

- Headache
- Fatigue
- Nausea
- Fever
- Vomiting

Antibodies to the hyaluronidase component of HyQvia were formed in some patients taking HyQvia. It is not known if there is any long-term effect. In theory, these antibodies could react with your body's own hyaluronidase (PH20). PH20 is present in the male reproductive tract. So far, these antibodies have not been associated with increased or new side-effects.

These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.

Please see Important Facts about HyQvia on the following page.

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.

What makes HyQvia different? Scan the code!

You can always visit **HyQvia.com/why-hyqvia** to learn what makes HyQvia different, and so much more.

Takeda

IMPORTANT FACTS about HYQVIA (Hi-Q-via) [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase] Solution, for subcutaneous administration

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

- HYQVIA can cause blood clots.
- Call your healthcare provider (HCP) if you have pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s), unexplained shortness of breath, chest pain or discomfort that worsens on deep breathing, unexplained rapid pulse, numbness or weakness on one side of the body.
- Your HCP may perform blood tests regularly to check your IgG level.
- Do not infuse HYQVIA into or around an infected or swollen area because it can cause infection to spread.

What is HYQVIA?

HYQVIA is a liquid medicine containing immune globulin and Recombinant Human Hyaluronidase. HYQVIA is given under the skin (subcutaneously) to treat primary immunodeficiency (PI) in people 2 years of age and older. HYQVIA contains IgG antibodies, collected from human plasma donated by healthy people. The antibodies help your body to fight off bacterial and viral infections. The hyaluronidase part of HYQVIA helps more of the immune globulin get absorbed into the body to fight infection.

What should I tell my HCP before I start using or while using HYQVIA?

Tell your HCP if you:

- Have or had any kidney, liver, or heart problems or history of blood clots because HYQVIA can make these problems worse.
- Have IgA deficiency or a history of severe allergic reactions to IgG or other blood products.
- Are pregnant, trying to become pregnant, or are breastfeeding. It is not known whether HYQVIA can harm the unborn baby or breastfed infant.

Who should not take HYQVIA?

- Do not take HYQVIA if you are allergic to IgG, hyaluronidase, other blood products, or any ingredient in HYQVIA.

How should I take HYQVIA?

- HYQVIA is infused under the skin (subcutaneously) up to once every 4 weeks.
- You can get HYQVIA at your HCP's office, clinic, or hospital.
- You can use HYQVIA at home. You and your HCP will decide if home self-infusion is right for you.

What are the possible or reasonably likely side effects of HYQVIA?

After HYQVIA infusion a temporary, soft swelling may occur around the infusion site, which may last 1 to 3 days, due to the volume of fluid infused.

The following local reactions may occur at the site of infusion and generally go away in a few hours. Local reactions are less likely after the first few infusions.

- Mild or moderate pain
- Redness
- Swelling
- Itching

The most common side effects of HYQVIA are: headache, vomiting, fatigue, nausea, and fever.

Antibodies to the hyaluronidase component of HYQVIA were formed in some patients taking HYQVIA. It is not known if there is any long-term effect. In theory, these antibodies could react with your body's own PH20. PH20 is present in the male reproductive tract. So far, these antibodies have not been associated with increased or new side effects.

Call your HCP or go to your emergency department right away if you get:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms, other than at the infusion site(s). These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, blue lips or extremities. These could be signs of a serious heart or lung problem.

These are not all of the possible side effects for HYQVIA. You can ask your HCP for information that is provided to HCPs. Talk to your HCP about any side effects that bother you or that don't go away.

How do I store HYQVIA?

Store HYQVIA refrigerated or at room temperature.

- You can store HYQVIA in the refrigerator (36°F to 46°F [2°C to 8°C]) for up to 36 months.
- You can store HYQVIA at room temperature (up to 77°F [25°C]) for up to 3 months during the first 24 months from the date of manufacturing (Mfg Date) printed on the carton.
- Do not return HYQVIA to the refrigerator if you take it out to room temperature.

Check the expiration date on the carton and vial label. Do not use HYQVIA after the expiration date.

Do not freeze.

Protect from light. You can use the original HYQVIA containers to protect it from light.

How do I get more information about HYQVIA?

The risk information provided here is not comprehensive. To learn more, talk about HYQVIA with your HCP or pharmacist. The FDA-approved Full Prescribing Information, including Information for Patients, can be found at www.HYQVIA.com or by calling 1-877-TAKEDA7 (1-877-825-3327).

US-HYQ-0299v4.0 06/23

have a mental health disorder compared to those without it.[5]

While it is best to stay home when you know there's a very real risk of exposing yourself to unwanted illness (such as visiting a friend who you know is sick) or when you're not feeling well yourself, it is equally important to know that over time, social isolation and loneliness can make you sick, too, because they put you at higher risk for high blood pressure, heart disease, obesity, a weakened immune system, anxiety, depression, cognitive decline, Alzheimer's disease and even death.[3]

Although being around others in a social setting does pose a risk, the benefits of social activity may outweigh the risk. According to Crawford, "There have been studies to show that socialization can be beneficial for one's immune system. There are precautions that can be taken to help mitigate those risks: possibly wearing a mask, washing hands, etc. But the neat thing is in this day and age, you do not necessarily have to leave your house for socialization."

People with PI are 91 percent more likely to have a mental health disorder compared to those without it.

If the idea of being around other people makes you nervous, remember: Over time, not being around other people could make you sick, too. So, whether you connect with a limited amount of people you trust, meet new people online or have a lot of friends out in the community, the point is: Stay active and get connected! It's vitally important to your health, too.

10 Ways to Stay Socially Active

1) *Figure out what's holding you back.* What barriers do you face? Does your budget, lack of transportation or a physical limitation keep you isolated? Or maybe a slew of "What if's" are holding you back: What if I'm exposed to something that makes me really sick? What if I get sick beforehand and have to cancel my plans? What if I can't hear what's going on? What if I can't get to a bathroom fast enough?

Obstacles are real, but instead of deciding you can't do anything, think about ways you can do something. Talk about it with someone you trust (a spouse, adult child, caretaker, friend). Tell them about the things you would like to do and the obstacles that make it difficult to do them. Ask them to help you think of ways to work around the problems. For example, if urinary incontinence makes leaving the house hard, consider wearing leak-absorbent underwear (such as Knix or Thinx) while you're out. If you love ballroom dancing but arthritis makes it too painful, consider taking an aqua dance class instead. If vision loss prevents you from joining a book club, participate by listening to an audio version of the book.

2) *Stay in touch with someone you already know.* It could be a family member or friend you know well, or even an acquaintance you would like to get to know better. Whoever it is, pick up the phone, send a quick text or write a handwritten letter. Reach out and invite that person to join you for a regular check-in over a cup of coffee, lunch, a walk through the park or, if you can't meet in person, a phone call or video chat.

3) *Seek out community centers.* According to Crawford, community centers and senior centers in your city or county always have activities going on, and they're especially helpful to adults ages 55-plus with their peers. If you have access to the Internet, search for local calendars online. If you don't have Internet access, or if you prefer to speak to someone in person, pop in for a visit or call and request information be sent to you by mail.

4) *Try something new.* Add something new to your social calendar. Perhaps there's an activity you've always wanted to do, but just haven't gotten around to it. Do yourself a favor and sign up for the class, buy tickets to the event or commit to a volunteer opportunity. Not sure where to start? Check your community event calendar for local options. Find something that interests you, whether it is in-person or online, and sign up to attend. Bring a friend or family member along for the fun!

5) *Pursue a hobby.* You know that hobby you love? Seek out groups of others who enjoy it, too, and attend events they sponsor. (Don't have a hobby yet? Take a quiz to discover something new! Try HobbyFinder.io.) You'll increase your chances of meeting people with whom you have things in common, and shared experiences naturally cultivate connection. If in-person events don't work for you, explore

online alternatives. "We have a resident here who plays virtual bridge with her family every Sunday," said Crawford, "and I have known of some residents whose book clubs also met virtually."

6) *Volunteer your time and talents.* Think about causes important to you, and inquire about ways to get involved. Perhaps politics are your thing: Sign up to help at your local polling place. Are you an animal lover? Contact a local shelter and ask how you can get involved. You can even combine your love of travel with volunteering your time and effort through Global Volunteers, an organization connecting seniors, travel and service projects. (See globalvolunteers.org for more information.)

7) *Make friends online.* Connect with others you wouldn't otherwise meet using the power of the Internet. Try a lesser-known friend-finding app such as Frienderapp.com, Nextdoor.com, Skout.com or Meetup.com to help you discover "your people" — the ones who share similar interests or life experiences and with whom you may develop a lasting friendship. If you have PI, get involved with the Immune Deficiency Foundation (IDF) Peer Support Program as a mentor, or join an IDF Get Connected Group to connect with other patients with PI, share experiences and offer support to each other. (Go to primaryimmune.org/living-primary-immunodeficiency/get-support/peer-support-program for more information.)

8) *Say yes.* When someone invites you somewhere, accept the invitation. Put it on your calendar and plan to attend, and then work out a plan to actually go later. (For example, if your granddaughter has a dance recital but you can't drive yourself to it, mark your calendar and then talk to friends and family to figure out how you'll get there.) True, you might end up having to cancel, but there's also a good chance you will be able to go, too! Don't miss out on an opportunity based on "What if?"

9) *Get a job.* Meaningful, productive work helps cultivate a sense of purpose. If you're not currently working, consider getting a job since it can provide a place to interact with others on a regular basis. If you are interested and able, plenty of in-person full- and part-time jobs are available that may align with your interests and/or natural talents. If you can't commit to leaving the house, explore remote jobs that can be done on your computer such as online teaching (try Outschool.com), tutoring, online coaching, customer service or telehealth nurse. Or, check out FlexJobs.com for more inspiration.

10) *Join an exercise group.* Sign up for a fitness class, take a water aerobics class or join a walking group or biking club. "These are amazing places to join a community and to build friendships!" says Crawford. If you can't get out of the house, silversneakers.com offers a wealth of live and on-demand online classes and workshops for aging adults, as well as a list of in-person classes in your area. There's even an app for on-the-go!

It's Work, but It's Worth It

Engaging in social activities is beneficial for mental health as people age. "Not having someone to talk to, relate to or connect with can cause feelings of loneliness," says Crawford. "Loneliness can spiral into depression and anxiety. But staying busy and having activities to look forward to and to feel 'normal' is important for mental health. Social activities are fun, and they also take brain power: Conversations and games can both help with a decrease in cognitive decline. And, volunteering makes people feel needed." Since those with PI are at a heightened risk for mental health disorders, it's even more important for them to prioritize staying social and cultivating meaningful connections.

Granted, sometimes you'll still have to say no (such as when a friend or family member asks you come over to visit them while they're sick or if an event happens on the same day as an infusion), but sometimes, saying yes is not only possible, but good for you (such as when a friend invites you to meet for coffee to chat about a book you both just finished reading).

Remember: Staying socially active as you age — especially when you have PI — is vitally important to your overall health and wellness. Yes, medicine adherence, a healthy diet, adequate sleep, plenty of fresh air and exercise are all key components to staying healthy, but so is social activity. Do something good for yourself and pick one small step to take today to start cultivating a social life that brings you joy. With time, effort and creativity, it will be worth it! IG

References

1. Malani, P, and Kullgren, J. On Pandemic's Third Anniversary, Loneliness and Isolation Are Down, But Still High, Among Older Adults. University of Michigan Institute for Healthcare Policy and Innovation press release, March 2023. Accessed at ihpi.umich.edu/news/pandemics-third-anniversary-loneliness-and-isolation-are-down-still-high-among-older-adults.
2. Centers for Disease Control and Prevention. How Does Social Connectedness Affect Health? Accessed at www.cdc.gov/emotional-wellbeing/social-connectedness/affect-health.htm.
3. Social Isolation, Loneliness in Older People Pose Health Risks. National Institute on Aging, April 23, 2019. Accessed at www.nia.nih.gov/news/social-isolation-loneliness-older-people-pose-health-risks.
4. Physical Health and Mental Health. Mental Health Foundation, updated Feb. 18, 2022. Accessed at www.mentalhealth.org.uk/explore-mental-health/a-z-topics/physical-health-and-mental-health.
5. Jackson-Cannady, A. What You Should Know About PI and Your Mental Health. HealthCentral, April 17, 2023. Accessed at www.healthcentral.com/condition/primary-immunodeficiency/pi-and-your-mental-health.

RACHEL MAIER, MS, is the associate editor of *IG Living* magazine.

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Abbie Cornett, MBA
IG Living Patient Advocate

Planes, Trains and Automobiles: Traveling with IG Therapy

By Wendie Chadd

PLANNING FOR travel can be stressful without a chronic health condition. But when traveling with a chronic illness and needing to also travel with immune globulin (IG) supplies, it is essential that you plan ahead. Proper research, proactive planning and preparation will allow you to travel with ease and confidence.

Regardless of your destination or mode of transportation, there are easy yet essential steps to prepare you for seamless travel. Optimal travel planning should start approximately 12 weeks prior to the scheduled departure date. Start by aligning travel dates with projected infusion dates. Proactive planning provides ample time to work with your physician's office and specialty infusion provider.

Use this travel planning guide to minimize stress and maximize confidence as you prepare for your travels:

1) Obtain a Letter of Medical Necessity

Most physicians' office staff are familiar with providing a "letter of medical necessity" (LMN) (Figure 1). The LMN should include the patient's name, date of birth, diagnosis and the medication/supplies needed while traveling. It should also state that it is medically necessary for the patient to travel with the medications, and that the medications must be within their possession at all times.

Figure 1. Sample Letter of Medical Necessity

Date

Patient's Full Name

Patient's DOB

To Whom It May Concern:

[PATIENT NAME, DOB] is under the care of [PHYSICIAN/OFFICE NAME] for care and treatment of [TREATING DIAGNOSIS]. The condition requires intravenous infusion of [MEDICATION]. It is medically necessary for [PATIENT NAME] to carry this/these medication(s), infusion pump and administration supplies with him/her at all times.

Administration supplies for completing the infusion include [DETAIL OUT INFUSION SUPPLIES]:

- Supply
- Supply
- Supply
- Supply or equipment

[PATIENT] should be permitted to keep these lifesaving medications with him/her at all times.

Please contact our office if you have any questions.

Thank you,

Prescribing Physician Signature

Physician Name

Title

Address

Phone Number

2) Partner with Your Specialty Infusion Provider

Contact your specialty infusion provider to discuss your travel details, projected infusion dates and to request a copy of your medication prescription. Your infusion provider can discuss options for infusion prior to your travel, as well as upcoming refill date(s) to ensure you will have adequate medication and supplies during your travels.

Ask your specialty pharmacy provider to package your travel dose(s) separately. Having your travel dose(s) clearly labeled by your pharmacy provider and already packed neatly in clear plastic bags allows for stress-free review and repacking for your upcoming travel.

If your infusions require nursing, your specialty infusion provider will be able to confirm your options for infusion services during your travels. Depending on your insurance coverage, your provider may be able to coordinate nursing services and/

or provide you with an infusion center in or around your destination in the U.S.

Optimal travel planning should start approximately 12 weeks prior to the scheduled departure date.

3) Purchase Protective and Portable Packaging

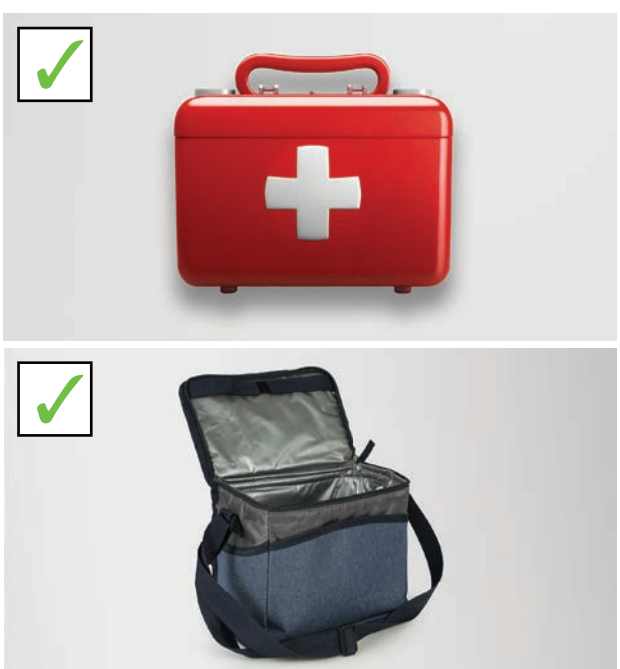
Knowing that your temperature-sensitive IG medications contain liquid and require specific equipment and supplies for administration, they should be placed in a dedicated carry-on size bag. Your medication, supplies and equipment should be treated as a carry-on bag whether you are traveling by car, bus, train or airplane. The bag should remain easily accessible and alongside you within the same safe, temperature-controlled passenger area. Your medications should never be checked in luggage when flying, placed in the luggage compartment of a bus/train or stored in the trunk of a car. This is because luggage storage compartments are not temperature- or pressure-regulated. Extreme temperatures, altitude and pressure changes can have a detrimental effect on medications and equipment.

Your dedicated carry-on bag should contain a copy of your LMN, your current prescription and all medications, supplies and equipment. This will keep them safe and accounted for throughout your travels.

4) Plan Ahead for Airport Screening

The Transportation Security Administration (TSA) does allow medically necessary medications through TSA checkpoints with the appropriate screening. Passengers with a current prescription, LMN and the proper identification are allowed to carry their medication, supplies and ice packs

Traveling with Liquid Medications

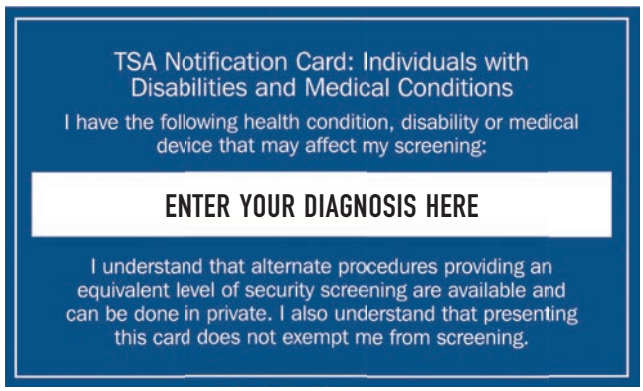


All IG medications, supplies and equipment should be placed in a dedicated carry-on bag, which should also contain a copy of your letter of medical necessity and current prescriptions.

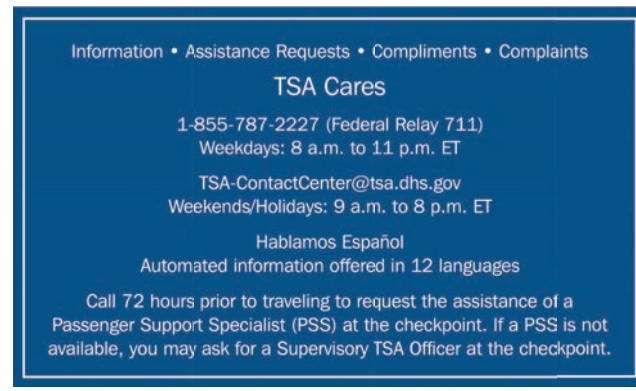
Because IG medications are temperature-sensitive, they should always be accessible and alongside. They should never be stored in a trunk or in a luggage compartment.

Figure 2. Sample TSA Notification Card

FRONT



BACK



through airport security, regardless of the fluids being greater than the 3.4 fluid ounce (100 milliliter) limit.

It can be helpful for you to obtain a TSA Notification Card (Figure 2). This is an online-accessible, personalized notification card that is well-recognized by TSA officers throughout the country. It is approximately the size of a driver's license or federal ID and can be personalized for your specific diagnosis. You can personalize and print the TSA Notification Card at www.tsa.gov/sites/default/files/disability_notification_card_508.pdf.

Note that TSA is required to screen all bags and medications. You may be asked to remove your medications from their carry-on bag and repackage them after the visual screening. These added screening steps are normal, and will take a bit more time, which is why you should allow for additional processing time prior to departure. Lastly, remain positive and supportive of your local TSA officers and their procedures. Their work is imperative to ensure safe travel for us all.

5) Follow Guidance for Traveling Abroad

The Centers for Disease Control and Prevention (CDC) website provides the necessary guidance and additional information for traveling internationally with your medication and supplies.

It is important to note that not all medications can be transported into or through all countries. Each country has its own regulations about which medications are legal, licensed and/or controlled. You, as the traveler, are responsible for confirming and meeting the requirements prior to your travel. Each country's embassy site should be checked to confirm that your specific medications are allowed and if there are any additional needs or requirements. Most countries will allow a 30-day supply of most medications with supporting documentation.

Your infusion provider can discuss options for infusion prior to your travel, as well as upcoming refill date(s) to ensure you will have adequate medication and supplies during your travels.

The CDC travel page (wwwnc.cdc.gov/travel) provides clear guidance, allowing you to travel with confidence and ease.

Don't Let Your Illness Prevent You From Traveling!

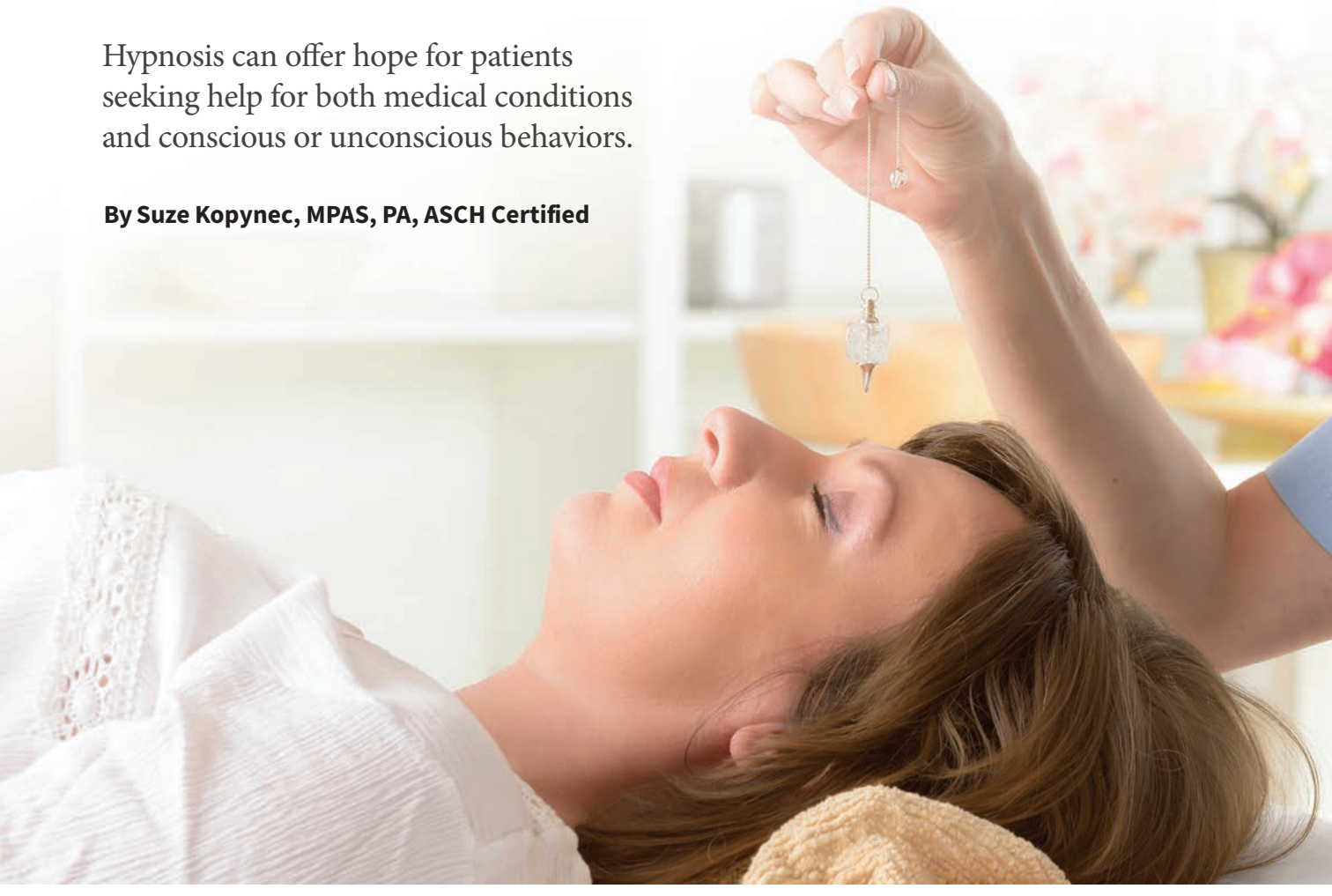
Living with a chronic condition can be challenging at times, yet it should not limit you from visiting friends, exploring new destinations or creating lifelong memories with loved ones. Communication and proactive planning will provide peace of mind, while allowing you to focus on the exciting pleasures awaiting you along your journey. IG

WENDIE CHADD is the senior director of patient care services at Nufactor, a specialty infusion company.

MEDICAL HYPNOSIS:
Evidence-Based Therapy for Chronic Pain and More

Hypnosis can offer hope for patients seeking help for both medical conditions and conscious or unconscious behaviors.

By Suze Kopynec, MPAS, PA, ASCH Certified



WE HAVE more control over our mind and body responses than we realize, even when diagnoses may cause us to feel powerless. When we are under mental or physical stress, often due to choices we make or circumstances that seem fully out of our control, we are more likely to have worsened pain, gastrointestinal symptoms, poor immune responses and susceptibility to illness because our bodies can't function optimally. Hypnosis is commonly used to help with these things, from habit control, phobias, weight loss, improved sports or testing performance, confidence or a myriad of other desired changes.

For instance, we've all made choices that have negatively impacted our lives — even repeatedly made poor choices without understanding why. Our responses come from witnessed, actual or implied input or behaviors from others that we have consciously or, in most cases, unconsciously accepted as our own. For example, we exercise (or not) or we eat healthy foods (or not), typically because we learned that behavior from the people with whom we were raised, observing what family, friends or others do (or don't do). We may get suddenly angry about something little, blowing it all out of proportion and don't know why, vowing never

to do it again, yet we do, sometimes over and over again. Consciously, we know how we want to respond and that we want to make different choices. Yet, although many of us really want to choose differently or be different, it can seem impossible because it feels "normal" or "right" or "like something we have no control over." These are all examples of behaviors or reactions that arise from unconscious patterns.

However, hypnosis helps us to choose differently, and choosing differently can get us out of the ruts worn in our brains (from reactions on repeat) and create new, desired responses. In addition, the tool of hypnosis (based on research when used by medical and mental health professionals) can also be used in clinical settings to improve medical problems, as well as facilitate desired changes by empowering us to make different choices. In fact, research has proven that medical hypnosis (generally referred to as "clinical hypnosis") is an effective treatment for countless medical and mental health conditions.

Following is an overview of clinical hypnosis, including brief technical explanations to highlight this effective, yet underutilized option for treating chronic pain and more.

What Is Hypnosis?

The word "hypnosis" typically brings to mind its portrayal in stage shows, television or movies. Stage-show hypnosis, unlike clinical hypnosis, is used purely for entertainment, offering no therapeutic claims. These performers choose extroverts from the audience who enjoy being the center of attention. These individuals are chosen because they are most likely to "go along" with the show, or there may be "plants" in the audience who appear randomly selected.

However, the authentic form of hypnosis referred to in this article is not contrived, and it is utilized solely by healthcare professionals. According to psychologist Irving Kirsch, PhD, hypnosis is both an experience and a procedure. "Hypnosis is a state of inner absorption, concentration or focused attention that assists in altering some aspects of thought, emotion, behavior or perception. Hypnosis is a procedure during which a health professional or researcher suggests that a client, patient or subject experience changes in sensations, perceptions, thoughts, feelings or behavior."[1] A simpler definition is that hypnosis focuses on what we desire, while shutting out our conscious thoughts or the external messages from others that get in the way.

The Mayoclinic.org website adds, "The essence of the hypnotic experience is a reduction in the general awareness of what is going on around you, and an increased focus-of-attention on internal experiences or on more narrowly defined external experiences. A goal of hypnosis is to access this experiential state and harness the power of it, allowing you to access your strengths and resources to resolve difficulties and promote the changes you desire."

Hypnosis typically involves four steps: 1) creating a state or condition for hypnosis to occur, 2) advancing the inner absorption that's been initiated, 3) providing repetitive messages related to an individual's desired outcomes and 4) the return to full awareness or alertness, generally feeling refreshed, energized, peaceful and relaxed, all of which nicely co-exist. Hypnosis enables one to imagine a different way of being, opening the door to change.

The Mind-Body Connection

Western medicine has taught us — healthcare professionals and patients alike — to separate issues into mental (mind) or physical (body). But new findings in neuroscience prove what many of us have known all along: That separation does not exist. Patients may have been told by their care providers

What Can Medical/Clinical Hypnosis Treat?

Hypnosis helps many medical and mental health conditions, in addition to general life issues:

- Phobias
- Behavior or habit control issues, including smoking cessation or addictions
- Weight issues
- Enuresis (bed-wetting)
- Self-confidence
- Performance enhancement
- Insomnia
- Asthma
- Hot flashes during menopause
- Gastrointestinal disorders (now known as functional gastrointestinal disorders)
- Pain control related to surgery, childbirth, cancer, fibromyalgia, burns, headaches (migraine and tension), etc.
- Skin conditions, including warts/psoriasis
- Side effects of medicines, cancer, chemotherapy or radiation treatment, including nausea and vomiting
- Trichotillomania (hair pulling)

Hypnosis continues to be explored for further use in many other conditions. It enhances traditional treatments and empowers those who use it to improve their health.

For the treatment of primary immunodeficiency in patients 2 years of age and older

XEMBIFY offers steady protection from infection with the convenience of subcutaneous administration[1,2]

Learn more at XEMBIFY.com

Xembify®
(immune globulin subcutaneous human-klhw) 20%

XEMBIFY® (immune globulin subcutaneous human–klhw) is a 20% immune globulin indicated for treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older. XEMBIFY is for subcutaneous administration only.

XEMBIFY should not be used if you have had a severe allergic reaction to human immune globulin, or if you have been told by a doctor that you are IgA deficient and have developed antibodies to IgA and hypersensitivity after exposure to a previous plasma product.

XEMBIFY Patient Speaker Programs

Join a virtual education session led by a healthcare professional to learn about PI, IG therapy, and XEMBIFY.

Scan the code or visit XembifyPatientProgram.com to learn more and register.

GRIFOLS

Please see Important Safety Information for XEMBIFY on the following page.

Xembify®
(immune globulin subcutaneous human–klhw) 20%

Important Safety Information

What is XEMBIFY®?

XEMBIFY® (immune globulin subcutaneous human–klhw) is a 20% immune globulin used in the treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older. XEMBIFY is for subcutaneous administration only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis (formation of blood clots within blood vessels) may occur with immune globulin products, including XEMBIFY. Before you take XEMBIFY, talk to your doctor if you:**
  - **Are older**
  - **Are sedentary (need to lie down or sit down) for long periods of time**
  - **Are taking estrogen-containing medicines (birth control pills, hormone replacement therapy)**
  - **Have a permanent intravenous (IV) catheter**
  - **Have hyperviscosity of the blood (diseases such as multiple myeloma or other causes of elevated proteins in the blood)**
  - **Have cardiovascular (heart) problems or previous history of stroke**
- **Thrombosis may occur even if you don't have any risk factors**
- **If you are at risk of thrombosis, your doctor may prescribe XEMBIFY at the minimum dose and infusion rate. Make sure you drink plenty of fluid before taking XEMBIFY. Make sure your doctor is checking you regularly for signs and symptoms of thrombosis and is checking your blood viscosity if you are at risk of hyperviscosity**

Who should not use XEMBIFY?

- XEMBIFY should not be used if you have had a severe allergic reaction to human immune globulin, or if you have been told by a doctor that you are IgA deficient and have developed antibodies to IgA and hypersensitivity after exposure to a previous plasma product

What are possible serious side effects of XEMBIFY?

- **Hypersensitivity.** Severe allergic reactions may occur with immune globulin products, including XEMBIFY. If you have a severe allergic reaction, stop the infusion immediately and get medical attention. XEMBIFY contains IgA. If you have known antibodies to IgA, you may have a greater risk of developing potentially severe allergic reactions
- **Aseptic meningitis syndrome (AMS).** Aseptic meningitis is a non-infectious inflammation of the membranes that cover the brain. It causes a severe headache syndrome, which may occur with human immune globulin treatment, including XEMBIFY. If you are showing signs and symptoms of AMS, your doctor may conduct a thorough neurological evaluation including spinal tap (sampling fluid which surrounds the spinal cord) to rule out other causes of meningitis. Stopping human immune globulin treatment has resulted in the end of signs and symptoms within several days. Treatment may include analgesics (pain medicines) and/or a special procedure known as a "blood patch" to stop headache
- **Kidney problems or failure.** Kidney problems or failure may occur with use of human immune globulin products, especially those containing sucrose (sugar). XEMBIFY does not contain sucrose. If you have kidney disease or diabetes with kidney involvement, your doctor should perform a blood test to assess your hydration level and kidney function before beginning immune globulin treatment and at appropriate intervals thereafter. If your doctor determines that kidney function is worsening, they may discontinue treatment
- **Hemolysis.** Your doctor should monitor you for symptoms of hemolysis (destruction of red blood cells causing anemia, or low red blood cell count). If your doctor suspects hemolysis, they should perform additional tests to confirm
- **Transfusion-related acute lung injury (TRALI).** TRALI is a rare but serious syndrome characterized by sudden acute respiratory distress following transfusion. If your doctor suspects TRALI, they will monitor you for any other lung issues. TRALI may be managed with oxygen therapy
- **Transmissible infectious agents.** Because XEMBIFY is made from human blood, it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases or CJD have been associated with the use of XEMBIFY
- **Interference with lab tests.** Because XEMBIFY contains a variety of antibodies, blood tests to determine antibody levels may be falsely elevated. Be sure to tell your doctor or lab technician that you are using XEMBIFY

What are other possible side effects of XEMBIFY?

- In clinical studies of XEMBIFY, some patients experienced local side effects (at the injection site) including pain, redness, puffiness, bruising, nodules, itching, firmness, scabbing and swelling at the site on the skin where the injection occurred. Some patients experienced non-injection-site side effects including cough and diarrhea.
- Use of XEMBIFY may interfere with the immune response to virus vaccines, such as vaccines for measles, mumps, rubella and varicella. Tell your doctor you are taking XEMBIFY before getting vaccinations

Please see the full Prescribing Information for XEMBIFY at XEMBIFY.com.

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.

References: 1. Sleasman JW, Lumry WR, Hussain I, et al. Immune globulin subcutaneous, human - klhw 20% for primary humoral immunodeficiency: an open-label, Phase III study. *Immunotherapy*. 2019;11(16):1371-1386.
2. XEMBIFY® (immune globulin subcutaneous human-klhw) 20% Prescribing Information. Grifols.

GRIFOLS

XEMBIFY®

XEMBIFY (immune globulin subcutaneous, human – klhw) 20% solution

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use XEMBIFY safely and effectively. See full prescribing information for XEMBIFY.

XEMBIFY (immune globulin subcutaneous, human – klhw) 20% solution

Initial U.S. Approval: 2019

WARNING: THROMBOSIS

See full prescribing information for complete boxed warning.

- **Thrombosis may occur with immune globulin products, including XEMBIFY. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **For patients at risk of thrombosis, administer XEMBIFY at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

---------- INDICATIONS AND USAGE ----------

XEMBIFY® (immune globulin subcutaneous, human- klhw) is a 20% immune globulin solution for subcutaneous injection indicated for treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older.

----------DOSAGE AND ADMINISTRATION ----------

For subcutaneous infusion only.

Before switching to XEMBIFY, obtain the patient's serum IgG trough level to guide subsequent dose adjustments.

Dose

- Switching from immune globulin intravenous (human), 10% (IVIG) to XEMBIFY: calculate the dose by using a dose adjustment factor (1.37)
- Weekly: Begin XEMBIFY one week after last IVIG infusion.
- Establish initial weekly dose by converting the monthly (or every 3 weeks) IVIG dose into an equivalent weekly dose and increasing it using a dose adjustment factor (1.37).

$$\text{Initial weekly dose (grams)} = \frac{\text{Prior IVIG dose (in grams)}}{\text{Number of weeks between IVIG doses}} \times 1.37$$

- Frequent dosing (2-7 times per week): Divide the calculated weekly dose by the desired number of times per week.
- Switching from immune globulin subcutaneous (human) treatment (IGSC): Weekly dose (grams) should be the same as the weekly dose of prior IGSC treatment (grams).

Administration

Infusion sites: up to 6 infusion sites simultaneously, with at least 2 inches (5 cm) between sites avoiding bony prominences. Rotate sites for each administration.

---------- DOSAGE FORMS AND STRENGTHS ----------

XEMBIFY is a solution containing 0.2 g/mL (200 mg/mL; 20%) protein solution for subcutaneous infusion.

---------- CONTRAINDICATIONS ----------

- Anaphylactic or severe systemic reactions to human immunoglobulin or inactive ingredients of XEMBIFY such as polysorbate 80.
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity.

---------- WARNINGS AND PRECAUTIONS ----------

- Hypersensitivity and anaphylactic reactions may occur. IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity or anaphylactic reactions.
- Aseptic Meningitis Syndrome (AMS) may occur within two days of treatment.
- Monitor for renal function in patients at risk for renal failure.
- Hemolysis can develop. Risk factors include high doses and non-O blood group. Closely monitor for hemolysis and hemolytic anemia.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- XEMBIFY is made from human plasma and may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
- Passive transfer of antibodies may confound serologic testing.

---------- ADVERSE REACTIONS ----------

The most common adverse reactions in ≥ 5% of subjects in the clinical trial were local adverse reactions including infusion site erythema (redness), infusion site pain, infusion site swelling (puffiness), infusion site bruising, infusion site nodule, infusion site pruritus (itching), infusion site induration (firmness), infusion site scab, infusion site edema, and systemic reactions including cough and diarrhea.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- DRUG INTERACTIONS ----------

The passive transfer of antibodies may transiently interfere with the response to live virus vaccines, such as measles, mumps, rubella, and varicella.

---------- USE IN SPECIFIC POPULATIONS ----------

Geriatric: In patients over 65 years, do not exceed the recommended dose and infuse XEMBIFY at the minimum rate practicable.

Manufactured by:
GRIFOLS
Grifols Therapeutics LLC
Research Triangle Park, NC 27709 USA
U.S. License No. 1871
3056462
Revised 8/2020

Hypnosis Resources

- American Journal of Medicine: www.amjmed.com/action/showPdf?pii=S0002-9343%2820%2930946-3
- American Psychological Association: www.apa.org/topics/psychotherapy/hypnosis
- American Society of Clinical Hypnosis: www.asch.net/aws/ASCH/pt/sp/home_page
- Cleveland Clinic: my.clevelandclinic.org/health/treatments/22676-hypnosis
- Medical Hypnosis: An Underutilized Treatment Approach by Brian Alman, PhD (2001): www.ncbi.nlm.nih.gov/pmc/articles/PMC6220618
- *Medical Hypnosis Primer Clinical and Research Evidence* by Arreed Franz Barabasz, Karen Olness, Robert Boland and Stephen Kahn (editors): www.routledge.com/Medical-Hypnosis-Primer-Clinical-and-Research-Evidence/Barabasz-Olness-Boland-Kahn/p/book/9780415871785
- Michael Yapko, PhD, Podcast Interview: feelinggood.com/2023/03/06/334-clinical-hypnosis-featuring-dr-michael-yapko
- Milton H. Erickson Foundation: www.erickson-foundation.org
- National Center for Complementary and Integrative Health: www.nccih.nih.gov/search?q=hypnosis&sitelimit=
- National Pediatric Hypnosis Training Institute: www.nphti.org
- Ran Anbar, MD, FAAP, Interview on "Crushing Doubt" Podcast (Dan Ratner, PhD, June 2, 2022): youtu.be/vX7DN2F7SHg
- Rich Roll Podcast: The Surprising Neuroscience of Hypnosis: Myths, Truths and Use Cases with David Spiegel, MD (Oct. 17, 2022): www.youtube.com/watch?v=O8fPExRLX2s
- Society of Clinical and Experimental Hypnosis: www.sceh.us
- Steve Eichel, PhD, ABPP (Zoe D. Katze's owner): www.dreichel.com/articles/dr_zoe.htm
- The Medical Power of Hypnosis (BBC, May 29, 2022): www.bbc.com/future/article/20220519-does-hypnosis-work

that either 1) nothing is wrong with them and it's all in their head or 2) they can't find anything abnormal, so there is nothing more they can do for them. Yet, we are whole beings, and in reality, we are not sectioned out into physical, mental, emotional, spiritual or social divisions. Humans simply created those divisions to discuss and explore them, and even use them for billing purposes.

Our thoughts affect the ability of our body to function. Thoughts or emotions trigger the release of hormones and neurotransmitters in the brain, which can affect various physiological responses such as heart rate, blood pressure, breathing, digestion and immune system functioning.

Negative thoughts and emotions can activate the sympathetic nervous system, which responds to outside threats, leading to chronic stress and the release of stress hormones. Positive thoughts and emotions promote relaxation, happiness and overall well-being, triggering the parasympathetic nervous system, which manages healing. The relationship between thoughts, physiology and emotions is complex and bidirectional. Any aspect of us affects all of our biology in some way, all the time.

Hypnosis is a powerful tool for accessing the subconscious mind, where beliefs and behaviors are rooted. When positive suggestions are repeated during hypnosis, they are integrated into the subconscious mind, allowing desired changes in behavior and thoughts to take place.

How Does Hypnosis Work?

Research keeps shedding light on how hypnosis works. And, rather than causing hypnosis to appear as mysterious or magical, the findings provide yet more evidence of the incredibly complex functioning of these miraculous bodies we inhabit. Objective evidence shows that hypnosis produces noticeable changes in the brain through available methods of testing typically reserved for research purposes.

• An electrodermal sensor measures changes in heat and electricity passed through the skin by nerves and sweat. The relaxation response is evidenced by findings of heart rate, heart rate variability, respiratory signals, electrodermal activity and other physiological or body function parameters.

• Functional magnetic resonance imaging (fMRI) studies compare blood flow increases believed to be related to neuronal activity, showing that hypnotic suggestions can activate specific brain regions called the anterior cingulate cortex, insula and prefrontal cortex. About eight years ago, researchers at Stanford Medical Center, headed by renowned psychiatrist and hypnosis researcher David Spiegel, MD, showed clear evidence of hypnosis in the brain that showed fMRI testing confirmed changes occurred during hypnosis (Figure 1).

• Electroencephalogram (EEG) testing involves sensors that record the electrical activity of the brain. Various studies using EEG testing during hypnosis found that early hypnosis shows movement from our usual active state (which appears as beta waves) into slower alpha waves and then, once deeper into hypnosis, these further slow down to reveal theta waves. Hypnosis is not "sleep," although to some it may appear that way. The brain waves that correlate with sleeping are delta waves, which less commonly present during very deep hypnosis.

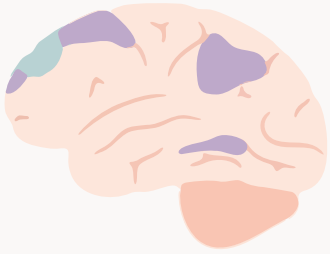
• Positron emission tomography (PET) shows 3D images of the inside of the body. PET scans can also be useful to

Figure 1. How Does Hypnosis Work?

1

In **diagram 1**, decreased activity occurs in the dorsal anterior cingulate cortex, shown in green, which correlates with relaxation and the ability to focus. This is part of the brain's salience network, which is responsible for psychological functions like decision-making, evaluation processes and emotional regulation.

2



In **diagram 2**, the dorsolateral prefrontal cortex (DPC), shown in blue, becomes less connected to the medial prefrontal cortex and the posterior cingulate cortex, which are parts of the default mode network of the brain, shown in purple. These connections are strongly associated with neural activity and cognitive tasks, so these decreased connections serve to quiet the critical mind, increasing openness to chosen suggestions.

3

In **diagram 3**, increased activity is seen between the DPC, shown in blue, and the insula, shown in tan. The DPC is associated with executive functions such as working memory and self-control, and the insula is a small region of the cerebral cortex that plays a significant role in pain perception, social engagements, emotions and autonomic control. The autonomic nervous system controls involuntary or unconscious responses to regulate physiological functions like breathing and the beating of our hearts. This increased activity improves the mind-body connection.

Source: Williams, SCP. Study Identifies Brain Areas Altered During Hypnotic Trances. Stanford Medicine News Center, July 28, 2016. Accessed at med.stanford.edu/news/all-news/2016/07/study-identifies-brain-areas-altered-during-hypnotic-trances.html.

show changes occurring in the brain during hypnosis. However, since this requires administration of radioactive material, it is infrequently used to validate changes related to hypnosis research.

Is Hypnosis Valid?

Many respected studies and journals establish the validity of hypnosis. There are two peer-reviewed professional hypnosis journals: 1) the American Society of Clinical Hypnosis' *American Journal of Clinical Hypnosis* and 2) the Society for Clinical and Experimental Hypnosis and The International Society of Hypnosis-affiliated journal titled the *International Journal of Clinical and Experimental Hypnosis*. Each has been publishing research related to hypnosis since the 1950s.

Further, a PubMed search for "hypnosis" returns 16,000-plus articles from these professional hypnosis journals and other respected journals. In addition, the National Center for Complementary and Integrative Health (under the National Institutes of Health) is currently funding large-scale studies evaluating the efficacy and mechanisms of hypnosis treatments.

Is Hypnosis Regulated?

Although research shows hypnosis is valid, there is not a standardized protocol for its regulation. In the United States, hypnosis is not regulated at the federal level, and only a small number of states specify guidelines for practicing "hypnotism" without a license. The remaining states do not regulate hypnosis, so there are zero requirements for practitioners' background, education or training.

All U.S. states, however, have laws prohibiting the practice of medicine without a license. Regulated, licensed health professionals with a master's or doctoral degree from an accredited institution can obtain training for clinical use of hypnosis. They have foundational knowledge about medical or mental health conditions, which is necessary to treat individuals most effectively, with or without the use of hypnosis. To ensure properly credentialed professionals are providing clinical hypnosis services, their state licensure and training should be confirmed by patients before seeking treatment.

While lay hypnotists can offer assistance for habits and vocational and avocational issues, it is illegal for them to

treat clinical conditions.

Beware: Lay hypnotists may display impressive-sounding "certifications" and even "degrees" that look official. However, individuals should not assume the awarding organizations are legitimate. Fraudulent organizations may be providing fake credentials without requirements other than a credit card to pay for them. An example of this is the story of Zoe D. Katze, PhD, who was granted her PhD and various "certifications" from multiple groups.[2] "Dr. Katze" is a cat whose story can be read by going to the website listed in the Hypnosis Resources.

Clinical Hypnosis: Another Option to Help Improve Life

Hypnosis is empowering. Once we understand the power of suggestion that may have caused us to feel stuck or unable to change, we begin to question everything that we had automatically accepted as fact. The tool of hypnosis can be used to facilitate change to a choice of our own choosing. It is a viable option that allows us to truly make a difference in the management of our health, emotions or simply life in general.

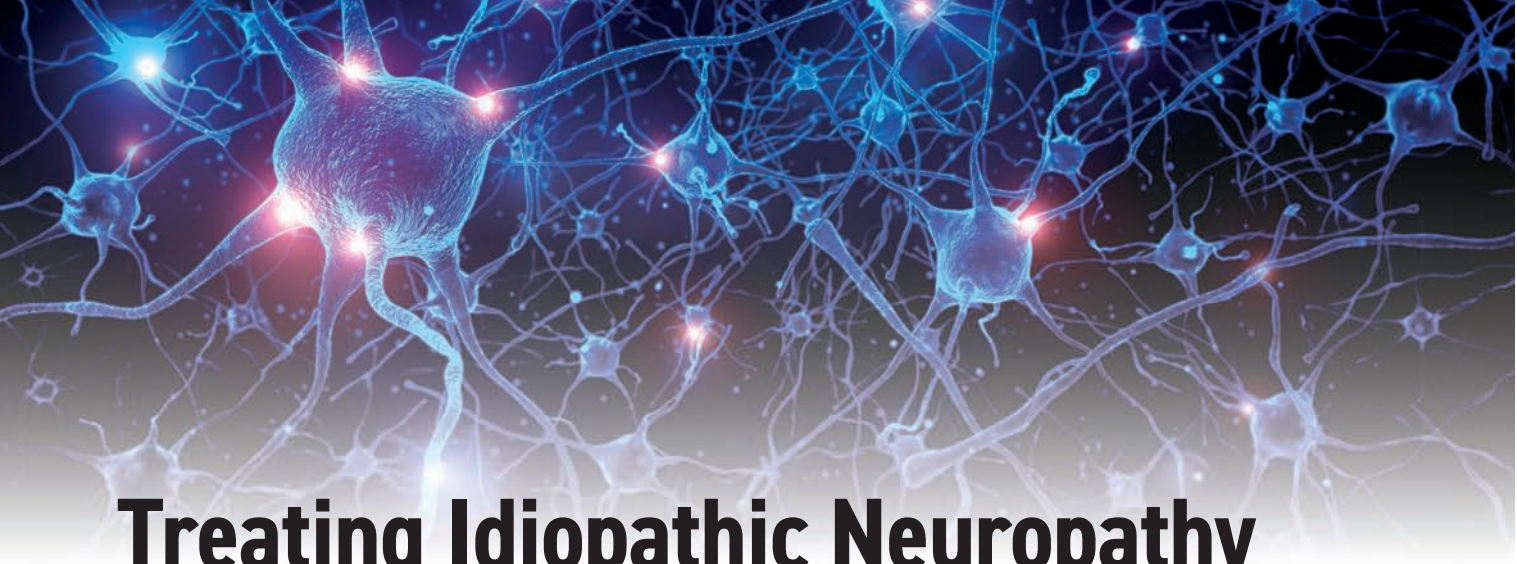
Clinical hypnosis can be effective for patients or someone they are caring for with a condition that is responding poorly to standard medical treatment. If patients are wondering how they can feel better or how unconscious patterns in life are keeping them from making needed changes, clinical hypnosis may be the most effective treatment to consider.

For those inspired to learn more, see Hypnosis Resources; it provides a list of reputable sources, many of which include stories about the ways patients have benefitted from clinical hypnosis.

References

1. Kirsch, I. Defining Hypnosis for the Public. *Contemporary Hypnosis*, 1994;11(3):142–143. Accessed at psycnet.apa.org/record/1995-22602-001.
2. Dr. Zoe D. Katze, Certified Hypnotherapist. Essex Watch, Jan. 23, 2014. Accessed atessexwatch.com/blog/1673/dr-zoe-d-katze-phd.

SUSAN (SUZE) KOPYNEC, MPAS, PA, ASCH Certified, is licensed to practice medicine and provide hypnosis sessions in the state of North Carolina. However, she is available as a resource to answer questions or assist in locating a properly trained professional within the United States or internationally. Her contact information can be found at Storychangers.com.



Treating Idiopathic Neuropathy with Intravenous Immune Globulin

While IVIG is a promising therapy for many types of idiopathic neuropathy, challenges remain regarding cost, safety and dosing.

By Surayyah Morris, PharmD

TREATING NEUROPATHY is nothing short of rocket science. No matter how neuropathy presents itself, treating it requires an individualized approach. The key is not to eliminate symptoms, but to mitigate them and improve quality of life, and one therapeutic avenue shows promise for doing just that: intravenous immune globulin (IVIG). While the root cause of idiopathic neuropathy continues to be elusive, IVIG provides both effective relief of symptoms and improved quality of life overall for many patients.

What Is Idiopathic Neuropathy?

Idiopathic neuropathy refers to a group of peripheral nerve disorders characterized by chronic pain, weakness and numbness without a known underlying cause, posing a significant challenge for managing them. Various types of idiopathic neuropathy exist, each with unique clinical presentations and challenges. Following are some of the prominent types of idiopathic neuropathy, their clinical features and the difficulties associated with their diagnosis and treatment.

• *Sensory neuropathy* primarily affects the sensory nerves, leading to symptoms such as tingling, numbness and a "pins and needles" sensation. Patients may also experience a loss of sensation, particularly in the extremities. Oftentimes, patients find it challenging to articulate and quantify sensory disturbances. Objective measures for diagnosis and treatment monitoring are limited.

• *Autonomic neuropathy* affects the nerves controlling involuntary bodily functions, leading to symptoms such as abnormal blood pressure and heart rate. Patients may experience dizziness, digestive issues and difficulty regulating body temperature. Diagnosis can be complex because its symptoms are diverse and may overlap with other conditions. Additionally, treatment focuses on symptom management rather than addressing the underlying cause.

• *Focal neuropathy* is damage to a single nerve or a group of nerves, leading to localized symptoms. This form of neuropathy often presents with sudden, severe pain in a specific area, weakness or muscle atrophy. Identifying the precise location of nerve damage can be challenging, and treatment strategies depend on the affected nerve. Management may involve pain control and physical therapy.

• *Chronic inflammatory demyelinating polyneuropathy (CIDP)* is a chronic, immune-mediated neuropathy characterized by symmetrical weakness, sensory disturbances and impaired reflexes. The condition may progress over time, leading to significant disability. CIDP can mimic other neuropathies, and establishing the diagnosis often requires a combination of clinical, electrophysiological and laboratory findings. Long-term management may involve immunomodulatory therapies, but the optimal treatment duration and approach are still being researched.

• *Small fiber neuropathy* affects the small nerve fibers responsible for pain and temperature sensations. Patients often

report burning pain, especially in the hands and feet, as well as altered sensation to temperature changes. There can be significant diagnostic challenges since standard nerve conduction studies may not detect it. Skin biopsy for intraepidermal nerve fiber density is one diagnostic tool, but its availability may be limited. Management focuses on symptomatic relief, but the underlying cause may remain elusive.

• *Idiopathic peripheral neuropathy* is neuropathy without a known cause. It often presents with a combination of sensory and motor symptoms, including pain, weakness and coordination difficulties. Various types of idiopathic neuropathy present a complex landscape for both patients and providers. Challenges in diagnosing and treating neuropathy highlights the need for ongoing research to unravel the underlying mechanisms and to develop targeted therapeutic interventions.

The Immune System's Role in Idiopathic Neuropathy

The journey to decode the immune system's role in idiopathic neuropathy is an ongoing endeavor. While a multitude of factors may contribute to neuropathy, the immune system plays a pivotal role in the initiation and progression of idiopathic neuropathies. Autoimmune mechanisms, described below, are thought to contribute to nerve damage, making immunomodulatory therapies the area of interest in the quest for effective treatment.

• *Autoantibodies.* Autoantibodies produced by the immune system can mistakenly target components of peripheral nerves, leading to inflammation and subsequent nerve damage.

• *T-cell involvement.* T lymphocytes, a crucial component of the adaptive immune system, have been implicated. Abnormal activation of T cells may contribute to the inflammatory milieu observed in affected nerves.

• *Cytokines and inflammation.* Dysregulation of pro-inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukins has been observed. Elevated levels of these cytokines contribute to inflammation.

• *Histopathological findings.* Biopsies of nerve tissues from patients with idiopathic neuropathy often reveal inflammatory infiltrates, suggesting an active immune response within the peripheral nerves.

• *Association with autoimmune diseases.* Idiopathic neuropathy frequently coexists with various autoimmune diseases, providing indirect evidence of immune system involvement. Conditions such as rheumatoid arthritis, lupus and Sjögren's syndrome often present with neuropathic symptoms, reinforcing the notion of immune-mediated neuropathic mechanisms.

• *Response to immunomodulatory therapies.* Because of positive responses to immunomodulatory therapies reported in some idiopathic neuropathy cases, treatments aimed at modulating the immune response further support the immune system's role.

Challenges, Limitations and Barriers to Treating Idiopathic Neuropathies with IVIG

While IVIG's effect on the immune system makes it a compelling candidate for neuropathy treatment, the absence of a clear etiology complicates diagnosis and treatment. This knowledge gap poses challenges in specifically tailoring IVIG treatment. Treatment involves addressing symptoms and improving quality of life through medications and physical therapy. Potential obstacles with IVIG that must be addressed to maximize efficacy and ensure patient safety include:

• *High treatment costs.* The high cost associated with IVIG treatment remains a significant barrier, potentially limiting its accessibility for a broader patient population.

Various types of idiopathic neuropathy exist, each with unique clinical presentations and challenges.

• *Risk of adverse events.* Despite its generally favorable safety profile, adverse events can include thrombotic complications, renal complications and allergic reactions.

• *Lack of standardized protocols.* Not having standardized protocols for treating idiopathic neuropathy with IVIG poses challenges in establishing optimal treatment dosages, durations and frequency of administration. This lack of consensus hampers efforts to define a unified approach to IVIG therapy. In addition, the diverse nature of idiopathic neuropathy poses challenges in pinpointing a

uniform immune-mediated pathway. Variations in disease presentation and progression make it difficult to identify specific immunological targets across all cases. Establishing definitive biomarkers would aid in stratifying patients, guiding treatment decisions and predicting responses to immunomodulatory treatments.

• *Genetic factors.* Genetic factors may influence susceptibility to immune-mediated neuropathy.

Treatment with IVIG

Treating idiopathic neuropathies relies heavily on an individualized approach to reach an individualized goal. The evolving landscape of idiopathic neuropathy treatment has witnessed IVIG as a promising therapeutic avenue. As research progresses and our understanding of the mechanisms underlying idiopathic neuropathy expands, implications for the future use of IVIG becomes increasingly significant. Following are key considerations that may shape the future of IVIG in idiopathic neuropathy management:

• *Rationale for immunotherapy.* The hypothesis implicating immune dysregulation in the pathology of idiopathic neuropathy has prompted investigations into immunomodulatory therapies. IVIG, with its ability to modulate the immune response, has emerged as a promising candidate for managing neuropathic conditions. IVIG's broad immunomodulatory effects, including the regulation of T and B lymphocytes, inhibition of pro-inflammatory cytokines and modulation of complement pathways, align with the potential immune-mediated components of idiopathic neuropathy.

• *Positive outcomes in small fiber neuropathy.* Some studies have reported positive outcomes in patients with small fiber neuropathy, a subset of idiopathic neuropathy. Improvements in pain, sensory symptoms and nerve conduction have been observed following IVIG treatment.

• *CIDP.* A variant of neuropathy with immune involvement, CIDP has been a focal point in IVIG research. Clinical trials and observational studies have demonstrated efficacy of IVIG in improving motor function, reducing disability and enhancing quality of life in CIDP patients.

• *Variability in treatment responses.* While some patients with idiopathic neuropathy experience substantial improvements with IVIG, treatment responses vary. Factors such as the specific subtype of neuropathy, disease duration and individual patient characteristics contribute to the complexity of evaluating overall efficacy.

Dosing IVIG

Dosing considerations for IVIG in the context of idiopathic neuropathy involve a nuanced approach, considering factors such as the specific subtype of neuropathy, the severity of symptoms, individual patient characteristics and the overall treatment goals. While there is no universally standardized dosing regimen due to the heterogeneity of idiopathic neuropathy, following are general dosing considerations and the need for individualized treatment plans.

• *Patient-specific factors.* Different subtypes of idiopathic neuropathy may necessitate varying approaches to IVIG dosing. For example, small fiber neuropathy and CIDP may require different dosages based on the nature and severity of nerve damage. Patients with more debilitating symptoms or rapidly progressing neuropathy may require higher doses to achieve optimal therapeutic effects. Patients who have previously undergone alternative treatments for idiopathic neuropathy such as corticosteroids or other immunomodulatory therapies may show varied responses.

• *Standard initial dosing practices.* Initial treatment often involves a loading dose of IVIG, typically administered over a few days to rapidly elevate immunoglobulin levels in the bloodstream. This loading phase aims to saturate the system with therapeutic immunoglobulins to initiate the desired immunomodulatory effects. Following the loading dose, maintenance doses of IVIG are administered at regular intervals. The frequency of maintenance doses can vary, ranging from weekly to monthly infusions, depending on the specific needs of the patient and the response to treatment. Consistency with IVIG treatment may be necessary for the effects to remain in the system at adequate levels.

• *Individualized dosing adjustments.* Regular monitoring of patients' response to IVIG treatment is essential for making informed dosing adjustments. Clinical evaluation, including assessments of symptom severity, neurological examinations and electrophysiological studies, helps guide the ongoing treatment plan. Individualized dosing adjustments may involve titrating the dosage based on patients' clinical response. Some patients may require higher or more frequent doses to achieve optimal outcomes, while others may maintain symptom control with lower doses.

• *Challenges and considerations.* The absence of a universally agreed-upon dosing protocol for idiopathic neuropathy with IVIG poses challenges, reflecting the need for individualized treatment plans. The high cost of IVIG treatment raises economic considerations, potentially influencing dosing

decisions. The frequency and duration of IVIG infusions can impact patient adherence to the treatment regimen. Balancing the need for efficacy with the practical aspects of patient compliance is essential.

Safety and Adverse Effects of IVIG Therapy

While generally considered safe, it's important to understand the safety profile of IVIG, common adverse effects and considerations for minimizing risks during its administration to ensure patient safety.

• *IVIG safety.* IVIG is derived from pooled human plasma obtained from thousands of donors. Rigorous screening and testing procedures are employed to minimize the risk of transmitting infections. The manufacturing process includes viral inactivation steps to further enhance safety. IG antibodies confer passive immunity and modulate the immune response, forming the basis of IVIG's therapeutic effects. The safety profile is influenced by the purity and composition of these immunoglobulins.

• *Common adverse effects.* Infusion-related reactions can range from mild symptoms such as headache, fever and chills, to more severe manifestations such as dyspnea, chest pain and hypotension. Pre-treatment with antipyretics and gradual infusion rate escalation may decrease these reactions. To help prevent allergic reactions, pre-treatment with antihistamines and close monitoring during infusion are essential precautionary measures. Patients with pre-existing risk factors for thrombosis, including immobility, obesity or a history of thrombotic events, require careful risk assessment and monitoring. IVIG can exert osmotic stress on the kidneys, leading to renal dysfunction. Adequate hydration before and after IVIG administration is recommended, and renal function should be closely monitored.

• *Patient-specific considerations.* Patients with underlying medical conditions such as cardiovascular disease, renal impairment or a history of thrombotic events require individualized risk assessments and may necessitate adjusted dosages of medications or alternative treatment strategies. Individuals who have undergone prior IVIG infusions may develop tolerance or experience diminishing adverse effects with subsequent treatments. However, monitoring is essential since severe reactions can still occur, particularly if there has been a significant time lapse between treatments. Tailoring IVIG therapy based on individual patient profiles contributes to safer treatment administration.

• *Mitigation strategies and precautions.* Comprehensive pre-treatment screening, including medical history, allergy assessments and laboratory evaluations, helps identify patients at higher risk for adverse effects. Gradual escalation of infusion rates during the initial stages of treatment reduces the likelihood and severity of infusion-related reactions such as headache and vomiting. This allows for monitoring patient responses to intervene promptly if adverse effects occur. Adequate hydration before and after IVIG infusions is a fundamental aspect of risk mitigation, especially in preventing renal complications. Maintaining optimal fluid balance supports renal function and reduces the risk of osmotic stress-related adverse effects. In addition, continuous monitoring during IVIG infusions is essential since prompt recognition and intervention can mitigate the impact of adverse effects. Comprehensive patient education regarding potential adverse effects, the importance of reporting any unusual symptoms and the need for adherence to pre-treatment recommendations creates an informed and collaborative approach. Obtaining informed consent also ensures patients are aware of potential risks.

IVIG therapy, while generally safe, requires careful consideration of potential adverse effects and meticulous strategies to ensure patient well-being. Understanding the intricacies of IVIG safety, patient-specific risk factors and implementing mitigation measures contribute to a balanced and effective treatment approach.

A Promising Treatment Future

The future of treating idiopathic neuropathy with IVIG holds immense promise, marked by advancements in precision medicine, targeted immunotherapies and refined treatment protocols. As research continues to unravel the complexities of immune-mediated neuropathy, the prospect of personalized, effective and accessible IVIG treatments for individuals grappling with idiopathic neuropathy becomes increasingly tangible. Collaborative efforts, innovative technologies and a patient-centered approach will collectively shape the trajectory of IVIG as a cornerstone in the multidimensional management of idiopathic neuropathy. IG

SURAYYAH MORRIS, PharmD, is an IG patient from Central Florida. As a medication therapy management and pain management specialty pharmacist, she enjoys supporting patients with chronic pain and chronic conditions to help find balance and improve quality of life.

Therapy and Adaptive Strategies for Multifocal Motor Neuropathy

Although this autoimmune disease makes activities of daily living more challenging, a combination of the right treatments and tools makes living well with it possible.

By Beth McNeal, OTRL, CHT

MULTIFOCAL MOTOR neuropathy (MMN) is a progressive muscle disorder characterized by weakness in the hands or feet, small uncontrolled twitching or spasms, muscle cramping and sometimes difficulty extending the wrist or fingers, a phenomenon known as wrist drop.

MMN is an abnormal response of the immune system, damaging the nerves so that the signals do not reach the muscles that dictate movement. It progresses slowly with no sensory issues (e.g., tingling, numbness or pain); yet absence of deep tendon reflexes in the affected limb and

excessive fatigue are commonly noted with ultimate atrophy or wasting of muscles occurring late in the course of the disease. It typically involves upper limbs more than lower extremities, but some patients will experience leg cramping or foot drop. Weakness is initially noted on one side of the body. And, symptoms usually appear during the fourth decade of life.

The etiology of MMN is unknown, yet it does not appear to be genetically linked. Therefore, the likelihood of passing it along to one's children is minimal. Prevalence in the United States is 3,000 to 6,000 people (or fewer than one person per 100,000), and it affects men much more often than women.

Taxing, but Treatable

While MMN is a chronic condition, it is not fatal, nor does it diminish life expectancy. A series of tests are performed to reach a diagnosis, including:

- Blood tests for GM1 antibody. (However, only 50 percent of people with MMN have antibodies. The lab work will contribute to a diagnosis, but it will not confirm or rule out suspicion of the motor neuron disease.)
- Electromyography, which may be performed to determine muscle weakness due to nerve function.
- Nerve ultrasounds and MRIs, which can also offer valuable diagnostic information.
- Electrodiagnostic studies, which are the hallmark finding of MMN because they detect motor conduction blocks. (A conduction block is when a nerve impulse does not travel all the way along the nerve and is not carried properly to the muscle.)

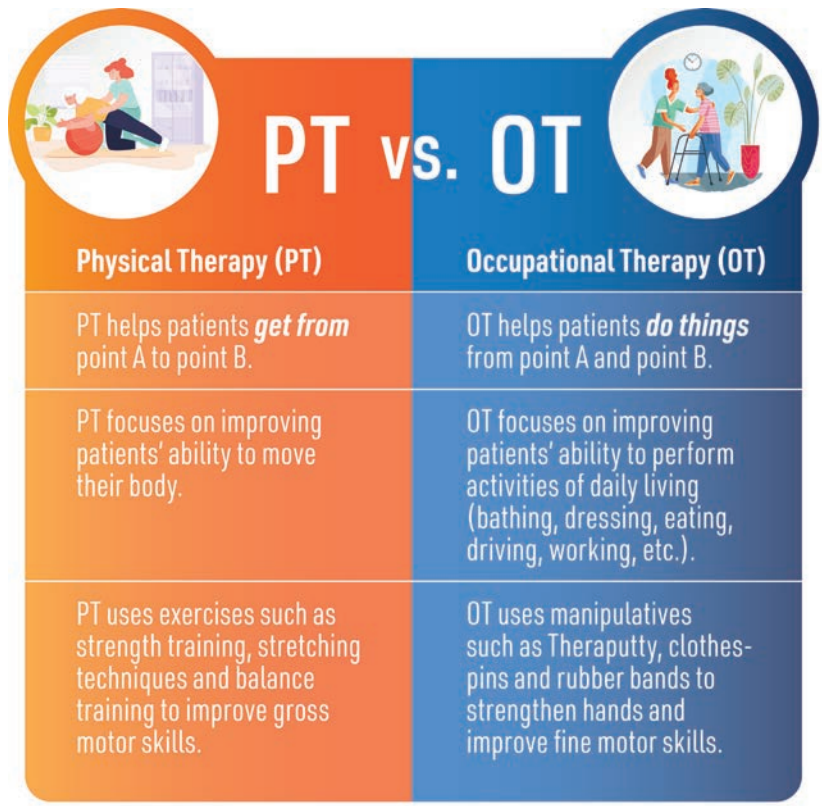
Accurate diagnosis of MMN is important to establish an effective plan to manage care. There is no cure for MMN, but treatment with intravenous immune globulin (IVIG) therapy can limit its progression and minimize symptoms over a prolonged period. In fact, as many as 80 percent of MMN patients respond favorably to IVIG therapy. Most who receive IVIG, coupled with occupational therapy (OT) and physical therapy (PT), will notice improvement in muscle strength within three to six weeks. Medical providers determine the necessary dosage, frequency and duration of treatment involving IVIG infusions. It is not uncommon for IVIG treatment to span months or years to manage MMN.

How PT/OT Can Help

Utilizing medical resources such as PT and OT may offer an individual diagnosed with MMN a better quality of life and help maximize functional capacities.

During a PT session, patients will engage in strengthening activities and conditioning exercises to build endurance, and will learn ways to stay active with reduced strength in areas affected with MMN. Thermal modalities are preferred during care, as extremely cold temperatures could exacerbate symptoms and be detrimental to patients. Rest periods are also incorporated into a therapy program since muscle fatigue is a common factor.

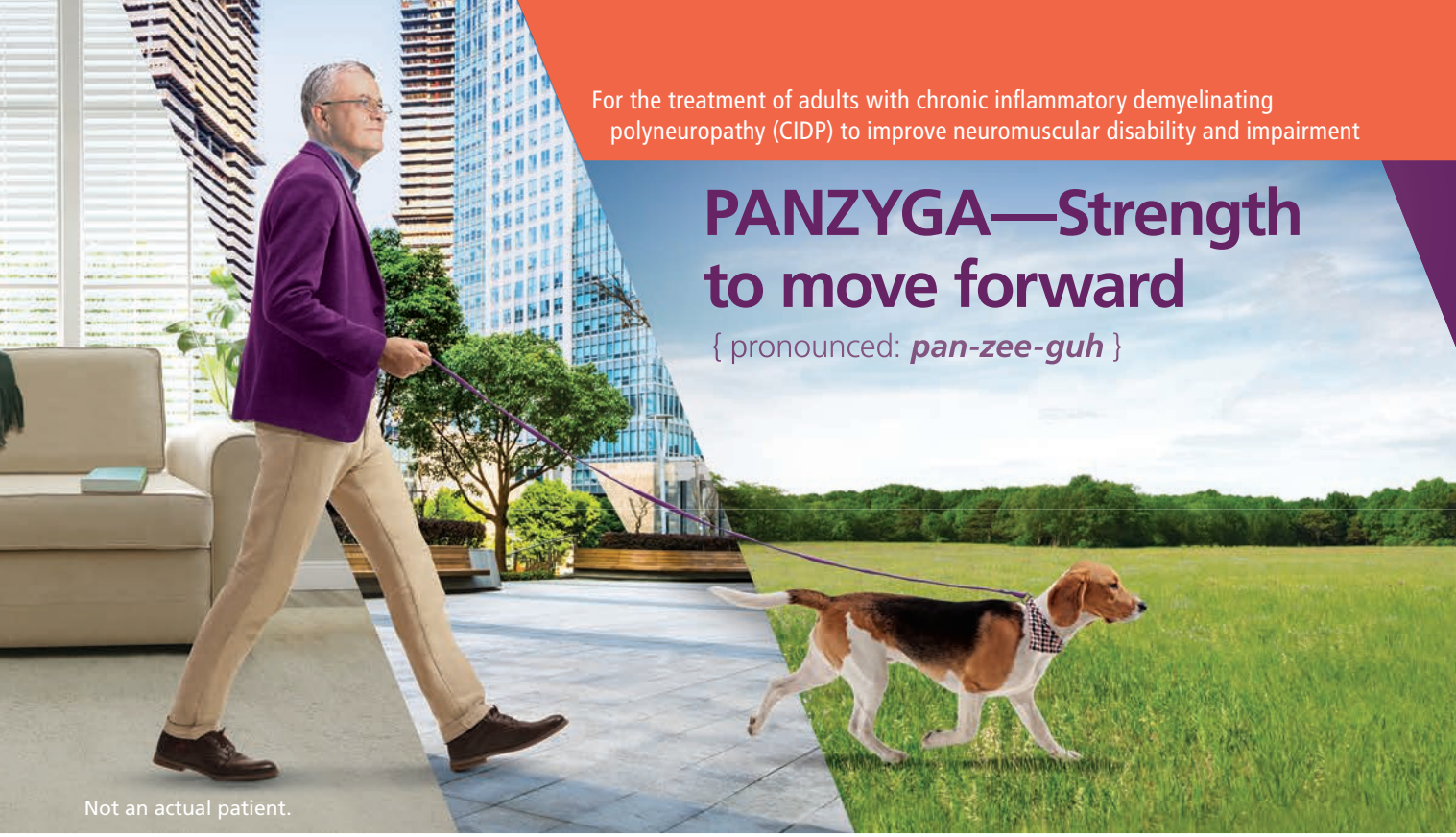
Like PT, OT offers patients strengthening exercises, but whereas PT focuses on gross motor skills, OT focuses on fine motor coordination and dexterity issues, and recommends adaptive equipment to assist that may improve patients' ability to perform activities of daily living (ADL). During an OT session, OT evaluates and identifies obstacles that



For the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment

PANZYGA—Strength to move forward

{ pronounced: ***pan-zee-guh*** }



Not an actual patient.

INDICATIONS AND USAGE

PANZYGA (Immune Globulin Intravenous [Human] – ifas) is indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older, chronic immune thrombocytopenia (cITP) in adults and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

PANZYGA is a liquid medicine for infusion that contains immunoglobulin G (IgG), which are proteins that help fight infection. It is made from human plasma that is donated by healthy people and contains antibodies. For patients with PI, PANZYGA helps replace the missing antibodies in the body. For patients with cITP, PANZYGA helps the body produce more platelets (the blood cells that help blood clot) to control or prevent bleeding. For patients with CIDP, PANZYGA may help improve mobility and hand strength.

PANZYGA is given into a vein (intravenously) in a hospital, infusion center, doctor's office, or at home by a trained healthcare provider (HCP).

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

See full prescribing information for complete BOXED WARNING

- **Thrombosis may occur with immune globulin intravenous (IGIV) products, including PANZYGA. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of IGIV products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. PANZYGA does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer PANZYGA at the minimum infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.**

Do not use PANZYGA if you:

- Have had a severe allergic reaction to immune globulin or other blood products
- Have a condition called selective (or severe) immunoglobulin A (IgA) deficiency, with antibodies against IgA and a history of hypersensitivity

What should I know before taking PANZYGA?

- PANZYGA can make vaccines (like measles/mumps/rubella or chickenpox vaccines) work less effectively for you. Before you get any vaccines, tell your healthcare provider that you take PANZYGA
- Decreased kidney function and kidney function failure can occur
- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting can occur
- Elevated blood pressure can occur particularly in patients who have a history of hypertension (high blood pressure)
- If you are elderly, with heart or kidney problems, discuss with your healthcare provider prior to initiating treatment with PANZYGA
- PANZYGA is made from human blood and therefore may have a risk of transmitting infectious agents, including viruses and, theoretically, the variant Creutzfeldt-Jakob disease (CJD) and CJD agent. The production and manufacturing process reduces this risk, but the risk cannot be eliminated

PANZYGA can cause serious side effects. If any of the following problems occur after starting PANZYGA, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting, or dizziness. These could be signs of a serious allergic reaction
- Bad headache with nausea, vomiting, stiff neck, fever, drowsiness, painful eye movements, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain

Please see Important Safety Information on adjacent page of this advertisement and Full Prescribing Information, including complete BOXED WARNING, at www.PanzygaInfo.com.

PANZYGA offers:

- **Improvement in arm and leg mobility, impairment symptoms, and hand strength***
- **Patient resources for each stage of your treatment experience**
  - Eligible, commercially insured patients taking PANZYGA may receive co-pay assistance of **up to $5,000** per calendar year, or the cost of a patient's co-pay in a 12-month period (whichever is less) for claims received by the program†
  - Adult patients with CIDP starting PANZYGA may be eligible for a refund of their out-of-pocket PANZYGA drug costs through the Pfizer Pledge Warranty Program.‡ Terms and conditions/eligibility requirements apply. See full terms and conditions at PanzygaInfo.com.

*Depending on the ongoing therapy dose.
†Terms and conditions apply. See full terms and conditions at PanzygaInfo.com.
‡Not available for residents of Puerto Rico.

IMPORTANT SAFETY INFORMATION (continued)

- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem (decreased kidney function or kidney failure)
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot, which could happen in the heart, brain, lungs, or elsewhere in the body
- Brown or red urine, swelling, fatigue, fast heart rate, difficulty breathing, or yellow skin or eyes. These could be signs of a liver or blood problem
- Chest pain or trouble breathing, or blue lips or extremities. These could be signs of a serious heart or lung problem
- Fever over 100°F. This could be a sign of an infection
- Headache, fatigue or confusion, vision problem, chest pain, difficulty breathing, irregular heartbeat, or pounding in your chest, neck, or ears. These could be signs of high blood pressure

Ask your HCP whether you should have rescue medications available, such as antihistamines or epinephrine.

What are the possible or reasonably likely side effects for PANZYGA?

The most common side effects that may occur with PANZYGA are:

- Headache
- Nausea
- Fever
- Increased blood pressure
- Dermatitis
- Fatigue
- Abdominal pain
- Dizziness
- Anemia

These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.

Tell your HCP if you are pregnant, or plan to become pregnant, or if you are nursing.

Patients should always ask their doctors for medical advice about adverse events.

You may report an adverse event related to Pfizer products by calling 1-800-438-1985 (US only). If you prefer, you may contact the US Food and Drug Administration (FDA) directly. The FDA has established a reporting service known as MedWatch where healthcare professionals and consumers can report problems they suspect may be associated with the drugs and medical devices they prescribe, dispense, or use. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

panzyga®

Immune Globulin Intravenous (Human) - ifas 10% Liquid Preparation

Talk to your doctor about PANZYGA and learn more at PanzygaInfo.com

PANZYGA is FDA approved for 3 indications:

- **CIDP** in adults
- **PI** in patients 2 years of age or older
- **cITP** in adults

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July 2022

panzyga®
Immune Globulin
Intravenous (Human) - ifas
10% Liquid Preparation

CONSUMER BRIEF SUMMARY

(PANZYGA: *pan-zee-guh*)

This brief summary highlights the most important information about PANZYGA. Please read it carefully before using PANZYGA and each time you have an infusion, as there may be new information. This brief summary does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have any questions after reading this, ask your healthcare provider. For more information, go to www.PanzygaInfo.com.

What is PANZYGA?

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This brief summary is based on the PANZYGA Prescribing Information (February 2021).

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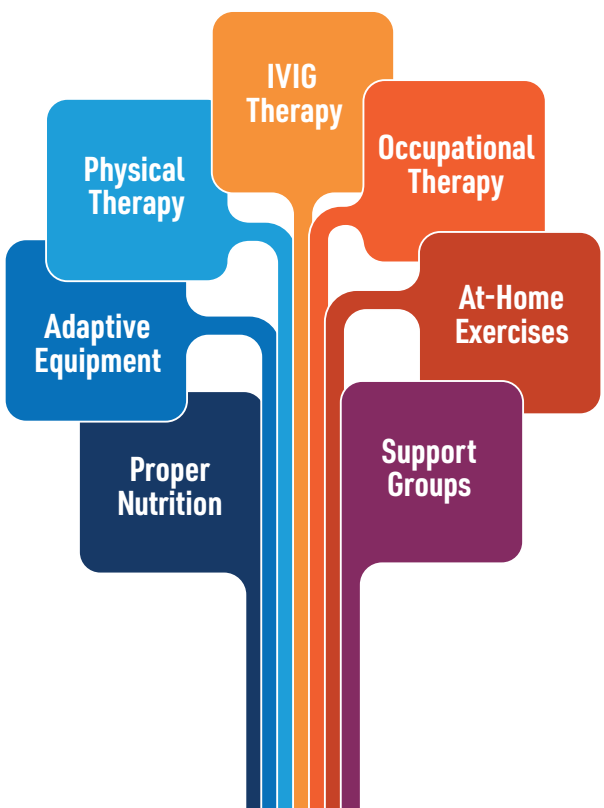
interfere with patients' ability to perform daily activities and helps them develop strategies to resume self-care, family and social responsibilities, as well as work-related skills so they can lead meaningful lives as independently as possible. Patients are also counseled on energy conservation measures, joint protection strategies and work simplification techniques to optimize ADL and avoid overuse of muscles. Therapists talk with patients about clothing choices and modified approaches to dressing or removing clothing, and educate them about strategies to manage driving, grocery shopping and meal preparation. When disability is more extensive, home renovations and environmental controls such as switches and voice activation options can be explored.

In short, PT focuses on improving patients' ability to move their bodies, while OT focuses on improving patients' ability to do things with their bodies. Patients with MMN should receive a customized PT and OT program tailored to their individualized needs.

Living Well with MMN



At-Home Exercises

Patients with MMN benefit from the following exercises outside of the clinical setting, too:

- Exercising in a warm, temperature-controlled pool is an ideal way to eliminate gravity and still benefit from building strength and endurance without the stress of weight-bearing exercises on land.

As many as 80 percent of MMN patients respond favorably to IVIG therapy.

- Yoga positively impacts mind and body, with the ability to vary intensity or modify techniques in accordance with an individual's tolerance.
- Sorting coins or buttons and sifting through rice, beans or corn develops fine motor coordination.
- Manipulating wooden spring clothespins, chip clips and Theraputty help develop pinch and grip strength.
- Exercising fingers with a rubber band placed around several fingertips creates tension against the fingers while trying to spread them apart, which builds power in deep hand-based muscles.
- Picking up toothpicks with tweezers helps with dexterity.
- Bending the wrist up and down over the edge of a table using one- or two-pound weights challenges the forearm muscles.

Impact on Daily Living

Upper-extremity weakness can have a significant impact on ADL such as cooking, eating, dressing, driving, writing and working. For example, loss of grip strength makes it difficult to perform typical everyday tasks such as cutting food, carrying pots or pans or even holding a fork or spoon; buttoning shirts or tying shoelaces; opening door handles, operating locks or gripping a steering wheel; and texting on a smartphone. Even hobbies, sports and recreational activities may be more taxing. Simple, everyday tasks become a source of frustration as fine motor skills are no longer performed without a struggle.

Adaptive Techniques

Occupational therapists can counsel patients on ways to modify the way they perform everyday tasks. For example, patients can push carts rather than pull them; perform some tasks while sitting down; and switch to lightweight and/or powered equipment, when possible, such as an electric can opener or mixer. It is possible splints may be issued to address functional positioning needs, rest muscles or respond to concerns for contractures, especially if wrist drop is evident.

There are numerous adaptive equipment options that help modify activities of daily living, allowing individuals with hand or upper-extremity weakness to remain independent.

To allow individuals with hand or upper-extremity weakness to remain independent, therapists may also recommend adaptive equipment options to help modify ADL such as:

- T-handle coffee mugs and two-handle cups to help patients grip and hold beverages.
- Ergonomically designed tools and household utensils with wider, non-slip handles to improve dexterity and control.
- Soft doorknob extensions and textured key grips to make opening doors easier.
- Spring-action scissors to make cutting paper and fabric easier.
- Rolling carts to help patients transport large or bulky items.
- A shower chair or tub bench to help patients avoid slips and falls while bathing.
- A raised toilet seat with handrails to make it safer and easier to sit and stand from the toilet.
- Dycem, a non-slip material, to hold objects firmly in place. (Dycem can be issued by an occupational therapist.)

Improving Quality of Life

People diagnosed with MMN are best served by a multidisciplinary approach, including working with a neurologist, occupational therapist, physical therapist, psychologist and dietician. Support groups are also an excellent resource that provide information and coping strategies for living with MMN. With collaborative effort, patient outcomes are more balanced and rewarding.

Home exercises, ADL adaptations and formal therapy sessions are all constantly evolving based on patient response to intervention. The main goal, of course, is to promote and optimize independence in ADLs that are most meaningful to the individual and maintain social and recreational activities that bring joy and purpose in life.

If you or a loved one has been recently diagnosed with MMN, it is important to consult your healthcare provider as soon as possible to discuss the best treatment options available, including IVIG, OT/PT and psychosocial supportive resources. Having a solid therapeutic plan with a supportive team will help patients contend with hurdles associated with the condition and promote a better quality of life. IG

Sources

1. Beadon, K, Guimarães-Costa, R, and Léger, JM. Multifocal Motor Neuropathy. *Current Opinion in Neurology*, 2018 Oct;31(5):559-564. Accessed at pubmed.ncbi.nlm.nih.gov/30102608.
2. Biessels, GJ, Franssen, H, Van den Berg, LH, et al. Multifocal Motor Neuropathy. *Journal of Neurology*, 1997 Mar;244(3):143-52. Accessed at pubmed.ncbi.nlm.nih.gov/9050954.
3. Jinka, M, and Chaudhry, V. Treatment of Multifocal Motor Neuropathy. *Current Treatment Options in Neurology*, 2014 Feb;16(2):269. Accessed at pubmed.ncbi.nlm.nih.gov/24395647.
4. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Society Guideline on Management of Multifocal Motor Neuropathy. Report of a Joint Task Force of the European Federation of Neurological Societies and the Peripheral Nerve Society, First Revision. *Journal of the Peripheral Nervous System*, 2010 Dec;15(4):295-301. Accessed at pubmed.ncbi.nlm.nih.gov/21199100.
5. Krarup, C, Stewart, JD, Sumner, AJ, et al. A Syndrome of Asymmetric Limb Weakness with Motor Conduction Block. *Neurology*, 1990;40:118–127. Accessed at pubmed.ncbi.nlm.nih.gov/2296357.
6. Lange, D, and Robinson-Papp, J. Multifocal Motor Neuropathy. UpToDate, Inc., Jul. 17, 2017. Accessed at www.uptodate.com/contents/multifocal-motor-neuropathy.
7. Lawson, VH, and Arnold, WD. Multifocal Motor Neuropathy: A Review of Pathogenesis, Diagnosis, and Treatment. *Neuropsychiatric Disease Treatment*, 2014;10:567-576. Accessed at www.ncbi.nlm.nih.gov/pubmed/24741315.
8. Léger, JM, Guimarães-Costa, R, and Iancu Ferfoglia, R. The Pathogenesis of Multifocal Motor Neuropathy and an Update on Current Management Options. *Therapeutic Advances in Neurological Disorders*, 2015 May;8(3):109-22. Accessed at pubmed.ncbi.nlm.nih.gov/25941538.
9. Multifocal Motor Neuropathy: Update on Clinical Characteristics, Pathophysiological Concepts and Therapeutic Options. *European Neurology*, 2010 April;63(4):193-204. Accessed at karger.com/ene/article/63/4/193/124825/Multifocal-Motor-Neuropathy-Update-on-Clinical.
10. GBS/CIDP Foundation International. National Health Council (2021). Multifocal Motor Neuropathy. Accessed at www.gbs-cidp.org/multifocal-motor-neuropathy.
11. National Institute of Neurological Disorders and Stroke. Multifocal Motor Neuropathy, March 3, 2016. Accessed at rarediseases.info.nih.gov/diseases/11011/multifocal-motor-neuropathy.
12. National Institute of Neurological Disorders and Stroke. Multifocal Motor Neuropathy, 2023. Accessed at www.ninds.nih.gov/health-information/disorders/multifocal-motor-neuropathy.
13. Katz, J, and Lewis, R. What Is Multifocal Motor Neuropathy? Neuropathy Action Foundation. Accessed at www.neuropathyaction.org/mmn_resource/index.htm.
14. Neuropathy Action Foundation Announces Results from Multifocal Motor Neuropathy (MMN) Survey. Neuropathy Action Foundation press release, Sept. 29, 2016. Accessed at www.prnewswire.com/news-releases/neuropathy-action-foundation-announces-results-from-multifocal-motor-neuropathy-mmn-survey-300335905.html.
15. National Organization for Rare Disorders. Multifocal Motor Neuropathy, updated Nov. 20, 2018. Accessed at rarediseases.org/rare-diseases/multifocal-motor-neuropathy.
16. The Foundation for Peripheral Neuropathy. Multifocal Motor Neuropathy. Accessed at www.foundationforpn.org/causes/multifocal-motor-neuropathy.
17. Tobon, A. The Role of Immunoglobulin in the Treatment of Immune-Mediated Peripheral Neuropathies. *Journal of Infusion Nursing*, 2017;40:375-379. Accessed at www.ncbi.nlm.nih.gov/pubmed/29112586.

BETH MCNEAL, OTRL, CHT, is an occupational therapist/certified hand therapist for Bryn Mawr Rehabilitation at Main Line Health in Media, Pa.

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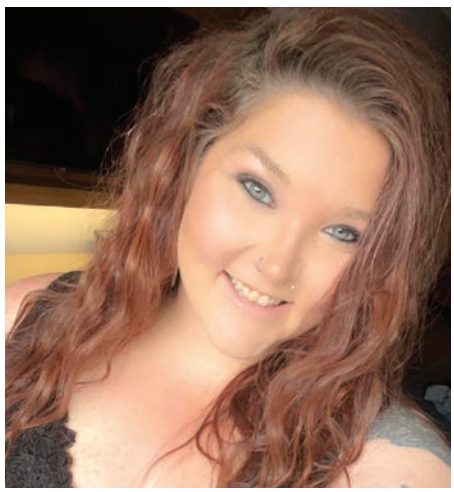
Produced by IG Living magazine, written for patients treated with immune globulin therapy and their caregivers

Profile: Ashley Wade



After viewing a TikTok video of a woman receiving an IVIG infusion for her immune disease, Ashley Wade realized how similar her symptoms were, which finally led to a diagnosis of CVID.

SOCIAL MEDIA has many benefits (and pitfalls), but rarely, it leads to something life-changing like a medical diagnosis. For Ashley Wade, the breakthrough came after watching an online video of someone receiving an intravenous immune globulin (IVIG) infusion. As the woman in the video described what she was doing and why, Ashley recognized some of her own ongoing health symptoms. Curious, she began to research immune disease and later pushed her doctor to run tests that eventually led to her diagnosis of common variable immune deficiency (CVID). A mother of two with a full-time job, Ashley is still learning what it means to navigate life with chronic illness, but she is passionate about embracing her new normal and helping others do the same.

By Trudie Mitschang

Trudie: Tell us about your diagnosis journey.

Ashley: I saw a gal on TikTok getting an IVIG infusion, and I was intrigued. As I was watching her video, she explained that she had an immune disorder called CVID, and she went on to explain her symptoms in detail. I thought to myself: "This sounds like me!" So, I did some more research, and every article I read felt like it was describing me and my situation. I went to my rheumatologist and explained my suspicions, and after some banter, she agreed to do the blood work to check my IgG levels. She was not convinced I was correct about my condition, but said she has been wrong before. My levels came back low, so she sent me to my primary care physician, who referred me to an immunologist. I live in a smaller town in Montana, so I had to travel seven hours to see the doctor. After that, it took almost a year to finally get my official diagnosis in September 2022.

Trudie: What were your symptoms prior to diagnosis?

Ashley: I would have recurrent upper-respiratory infections with coughs that would last upwards of three months, antibiotic use for two or more months with no relief, sinus infections, severe fatigue, weight gain, painful joints and ear infections. I had never heard of CVID before I saw the video.

Trudie: What is your treatment plan?

Ashley: When I was first diagnosed, they wanted me to try prophylactic antibiotics to see if that helped. I was on two high-dose antibiotics for almost 10 weeks and still ended up with Strep twice, two urinary tract infections and a sinus infection. They did a scope of my nose, took chest X-rays and did lots of blood tests. Finally, they were able to prove to my insurance company that I needed IVIG infusions. I have now switched to weekly subcutaneous IG (SCIG).

Trudie: How is your health now?

Ashley: My health today seems OK. I am hoping the infusions really help level things out so I can go more than a couple weeks without some sort of infection. Although I am still exhausted, I have found I do not have as much sinus congestion, but they did say it could take about six months before I notice a true difference. So, it's still a work in progress. Thankfully, the only side effect I have right now is some site pain and redness from the SCIG needles.

Trudie: Tell us how CVID has impacted your lifestyle.

Ashley: I work in healthcare, so it has a drastic impact because I am always sick. Some days are better than others, but there are times when I am so sore that it is hard to move or I have a massive migraine. It's hard in my personal life, too, because my friends and family don't understand how debilitating it can get. It is often very difficult to navigate an average day.

Trudie: Do you still work full time?

Ashley: Yes. I am the practice manager of two urgent care clinics in my state. The clinics are about 66 miles apart, so that requires me to travel two to three times per week. I oversee

the clinics and teams, as well as other items within the clinics. I also will fill in as a medical assistant or front desk receptionist if we are short staffed.

Trudie: What support groups have you found helpful?

Ashley: I am part of a few Immune Deficiency Foundation groups and a couple of groups specifically for CVID. This is all new to me, so I am still trying to figure out how I can be a part of things and advocate for others.

Trudie: What has this experience taught you?

Ashley: This experience has taught me to advocate for myself and keep pushing. I know my body better than anyone or any doctor. You can't give up. I have also learned to fight for myself. "Normal" people don't understand what we go through on a daily basis. Things aren't normal or easy for us, and it can be perceived as whiny or overly dramatic.

Trudie: Patients with invisible illness are often told "they don't look sick." Have you experienced that?

Ashley: One comment I get is, "I don't know why you are so tired and sick all of the time." I then have to explain that my body is attacking itself and it takes a lot of energy to do that. I also explain that a healthy person's cold may last two to five days, while mine lasts two to three months. Some days, my scalp just hurts and I have no explanation why! It is very difficult to get people to even remotely understand what we go through on a daily basis and the struggles we face with simple tasks.

Trudie: How do you keep a positive attitude?

Ashley: You have to remain positive in situations like this because you can't just give up in hopes it goes away. You have to push through and find ways that work for you to pursue a normal life. You have to be able to continue to fight and push to educate others in hopes they will understand. I also have two kiddos who look to me, and if I'm not positive, what is that teaching them and what example am I setting? They need to know that mama is different, but it's all about perspective.

Trudie: How has your diagnosis impacted your abilities as a mom?

Ashley: My kiddos are 3 and 8, which is a very hard age because they are so active and involved in extracurricular activities. It is hard sometimes because the fatigue I face is overwhelming, and just being sick all the time wears me out to the point I don't feel like doing anything. I just want to relax or sleep. I definitely have to push myself to make sure I am not ignoring them and to make sure they are still getting an adequate amount of time with me. I don't want them to ever feel dismissed because "mommy is tired."

Trudie: How has your family dynamic shifted?

Ashley: It is hard for all of us physically and emotionally as well, because they don't fully understand what this is like for me. It was hard on my husband at first because he didn't understand why I am so tired and sick all of the time, especially since he is completely healthy. It took some time for him to truly comprehend what I go through on a daily basis.

Trudie: What do you do to practice self-care?

Ashley: I honestly wish I did practice more self-care. One advantage is that I live in Montana and we have a lot of natural hot springs. So I try to escape to one of those as much as I can to just soak my muscles. Plus, the steam is good for my sinuses. On my infusion days, I will also take a long hot shower and relax, and then I go to sleep early that night soon after my infusion is complete.

Trudie: What advice do you have for others with chronic illness?

Ashley: The advice I would have for those who are still trying to find a diagnosis or who were recently diagnosed would be to keep advocating for yourself and keep pushing for answers. You are living with something that is overwhelming, scary and irritating, but it is also something that can be wonderful because you can advocate for those who can't or don't know what to do. You will have good days and bad days, but take the time you need to handle those days. Reward yourself for the work your body is doing to fight for you! If you feel defeated, do something to treat yourself. Ultimately, don't give up! I think I have said this a few times, but advocating for yourself is so insanely important. No one else knows what you are going through, and you know your body better than anyone. You can't always depend on others to find a solution.

Trudie: What are your goals for the future?

Ashley: In the long term, I just want to feel human again. I want to feel like I can breathe and have energy to perform simple basic tasks and not feel like I got hit by a Mack truck at the end of each day. I am hoping it shows my kids that although it can be a setback, it doesn't stop me from doing what I set my mind to.

TRUDIE MITSCHANG is a contributing writer for *IG Living* magazine.

How to Take a Trip by Yourself

By Michelle Searle

SPRING IS here, so it's a great time to start thinking about possible trips you might want to take this year. Maybe you want to soak up the warm summer sun in August or beat the crowds and travel as the leaves start to change colors in the fall. It can be easy to get swept up in doctor appointments, infusions, medications and sicknesses that cause the weeks and months to fly by. Of course, when you're sick, time doesn't fly by quite as fast, but once you start to feel better, you realize how much time has passed. I'm here to remind you to focus on your personal wants and dreams, and what better way to treat yourself than to take a trip by yourself?

I'm very passionate about traveling and love to travel whenever I can. I enjoy traveling with others and by myself. Many people feel uncomfortable taking a trip by themselves, which is understandable; however, it can be freeing, a lot of fun and a learning experience. It's important to feel comfortable by yourself and to take the time to put yourself first. While living in Italy, most of the trips I took were by myself. This was mainly because I had no one to travel with, but I wasn't going to stay at home because I had no one to travel with. I'm also not going to wait around for others to take a trip with me since that often results in plans never being made. What's more, I'm selective with whom I travel because we all have different traveling styles, and some don't mesh well with others. Once I started taking trips by myself, I learned how much I love it! I can structure the days the way I like, eat where and when I want, and meet other people more easily. I've also realized I do and see so much more when I travel by myself than when I travel with others.

If you haven't already done so, figure out what type of traveler you are in this stage of your life. Do you prefer spontaneity and letting the day take you where it may? If so, maybe a backpacking trip would be fun for you. If you have to travel with too much to fit in a backpack, you can still travel spontaneously by bringing luggage and planning where you're going to stay, but not planning where you're going to eat or all the places you're going to visit. If you prefer to plan each part of your trip, I recommend using an app to help you plan where to eat, what to see and how you're going to travel from place to place. My favorite trip planner is Wanderlog. I use it online and as an app on my phone, and I no longer take trips without it. When I get ready to travel, I plan where I'm staying, and I make a list of places I'd like to visit and what local foods I'd like to try. I also leave room throughout the trip to be flexible with my plans. I often learn from locals such as the Uber driver, hotel concierge or Airbnb host about cool things to see or do and where to eat when arriving in a new city or country. Some of the best food I've eaten was found by asking locals for recommendations.

The thought of taking a trip by yourself may feel overwhelming, but a trip doesn't need to be a 10-day excursion hiking in the Amazon Rainforest alone. It can be something as simple as going away for the weekend to another part of town. It can be a night away at a hotel in a city you'd like to explore in your state. You can even take a day trip into the mountains, to a beach or lake, or to a new mall. Taking a trip by yourself does not need to be elaborate or expensive. It also does not need to be done entirely by yourself if you're not ready or comfortable with that. A great first step is to start a trip with friends or family and stay a day or two longer by yourself. This will help you feel more comfortable being by yourself in an unfamiliar place since you've already spent time getting to know the area. Whether you're going to a new city, state or country, just go, and enjoy the time for yourself! Also, make sure to step outside your comfort zone a little because if you don't, you won't be able to grow and learn. You'd be surprised how much fun it can be and what you can learn about yourself and the world around you when you take a trip by yourself! IG

MICHELLE SEARLE is a teacher from South Florida who was diagnosed with common variable immunodeficiency at 11 years old. She is currently living in New York where you will most likely find her eating pizza or trying to make friends with the local cats.

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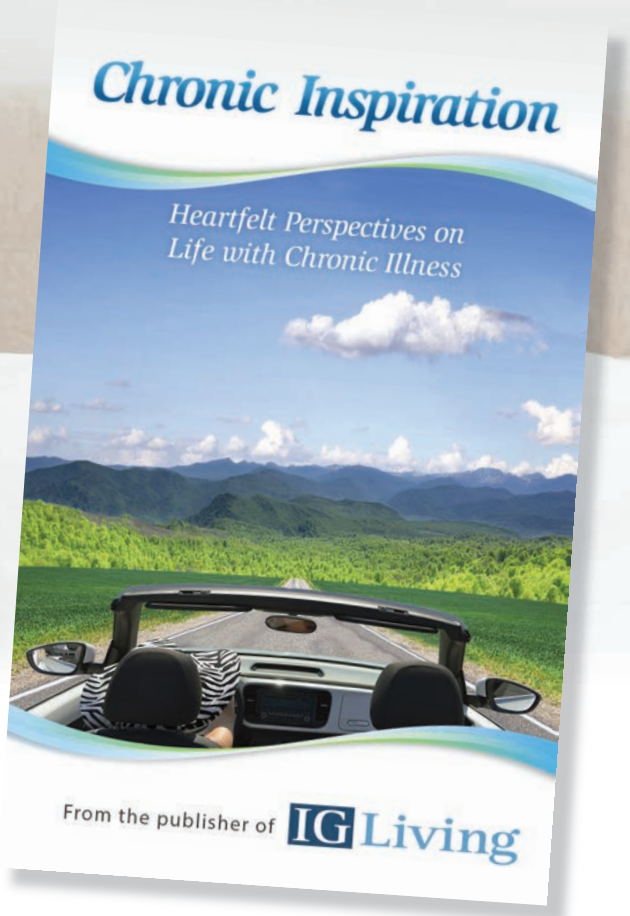

"You can lament what is lost to you, whether it's opportunity, a person or your health, but clinging to anger is no way to experience life." — Rebecca Zook in "Life Lessons," excerpted from *Chronic Inspiration.*

Download a daily dose of inspiration with this heartfelt compilation of writings on life with chronic illness. From coping strategies and parenting tips to "from the trenches" advice on dealing with family and friends who simply don't get it, these personal stories are sure to uplift, challenge and inspire. Honest and candid, Chronic Inspiration: Heartfelt Perspectives on Life with Chronic Illness gives voice to those who refuse to let their diagnosis define who they are or what they can accomplish.

"For the patient community, this was invaluable. When I downloaded it, I knew this would be something I would refer to over and over again."

— Jenny Gardner

IG Living

Chronic Inspiration can be purchased on iTunes, Amazon and Barnes and Noble.com

Reconnect with volunteer days

People with primary immunodeficiency (PI) who infuse CUVITRU weekly or every other week may be able to experience more of these moments.

What is CUVITRU®?

CUVITRU [Immune Globulin Subcutaneous (Human)] 20% Solution is a ready-to-use liquid medicine that is given under the skin (subcutaneously) to treat primary immunodeficiency (PI) in people 2 years and older.

IMPORTANT SAFETY INFORMATION

What is the most important information I need to know about CUVITRU?

CUVITRU can cause the following serious reactions:

- Severe allergic reactions causing difficulty in breathing or skin rashes
- Decreased kidney function or kidney failure
- Blood clots in the heart, brain, lungs, or elsewhere in the body
- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting
- Dark colored urine, swelling, fatigue, or difficulty breathing

Who should not use CUVITRU?

Do not use CUVITRU if you:

- Have had a severe allergic reaction to immune globulin or other blood products.
- Have a condition called selective (or severe) immunoglobulin A (IgA) deficiency.

What should I avoid while taking CUVITRU?

- CUVITRU can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your healthcare provider (HCP) that you take CUVITRU.
- Tell your HCP if you are pregnant, or plan to become pregnant, or if you are nursing.

What are the possible or reasonably likely side effects of CUVITRU?

CUVITRU can cause serious side effects. If any of the following problems occur after starting CUVITRU, stop the infusion immediately and contact your HCP or call emergency services:

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation and swelling of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot.

Cuvitru
[Immune Globulin Subcutaneous (Human)] 20%

Proven protection from infection

In the North American (NA) study, there were 0.012 acute serious bacterial infections (ASBIs) per patient-year.*† This exceeds the FDA standard for effectiveness, which is one serious ASBI per year.

Nearly all infusions (99.8%) were completed without reduction, interruption or discontinuation due to tolerability

No patients discontinued due to local adverse reactions (ARs) and 0 serious ARs related to CUVITRU were reported.

The most common adverse reactions observed in clinical trials in ≥5% of patients were: local adverse reactions including mild or moderate pain, erythema, and pruritus, and systemic adverse reactions including headache, nausea, fatigue, diarrhea, and vomiting.

Flexible administration that can be tailored to fit your lifestyle‡§

CUVITRU can be infused at the fastest rates and highest volumes with the fewest infusion sites of any subQ IG.§

In the NA clinical study, CUVITRU was studied in 77 people with PI ≥2 years of age. The main goal of the study was to measure how many acute serious bacterial infections (ASBIs) were experienced over the course of 1 year. ASBIs are short-term but serious infections that require immediate medical care. ASBIs were evaluated in 74 people taking CUVITRU for an average of 380.5 days (range, 30-629 days).
*One ASBI that occurred during the study was a case of pneumonia in a 78-year-old person.
†A patient-year is a patient experience in a clinical trial over the course of 1 year. One patient-year is equal to, for example, the experience of 2 patients for 6 months, or 12 patients for 1 month each.
‡In the NA study, the average infusion time was 0.95 hours (range 0.2-6.4 hours) and most (84.9%) used 1 to 2 needlesticks.
§You'll infuse your first 2 infusions at 10 to 20 mL/hr/site. After that, you'll be able to increase your rate up to 60 mL/hr/site as tolerated. Infuse at up to 4 sites simultaneously.
SubQ IG=subcutaneous immune globulin.

IMPORTANT SAFETY INFORMATION (continued)

- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, or blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be sign of an infection.

The following one or more possible side effects may occur at the site of infusion. These generally go away within a few hours, and are less likely after the first few infusions.

- Mild or moderate pain
- Redness
- Itching

The most common side effects that may occur are:

- Headache
- Nausea
- Fatigue
- Diarrhea
- Vomiting

These are not all the possible side effects. Talk to your HCP about any side effect that bothers you or that does not go away.

Please see Important Facts about CUVITRU on the following page.

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.

Up to 100% of out-of-pocket co-pay costs could be covered.

Scan the QR code to learn more about CUVITRU, including co-pay costs.

Takeda

IMPORTANT FACTS about CUVITRU (CUE-vih-troo) [Immune Globulin Subcutaneous (Human)] 20% Solution

What is the most important information I need to know about CUVITRU?

CUVITRU can cause the following serious reactions:

- Severe allergic reactions causing difficulty in breathing or skin rashes
- Decreased kidney function or kidney failure
- Blood clots in the heart, brain, lungs, or elsewhere in the body
- Severe headache, drowsiness, fever, painful eye movements, or nausea and vomiting
- Dark colored urine, swelling, fatigue, or difficulty breathing

What is CUVITRU?

CUVITRU is a ready-to-use liquid medicine that contains immunoglobulin G (IgG) antibodies, which protect the body against infection. CUVITRU is used to treat patients with primary immunodeficiency diseases (PI).

There are many forms of PI. The most common types of PI result in an inability to make a very important type of protein called antibodies, which help the body fight off infections from bacteria or viruses. CUVITRU is made from human plasma that is donated by healthy people. CUVITRU contains antibodies collected from these healthy people that replace the missing antibodies in PI patients.

Who should not use CUVITRU?

Do not use CUVITRU if you have a known history of a severe allergic reaction to immune globulin or other blood products. If you have such a history, discuss this with your healthcare provider (HCP) to determine if CUVITRU can be given to you. Tell your HCP if you have a condition called selective (or severe) immunoglobulin A (IgA) deficiency.

How should I use CUVITRU?

CUVITRU is given under the skin (subcutaneously). Most of the time, infusions under the skin are given at home by self-infusion or by caregivers. Instructions for giving CUVITRU under the skin (subcutaneously) are provided in the FDA-approved patient labeling (Information for Patients and Instructions for Use). Only use CUVITRU by yourself after you have been instructed by your HCP.

What should I avoid while taking CUVITRU?

CUVITRU can make vaccines (like measles/mumps/rubella or chickenpox vaccines) not work as well for you. Before you get any vaccines, tell your HCP that you take CUVITRU.

Tell your HCP if you are pregnant, or plan to become pregnant, or if you are nursing.

What are the possible or reasonably likely side effects of CUVITRU?

The following are one or more possible reactions that may occur at the site of infusion. These generally go away within a few hours, and are less likely after the first few infusions.

- Mild or moderate pain
- Redness
- Itching

The most common side effects of CUVITRU are headache, nausea, fatigue, diarrhea, and vomiting.

If any of the following problems occur after starting treatment with CUVITRU, stop the infusion immediately and contact your HCP or call emergency services. These could be signs of a serious problem.

- Hives, swelling in the mouth or throat, itching, trouble breathing, wheezing, fainting or dizziness. These could be signs of a serious allergic reaction.
- Bad headache with nausea, vomiting, stiff neck, fever, and sensitivity to light. These could be signs of irritation of the lining around your brain.
- Reduced urination, sudden weight gain, or swelling in your legs. These could be signs of a kidney problem.
- Pain, swelling, warmth, redness, or a lump in your legs or arms. These could be signs of a blood clot.
- Brown or red urine, fast heart rate, yellow skin or eyes. These could be signs of a liver or blood problem.
- Chest pain or trouble breathing, or blue lips or extremities. These could be signs of a serious heart or lung problem.
- Fever over 100°F. This could be a sign of an infection.

These are not all the possible side effects. You can ask your HCP for a physician's information leaflet. Tell your HCP about any side effect that bothers you or that does not go away.

Whenever giving yourself treatments at home, you should have another responsible person present to help treat side effects or get help if you have a serious adverse reaction occur. Ask your HCP whether you should have rescue medications, such as antihistamines or epinephrine.

How do I store CUVITRU?

Store CUVITRU refrigerated or at room temperature.

- You can store CUVITRU in the refrigerator (36°F to 46°F [2°C to 8°C]) for up to 36 months or
- You can store CUVITRU at room temperature (up to 77°F [25°C]) for up to 24 months.
- Do not return CUVITRU to the refrigerator if you take it out to room temperature.
- Do not freeze.
- Do not shake.
- Check the expiration date on the carton and vial label. Do not use CUVITRU after the expiration date.
- Protect from light. You can use the original CUVITRU containers to protect it from light.

How do I get more information about CUVITRU?

The risk information provided here is not comprehensive. To learn more, talk about CUVITRU with your HCP or pharmacist. The FDA-approved Full Prescribing Information, including Information for Patients, can be found at www.CUVITRU.com or by calling 1-877-TAKEDA7 (1-877-825-3327).

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Recharge for Resilience

By Megan Ryan

RESILIENCE IS the key to living with chronic illness, and for years, I thought the key attribute associated with resilience was the ability to endure. After all, living with a primary immunodeficiency (PI) comes with ups and downs and often, like Dory in *Finding Nemo*, those of us living with one have to "just keep swimming." I would "just keep going" and think it meant I was able to endure.

Endurance, stamina, fortitude and perseverance — just keep going and you'll get through this. Not this year. This year, I had to reframe what "just keep going" looked like for me.

My experiences during the past year reminded me that sometimes I can't just keep going. Resilience is about more than endurance, and I can get through the roller coaster of chronic illness by employing resilience techniques.

There's no one right way to recharge to increase your resilience, but you do have to find what works best for you.

Famous inspirational words written by great leaders influence our ideas about resilience. For example, Nelson Mandela's "Do not judge me by my success, judge me by how many times I fell down and got back up again" and Winston Churchill's "If you're going through hell, keep going" focus on stamina, fortitude and perseverance in periods of difficult situations. Yet, I've learned that while these are great messages, they may not offer the best advice for those living with a chronic or rare disease.

This year has been a roller coaster ride of ups and downs for me. Just when I thought I'd mastered my PI after 22 years, new complexities and challenges surfaced this year, so all my thoughts about resilience were front and center. Finding ways to recharge was central to strengthening my resilience.

Everyone has different approaches for how to recharge their minds and bodies. Some find they recharge by spending time alone, while others recharge by spending time with friends and family. Some people recharge by engaging in more passive activities such as watching a television series or listening to music. Others find more active activities are important for recharging such as going for a walk in the neighborhood or exploring nature at a local garden or arboretum. There's no one right way to recharge to increase your resilience, but you do have to find what works best for you. I find I need a mix of activities.

If you need some fresh ideas to recharge, here's a list of activities I've used:

- Go for a walk.
- Try guided meditation or deep breathing exercises online or via an app.
- Read a book.
- Take a nap.
- Color, draw, paint or craft.
- Work in the garden — even a small container garden.
- Pick up the phone and call a friend.
- Listen to music — maybe experience a new genre of music.
- Enjoy a bath or shower.
- Take a break from social media or technology.
- Listen to a podcast or an audiobook.
- Try to cook or bake a new recipe, or pull out an old favorite recipe.
- Write in a journal.

So whether it's Dory's words of "just keep swimming" or the inspirational words of world leaders, sometimes words need to be put aside and traded for practical tools when living with a chronic illness. Recharging may be your best tool for building resilience, so let's revise Dory's words to "Just keep recharging!"

MEGAN RYAN is a native Texan, lover of flowers, plants and gardening and always planning for an upcoming travel adventure. For more than 22 years, Megan has lived with common variable immune deficiency. She's taken her weekly treatments on the road to more than 20 countries and four continents so far.

Transitioning to the Teen Years: How Relationships Change

By Jessica Leigh Johnson

IN MY family, we have two adult children and two teens. Whenever I look back at photographs or videos of my kids when they were younger, I definitely get a little misty-eyed. I miss those chubby little faces and the totally hilarious things my toddlers would say. Their high-pitched voices and the way they mispronounced certain words made me smile. In fact, it was a sad day when my youngest son realized, at age 7, that the word "finger" started with an f and not th. I told him he could keep saying it his way (at least for a little longer), but he was getting older, so he made the change.

Kids have to grow up eventually. They can't behave like preschoolers when they're adults. They can't continue to pronounce words incorrectly when they're 30 years old, or expect their parents to cut their chicken into bite-sized pieces at the dinner table. Throughout their lives, children are slowly transitioning from babies to adults, with the most marked changes occurring during adolescence. And while it can be hard for parents to witness these changes and say goodbye to the past, the shift must occur if we want our children to become fully functioning, self-sufficient adults who can live on their own and contribute to society.

One of the biggest changes in adolescence is how these older kids relate to and interact with others. The physical, mental and developmental changes that are taking place within their adolescent bodies are accompanied by big changes in their relationships with family and friends.[1] During puberty, family relationships are often reorganized and

reprioritized. As teens begin to desire more independence, they may put more emotional distance between themselves and their parents. Their focus often shifts to social interactions and friendships.[1]

Relationships with Parents and Caregivers

During adolescence, the parent-child relationship changes dramatically as young people gain more independence and begin to make their own decisions. Parents have to be ready for their role to shift from that of "primary decision-maker" for their once-young children to that of a guide, helping older children and adolescents make decisions on their own (while still being close enough to prevent them from engaging in dangerous or high-risk behaviors).[2]

Even with the increasing independence that adolescence brings, the relationship between older children and their parents or caregivers is still one of the most important relationships in children's lives. Parental involvement influences adolescents' plans for the future, their moral and social values, and their broader worldview.[2] This foundation becomes very important as adolescents take on more responsibilities, begin making decisions for themselves and use their own judgment to work out problems.[1]

As adolescents gain an increased capacity for logical reasoning, they may begin to demand an explanation for things they would never have questioned before. And instead of accepting a parent's answer, they may argue or try to prove that the opposite is true. With a growing set of critical-thinking skills available to them, teens are less likely to conform to parents' wishes or accept parents' rules like they did in childhood.[3]

These changes in the way teens respond to parents can lead to conflict in the parent-adolescent relationship — and that's totally normal. Most parents can probably remember the days when it seemed their parents didn't understand or were too over-protective or unreasonable. In most cases, this dissonance is temporary. Even when teens seem distant or aloof, most of them still rely on their parents or caregivers for emotional support and boundaries, both of which are linked to positive adolescent development and closer parent-child relationships.[2]

Changes in Peer Relationships

As adolescents put more distance between themselves and their parents and family members, they may spend

3 Major Areas Crucial to the Parent-Adolescent Relationship

more time with friends, simply because they feel more understood and accepted by them. Adolescents are learning to become more independent, and their relationships with their friends play an important role in this process.[2] Friends help teens develop their own identity and tackle self-esteem issues.

In childhood and younger adolescence, friendships tend to be based on common activities and may be driven by a desire to be accepted by peers.[2] If a child is on the soccer team, his friend base is likely to consist of his teammates. The friends of a kindergartner are usually limited to the kids in her classroom. Young kids may decide what activities to participate in or what they're interested in based on what their friends are doing. But once they reach later adolescence, these same kids may have a more diverse group of friends. They'll develop their own interests based on personal likes, dislikes, strengths and talents, regardless of what others are doing. Teens will then form new friendships with those who have similar attitudes, values and shared activities.[2]

Parents are Changing, Too

One element of parent-child relations in adolescence that is not often considered is the fact that changes in the parents' lives can also greatly affect the relationship dynamic.[3] Obviously, adolescents change significantly as they transition from childhood to adulthood, but their parents are also changing during this time — not only in response to their children, but also in response to challenges they face in their own lives. Parents of adolescents are typically in or approaching middle age. At this stage of life, it's not uncommon for parents to face issues such as lowered self-esteem, increased anxiety, increased depression, decreased life satisfaction and negative thoughts about middle age in general.[3]

Parents in midlife may be faced with the reality that their future might not get a whole lot better than what their present lives look like. They may feel increasingly pessimistic to the same degree that their children are overflowing with optimism. Additionally, middle age can give rise to a decline in both physical health, stamina and attractiveness, which can seem magnified when parents' children are blossoming into young adults, full of life and energy — not to mention an absence of wrinkles, gray hair or an enlarging waistline.[3] Considering all this, it may be worth the time for parents to examine their own insecurities and emotional deficits if their relationship with their adolescent children seems strained.

Parenting Is a Lifelong Role

Although teens crave increasing independence from their families as they get older, parents and caregivers still play an important and central role in their lives.[2] And while parenting adolescents is far less hands-on than caring for toddlers or young children, teens still need their parents to be a positive influence and a reliable source of support. IG

References

1. Stanford Medicine. Teens: Relationship Development. Accessed at www.stanfordchildrens.org/en/topic/default?id=relationship-development-90-P01642.
2. U.S. Department of Health and Human Services. Healthy Relationships in Adolescence. Accessed at opa.hhs.gov/adolescent-health/healthy-relationships-adolescence.
3. ActForYouth.net. Parent-Child Relations in Adolescence. Accessed at actforyouth.net/resources/rf/rf_parent_0302.cfm.

JESSICA LEIGH JOHNSON is a stay-at-home mom and mother of four kids, three of whom have X-linked agammaglobulinemia. She is a member of American Christian Fiction Writers and has written one book about the loss of her son to a primary immunodeficiency.

Alternative Pain Relief: Hippie-Dippie Hype or Trustworthy Trend?

By Rachel Maier, MS

DO YOU suffer from aches and pains? According to the National Institutes of Health's Pain Consortium, 65 percent of U.S. adults over the age of 65 report suffering from pain, and up to 30 percent of older adults report suffering from chronic pain.[1] That's a lot of suffering!

Seeking relief from a pill bottle every time something hurts might ease the pain temporarily, but drug-based pain relievers can cause many other problems when taken inappropriately or too often. Over-the-counter medicines such as ibuprofen can cause gastrointestinal distress, kidney damage, stroke, ulcers and even heart attacks, among other ailments; and acetaminophen can cause liver problems. Prescription narcotics such as oxycodone and hydrocodone, among others, are safe when used appropriately, but can cause addiction, overdose and even death.

Drug-based pain relievers are one option for easing discomfort, but they are not the *only* answer. Alternative therapies abound — but do they really work? After all, serious pain calls for serious relief.

What Is "Alternative Pain Relief" Anyway?

First, let's be clear about what alternative pain relief is *not*: a hyped up, hippie-dippie approach to pain management that doesn't really work. Instead, "alternative" refers to anything that can be used instead of mainstream, conventional drug-based options. These remedies often include acupuncture, chiropractic care, physical therapy, herbal remedies, massage, magnetic waves, biofeedback, meditation and more,[2] not to mention good old-fashioned warm compresses or ice packs.

Are Alternative Pain Relievers Natural?

If "natural" means "drug-free," then yes, alternative pain relievers are natural. But, if "natural" means homemade salves made from things you can find in the forest, then no, alternative therapies are not necessarily "natural."

True, there are plenty of natural pain-relieving properties in things such as Arnica montana plants and turmeric that have been used to ease inflammation and treat ailments without synthetic, chemically-derived drugs for generations, and our shopping guide highlights two products utilizing some of them. But more and more, alternative pain relief refers to drug-free therapies that use natural materials combined with human effort and ingenuity (such as a microwaveable heating pad filled with dried corn kernels or devices that use electric currents to interact with the brain's pain signals).

High-Tech Help

In fact, high-tech pain relievers are booming. Gadgets programmed to interact with your body to relieve pain are some of the most popular alternatives today. Electromagnetic fields that moderate nerve activity and reduce the perception of pain by the human brain, transcutaneous electric nerve stimulation (TENS) and red light therapy are just three examples.

Trends Worth Trying

It might be intimidating to think about trying something so new (especially given the price tag!), but rest assured these new gadgets are designed to be safe and easy to use, and many come with a money-back guarantee, making them worth your while to try — especially if they really do provide the relief you need. See the shopping guide for details. IG

References

1. National Institutes of Health Pain Consortium. Chronic Pain in Older Adults. Accessed at www.painconsortium.nih.gov/sites/default/files/documents/aging_and_chronic_pain_infographic_508.pdf.
2. Alternative Medicine — Pain Relief. MedlinePlus, reviewed Nov. 9, 2021. Accessed at medlineplus.gov/ency/article/002064.htm.

RACHEL MAIER, MS, is the associate editor of *IG Living* magazine.

Omron Total Power + Heat TENS Unit

The Omron Total Power + Heat TENS Unit is a powerful, drug-free device that relieves chronic, acute and arthritic pain through the combination of soothing heat and TENS technology. TENS relieves pain with electrical pulses transmitted across the skin and alongside nerves, preventing the brain from receiving pain signals. The electrical stimulation also releases endorphins in the body that are a natural pain reliever.

$94.50; omronhealthcare.com/products/total-power-heat-tens-unit-pm800

The Original Microwavable Corn Bag

Made with 100 percent breathable cotton fabric, along with all-natural, triple-cleaned and microwavable whole kernel corn, these weighted heat bags soothe and relax tight muscles, stimulate circulation and improve flexibility. Great for back pain, migraines, fibromyalgia, arthritis, lupus, diabetes, scleroderma, poor circulation and more!

Start at $11.99; www.corn-bags.com

Shopping Guide for Alternative Pain Relief

Relief Factor

Relief Factor is a daily supplement meticulously formulated by doctors. It contains a powerful combination of four ingredients (turmeric, resveratrol, omega-3 and icariin) specifically balanced to help support certain pathways in the body that are associated with pain and inflammation. Taken over time, Relief Factor can reduce or even eliminate joint and muscle pain.

$93.95 for a single purchase of a one-month supply, or $79.95 per month for a subscription; www.relieffactor.com

Arnicare Gel

Made from a tincture of the fresh, whole Arnica montana plant, Arnicare gel temporarily relieves muscle pain and stiffness. And, this powerful gel also reduces swelling and discoloration from bruises.

Starts at $8.99; www.boironusa.com/product/arnicare-gel

Novaa Light Pad — the Deep Healing Therapy

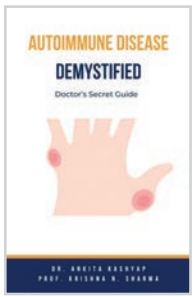
Recognized by the FDA as a medical device, the Novaa Deep Healing Pad delivers wavelengths that send healing energy into the injured cells of your body. Twenty minutes of healing light per day increases circulation and promotes the healing process. Ease pain in your back, knees and neck; reduce pain from arthritis; treat neuropathy and other chronic pain conditions; and heal faster after surgery. The Novaa Light Pad with remote control is pricey, but with a 60-day money back guarantee, it's definitely worth trying.

$600; novaalab.com

Kailo Natural Pain Patch

Kailo is a non-invasive patch that's embedded with billions of tiny microcapacitors that work together to talk to your brain's electrical system to "turn down the volume" of the pain signal (like a "bio-antenna") to naturally relieve pain in seconds. Simply stick the 100 percent drug-free Kailo patch to your body wherever it hurts. Safe and effective, the patch can be worn every day!

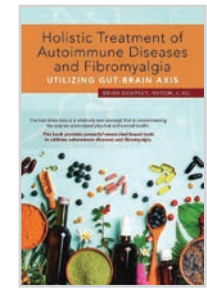
Starts at $119; gokailo.io



Autoimmune Disease Demystified: Doctor's Secret Guide

Authors: Ankita Kashyap, MD, and Krishna N. Sharma, PhD
Publisher: Virtued Press

This comprehensive guide delves into the intricacies of autoimmunity. From early warning signs to the diagnostic journey, readers will discover the psychosocial impact and myths surrounding autoimmune conditions. The guide introduces the Biopsychosocial Model, emphasizing the interconnection of mind and body; explores the pillars of health-biological, psychological and social; offers preventive strategies; emphasizes the role of social support; explains the gut-immune connection, anti-inflammatory foods and practical meal planning; uncovers the power of movement with safe exercise practices for autoimmune conditions, physiotherapy, yoga and Tai Chi; delves into stress management, sleep hygiene and self-care, recognizing the impact of chronic stress on autoimmune health; explores emotional well-being, coping strategies and the therapeutic approaches to mental health; and more.



Holistic Treatment of Autoimmune Diseases and Fibromyalgia Utilizing Gut-Brain Axis

Author: Brian Dempsey
Publisher: Ganapati Publisher

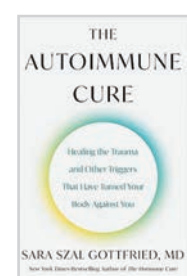
This book offers insights on how to use holistic strategies to address autoimmune diseases and aid patients in feeling better through natural treatments. Many patients have found that by adopting a therapeutic diet and incorporating holistic approaches such as acupuncture and herbal therapy, they experience significant improvement. In many cases, their autoimmune disease even goes into remission. This mirrors the author's own observations, having seen hundreds of patients who sought alternative therapies for their autoimmunity.

New and Useful Reading

Exercise Well with Autoimmunity

Author: Zoe Mckenzie
Publisher: Yellow Kite

This is the definitive book people with an autoimmune disease need to help them understand and support their body. The author talks about her own health journey while exploring the benefits of exercise for someone with an autoimmune condition and how to create a plan that suits individual needs. She uses case studies, experts and her own research to explore the benefits and barriers to exercising with a chronic condition (and how to overcome them); explain how to stay motivated when exhausted; indicate exercises to be performed (complete with illustrations); explain how to adapt exercises depending on the condition; and prepare individuals for how to get into the right mindset with exercise.



The Autoimmune Cure: Healing the Trauma and Other Triggers That Have Turned Your Body Against You

Author: Sara Szal Gottfried, MD
Publisher: Harvest Publications

With *The Autoimmune Cure*, there is hope on the horizon for the tens of millions of people who suffer from autoimmune disease. Dr. Gottfried has created a program designed to break the vicious cycle of autoimmune disease, reset the immune system and restore health, with advice on diet, sleep, supplements, breathwork, microbiome restoration, somatic therapy, ketamine-assisted treatment, microdosing psilocybin and MDMA-assisted therapy. The book offers a road map to lasting relief from autoimmune disease by addressing the root cause of the condition and healing the body, mind and spirit.

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Ataxia Telangiectasia (A-T)

Websites

- A-T Children's Project: www.atcp.org

Chronic Inflammatory Demyelinating-Polyneuropathy (CIDP)

Websites

- GBS/CIDP Foundation International: www.gbs-cidp.org

Evans Syndrome

Online Peer Support

- Rare Connect Evans Syndrome Community Group: www.rareconnect.org/en/community/evans-syndrome/faqs

Guillain-Barré Syndrome (GBS)

Websites

- GBS/CIDP Foundation International: www.gbs-cidp.org
- The Foundation for Peripheral Neuropathy: www.foundationforpn.com

Online Peer Support

- GBS Support Group: www.gaincharity.org.uk
- GBS/CIDP Foundation International Community Forums: forum.gbs-cidp.org

Immune Thrombocytopenia (ITP)

Websites

- ITP Support Association – UK: www.itpsupport.org.uk
- Platelet Disorder Support Association: www.pdsa.org

Kawasaki Disease

Websites

- American Heart Association: www.heart.org/en/health-topics/kawasaki-disease
- American Academy of Family Physicians: www.aafp.org/afp/2006/1001/p1141.html
- Kawasaki Disease Foundation: www.kdfoundation.org
- KidsHealth: www.kidshealth.org/parent/medical/heart/kawasaki.html

Mitochondrial Disease

Websites

- United Mitochondrial Disease Foundation: www.umdf.org
- MitoAction: www.mitoaction.org

Multifocal Motor Neuropathy (MMN)

Websites

- The Foundation for Peripheral Neuropathy: www.foundationforpn.com

Multiple Sclerosis (MS)

Websites

- Multiple Sclerosis Association of America: www.mymsaa.org
- Multiple Sclerosis Foundation: www.msfocus.org
- National Multiple Sclerosis Society: www.nationalmssociety.org

Online Peer Support

- Friends with MS: www.FriendsWithMS.com
- MSWorld's Chat and Message Board: www.msworld.org
- Overcoming Multiple Sclerosis: www.overcomingms.org/community

Myasthenia Gravis (MG)

Websites and Chat Rooms

- Myasthenia Gravis Foundation of America (MGFA): www.myasthenia.org
- Myasthenia Gravis Association: mgakc.org

Online Peer Support

- Genetic Alliance: www.geneticalliance.org

Myositis

Websites

- The Myositis Association: www.myositis.org
- International Myositis Assessment and Clinical Studies Group: www.niehs.nih.gov/research/resources/imacs/index.cfm

Online Peer Support

- Juvenile Myositis Family Support Network: www.curejm.org/fsn/index.php
- The Cure JM Foundation: www.curejm.org
- Myositis Association Support Group: www.myositis.org/patient-support/support-groups
- Myositis Support Group – UK: www.myositis.org.uk

Pediatric Autoimmune Neuropsychiatric Disorder Associated with Streptococcus (PANDAS)

Websites

- PANS/PANDAS UK: www.panspandasuk.org
- PANDAS Network: www.pandasnetwork.org
- PANDAS Physician Network Family Resources: www.pandasppn.org/parent-information
- National Institute of Mental Health: www.nimh.nih.gov/health/publications/pandas/index.shtml

Pemphigus and Pemphigoid

Websites

- The International Pemphigus and Pemphigoid Foundation: www.pemphigus.org

Peripheral Neuropathy (PN)

Websites

- Neuropathy Action Foundation: www.neuropathyaction.org
- Western Neuropathy Association: www.pnhelp.org
- Neuropathy Alliance of Texas: www.neuropathyalliancetx.org
- The Foundation for Peripheral Neuropathy: www.foundationforpn.com

Primary Immune Deficiency Disease (PI)

Websites

- Immune Deficiency Foundation: www.primaryimmune.org
- Jeffrey Modell Foundation: www.info4pi.org
- The National Institute of Child Health and Human Development (NICHD): www.nichd.nih.gov/Pages/index.aspx
- American Academy of Allergy, Asthma & Immunology: www.aaaai.org
- International Patient Organisation for Primary Immunodeficiencies (IPOPI) — UK: www.ipopi.org
- Rainbow Allergy-Immunology: www.uhhospitals.org/rainbow/services/pediatric-allergy-and-immunology

Online Peer Support

- IDF Friends: www.idffriends.com
- Jeffrey Modell Foundation Facebook Page: www.facebook.com/JMFworld
- IDF Peer Support Program: www.primaryimmune.org/idf-peer-support-program

Scleroderma

Websites

- Scleroderma Foundation: www.scleroderma.org
- Scleroderma Research Foundation: www.srfcure.org
- Johns Hopkins Scleroderma Center: www.hopkinsscleroderma.org

Online Peer Support

- Scleroderma Support Forum: www.curezone.com/forums/f.asp?=404

Stiff Person Syndrome (SPS)

Websites

- American Autoimmune Related Diseases Association Inc.: www.aarda.org
- Genetic Alliance: www.geneticalliance.org
- Living with Stiff Person Syndrome (personal account): www.livingwithsps.com

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