June-July 2025

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Health Screenings

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Harnessing the Power of Nature's Healing Benefits

Diagnosing and Treating CVID

Transitioning to a Plant-Based Diet

FOR PATIENTS WITH PRIMARY HUMORAL IMMUNODEFICIENCY (PI)

IT'S WHAT'S INSIDE THAT COUNTS

ASCENIV™

IMMUNE GLOBULIN INTRAVENOUS (HUMAN) – slra 10% LIQUID

DESIGNED TO DELIVER

Talk to your doctor about whether ASCENIV™ is right for you asceniv.com

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

Departments

Columns

Sources

Advertising in IG Living
IG Living Magazine is read by 30,000 subscribers who are patients that depend upon immune globulin products and their healthcare providers. For information about advertising in IG Living, download a media kit at igliving.com/advertise/advertise.html. Or contact advertising@igliving.com.

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

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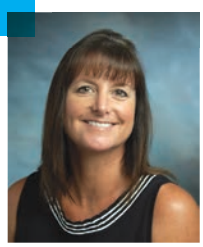
Subscriptions to IG Living are free, and readers may subscribe at IGLiving.com or by calling (800) 843-7477 x1461.

Beyond Disease: Prioritizing Whole Health



IT CAN be easy to get caught up in the daily challenges of managing a chronic illness, but prioritizing whole health on a regular basis is just as crucial. This means focusing not just on your diagnosis, but on all aspects of your physical health and mental well-being.

Regular checkups are one of the most important parts of whole health. In our article "Staying Up to Date with Health Screenings and Lifestyle Adjustments" (p.30), we discuss how preventive healthcare measures such as screenings, nutrition, exercise, sleep and stress management can increase your quality of life, prevent chronic diseases and extend your life expectancy. We make suggestions for how to optimize whole health by paying attention to specific types of health screenings, as well as how to make dietary adjustments, fit in the optimum amount of exercise, benefit from the proper amount of sleep and adopt stress-management techniques.

Regular dermatological checkups are an important type of screening that can alert you to health issues. Indeed, what many people don't realize is that our skin can tell us a lot about our health. While skin changes all the time, some of these changes are normal, but others are not. So, in our article "Cutaneous Cues: What Your Skin May Be Trying to Tell You" (p.34), we describe the types of noninfectious and infectious skin conditions of which you should be aware, and we highlight the types of skin changes primary immunodeficiency patients should pay close attention to since they are more susceptible to infections due to their weakened immune systems.

What we eat can have a significant effect on our physical health. These days, there is a growing interest in what is known as a plant-based diet. Registered dietitian Emily Cooper explains what this diet is and how to incorporate it into your lifestyle in our article "Plant Forward: How to Add More Plant-Based Foods to Your Diet" (p.44). If this is something in which you're interested, she makes specific recommendations for how to incorporate the ingredients in this diet into every meal of the day.

When it comes to both physical and mental well-being, it's amazing how beneficial nature can be. In fact, as we share in our article "Nurturing in Nature" (p.38), it's scientifically documented that spending time outdoors can reduce stress, improve sleep, reduce blood pressure and improve mindfulness. And, we explain how you can easily reap these benefits by employing your five senses: touch, sight, hearing, smell and taste.

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.

Maximizing Comfort During IVIG and SCIG Therapy

By Abbie Cornett, MBA

IF YOU are treated with immune globulin (IG) therapy, either intravenously (IVIG) or subcutaneously (SCIG), you know how important it is for managing your condition! Treatment days can be long and uncomfortable. The good news is there are several simple steps you can take to make the experience easier.

Prepare for treatment. Before treatment, taking time to prepare can help you feel more comfortable and relaxed throughout the day:[1]

- Get a good night's sleep the night before. Going to bed around the same time each night helps, and it's best to stay away from caffeine and electronics before bed.
- Drink plenty of water before and after your infusion to help you feel better. If you're being treated with IVIG, start drinking more water the day before. Avoid having too many sugary or caffeinated drinks since they can dehydrate you.
- Wear soft, comfortable clothes. If you're receiving IVIG, wear loose sleeves so the nurse can access your arm easily. If you're receiving SCIG, wear clothes that don't press on the area where you place the needles.
- Bring what you need to be comfortable. A blanket or hoodie is good to bring, since the room may be cold. Bring snacks, water and something to keep you busy such as a book, music or a tablet.
- If you are receiving treatments at home, try to minimize distractions. Partition pets in an area away from the infusion area. Arrange childcare, when possible, for at least the first hour of the infusion. And, limit the number of people in the room where you are infusing.

Stay comfortable during treatment. Being comfortable during treatment makes a big difference. If you are receiving IVIG, make sure the chair you're in feels good and supports your back. A small pillow can help, too. If you are receiving SCIG at home, choose a quiet, cozy spot where you can sit or lie down without trouble. Don't forget: Infusion rooms can get cold, so wear layers or bring a blanket.

Stay entertained. IVIG infusions can take several hours, and SCIG treatments often last one to two hours.[2] Find ways to keep yourself occupied to make it pass more quickly. Reading a book or listening to an audiobook can help you to focus on something other than the treatment. Watching TV or movies, listening to music or podcasts and engaging in hobbies such as coloring, knitting or journaling can also help.

If your IVIG infusion is at an infusion center, talking with other patients or nurses can provide a distraction. If you are receiving SCIG infusions at home, try video chatting with a friend or family member who can offer support and company.

Hydrate. Hydrate, hydrate, hydrate! Water is one of the best ways to support your body during IVIG or SCIG treatment. But if you don't like water, there are plenty of other options. Diluted sports drinks, coconut water, Pedialyte or herbal teas can also help keep you hydrated. Just be sure to talk to your doctor first, especially if you have another condition such as diabetes, kidney disease or heart problems.

After-treatment care. Some people feel fine after an infusion, while others feel tired, so it's important to listen to your body and rest if needed. Don't push yourself, and keep drinking water to help your body process the medicine. If you get a headache, try drinking more water or another drink containing electrolytes. Call your doctor if your headache is severe or your SCIG site looks red, swollen or infected. If you get a fever, rash or have trouble breathing, get medical help immediately since these could be signs of a serious problem.[3]

Having a chronic illness is stressful enough, but with a bit of preparation, infusion day doesn't have to be. Simple things such as staying hydrated, wearing comfortable clothes and bringing something to pass the time can make a big difference. Everyone is different, so finding what works best for you is important. And remember: If something doesn't feel right, talk to your doctor — there may be ways to make treatment easier and more comfortable. IG

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3. Immune Deficiency Foundation. Safety Important for Successful Immunoglobulin Replacement Therapy, Oct. 24, 2023. Accessed at primary immune.org/resources/news-articles/safety-important-successful-immunoglobulin-replacement-therapy.

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.

Are Alternative Funding Programs Putting Your Treatment at Risk?

Patients with chronic illnesses are facing a new challenge: alternative funding programs that claim to reduce healthcare costs but often leave patients without guaranteed access to their medications. These programs remove specialty drugs from insurance coverage, forcing patients into uncertain third-party funding systems.

Our article titled "What Are Alternative Funding Programs" on page 38 of the February-March 2025 issue explains how these programs work, why they are problematic and what patients need to know to protect their access to treatment.

Reader response: Also, be careful of "reference-based payers." They sometimes explain themselves as a more cost-effective form of insurance. But they aren't traditional insurance, and they will make you do all the calling back and forth between the company and the healthcare financial services. All the while, they will claim you owe nothing, but in the end, they delay and continue to low-ball settlement offers with the healthcare provider until the time passes and you are taken to collections. I'm still digging myself out of the hole I was left in after my employer chose this format for a year.

How Have You Handled Medical Setbacks?

Medical setbacks can feel like one step forward and two steps back, but every challenge is a chance to learn and grow. Our latest article titled "How to Handle Medical Setbacks" on page 34 of the February-March 2025 issue offers practical strategies for building resilience and managing difficult health moments.

Reader response: For those who have a primary immunodeficiency and live alone, we can't always rely on the help of others. No matter how sick we feel, we still have to get up and take care of ourselves. Please consider addressing the times when your body says, "I can't." There are times when my body has physically said to me, "I can't get up and get breakfast."

With Whom Should You Share Your Health Diagnosis?

Deciding who to share a health diagnosis with can feel overwhelming. Whether it's a life partner, family, friends or even social platforms, it's a deeply personal choice. Prepare ahead to handle these difficult discussions with grace and create a safe space for yourself and others.

Reader response: I share my diagnoses with anyone who asks about my conditions. When my daughter was pregnant, I gave her a list of my conditions for her to inform her ob/gyn. I'm very vocal on my social media sites about the different diagnoses.

Join the conversation! Connect with other immune globulin patients through IG Living's Facebook page at www.facebook.com/IGLivingMagazine. Each day, we post interesting articles and facts, as well as thought-provoking questions you can weigh in on. These are some snapshots of what's being discussed.

Could the Antibodies in IG Therapies Be Affected by the COVID-19 Vaccines?

In 2023, I got sick in October and did not get healthy again until March 2024. During that span, I was prescribed antibiotics on several occasions. Fast forward to October 2024, and I got a cold again for which I had to take antibiotics. About a week after finishing the antibiotic, another cold started. I feel like I have not been this sick since prior to starting intravenous immune globulin (IVIG) therapy. Could it be that the antibody supply change has been negatively affected by the COVID-19 vaccines? I hear of a lot of controversy about the mRNA vaccines.

Abbie: I spoke with Roger Kobayashi, MD, an allergist-immunologist in Omaha, Neb., who assured me that neither the COVID-19 nor mRNA vaccines have impacted the IG products' efficacy. However, he did say that if you are experiencing persistent or recurrent infections, there could be several underlying causes that need careful investigation.

Dr. Kobayashi emphasized that it is essential to work closely with an experienced immunologist who can thoroughly evaluate your situation. A well-trained immunologist will be able to assess whether low-grade chronic infections might be contributing to the issue. These infections can sometimes not be immediately obvious but are often found in the sinuses or lungs, which are common sites for such problems.

If you are not already under the care of an experienced immunologist, he recommends seeking a referral to one. A detailed evaluation by a specialist is crucial to uncovering any underlying conditions and determining the best course of action. This approach will help ensure any potential chronic infections or other contributing factors are identified and appropriately addressed.

How Can I Connect with Other Patients Who Truly Understand the Challenges of Managing CIDP?

I have chronic inflammatory demyelinating polyneuropathy (CIDP). Is there a way I can connect with other patients who truly understand the challenges of managing a chronic illness like CIDP so I don't feel isolated or alone in my journey?

Abbie: Living with a long-term illness like CIDP can sometimes feel very lonely, but connecting with people who understand what you are going through can help a lot. One way to feel more connected is by joining social media communities. At IG Living, we have Facebook and Instagram pages where we share news, updates and tips for living with chronic illnesses like CIDP. These platforms are a safe space where you can join in conversations, share your story and see how others are coping.

It might also be helpful to talk with a counselor or therapist if you ever feel overwhelmed. Counseling can provide you with a safe place to share your feelings and even suggest more ways to find support. Additionally, your doctor or local hospital might know about support groups or events in your area where you can meet others in person.

At IG Living, our goal is to help you feel less alone and more connected. If you need more support or just someone to talk to, please feel free to email me at acornett@igliving.com.

» 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.

Tips for Talking to Children About Illness

By Mairead McConnell, PhD

LIVING WITH a chronic illness or immune deficiency comes with many challenges, including communicating about your health, needs and limitations with loved ones. It can be especially difficult to know how or when to address these topics with the children or teenagers in your life. You may worry that sharing about your health challenges will upset them or wonder how to present the information in a way they can understand and digest. Consider the strategies below to help get the conversation started.

Honesty Is Honestly the Best

When it comes to sharing with children, honesty is your best bet. However, providing accurate information doesn't mean you have to provide all the details. You can keep the explanation age-appropriate, but make sure the story is truthful. Children are perceptive, and if they are not given a narrative that matches the reality they are experiencing, they will fill in the blanks on their own.

Call It By Name

When discussing your condition, use the name of the condition or disease as you would with an adult. Children are likely to hear it eventually, and knowing the name will allow them to feel informed and empowered. This also prevents confusion and allows children to differentiate one illness from another.

Provide Reassurance and Rhythm

The most common concerns for children in these scenarios are, "Did I cause it?" and "What will happen to me?" Even if the cause of the disease is unknown, make it clear to children that they did not cause it, and that the illness is not contagious (if that is true). Reassure them that they will be cared for both with your words and actions. Keep routines and rhythms consistent and predictable, when possible, and inform them when and why rhythms may need to change.

Encourage Expression

It is healthy and necessary for children to express their emotions, but it may not always look how we expect. Invite children to ask you questions and share their feelings both with you and also with supportive others, since some kids may find it difficult to talk to the person with the illness about the illness. Therefore, it is best to inform other caregivers and supportive adults in children's circles about the illness and your approach to discussing it with them. Expect that young children might incorporate this information into their play, and that teens may prefer to process feelings with their peers rather than with you.

Allow Kids to Be Kids

Most importantly, children need to be safe, loved and allowed to just be kids. Provide opportunities for play and carefree time, even if you aren't always able to join. If you have teens or young adults in your life, they may very appropriately step up to help out more; they may even help care for younger children. Notice if they are becoming overburdened, and make sure your primary sources of support are other adults in your life so the children can focus on being children.

Support Is Out There

If you or the children in your life need more support in coping with illness, check out Wonders & Worries (www.wonderandworries.org), a wonderful organization that helps parents and families dealing with serious illness or injury. Caring for yourself and your family sometimes means accepting support from professionals and agencies that are trained to help.

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.

If you're an adult living with primary immunodeficiency (PI), ALYGLO™ can reduce the risk of infection from PI and its impact on your daily life.[1]
Based on a clinical study of 33 adults ages 17-70 in North America.[1]

0.03 SERIOUS INFECTIONS per patient year[1]

0.2 DAYS OF HOSPITALIZATION per patient year[1]

6 DAYS MISSED OF WORK OR SCHOOL per year[1]

INDICATION

ALYGLO™ is indicated for the treatment of primary humoral immunodeficiency (PI) in adults aged 17 years and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency (CVID), Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

IMPORTANT SAFETY INFORMATION

- **Thrombosis (blood clot formation) can happen with ALYGLO. Factors that increase this risk include advanced age, prolonged immobility, certain medical conditions, and cardiovascular risk factors.**
- **ALYGLO may affect the kidneys. In some cases, it can lead to acute renal failure or death.**
- **If you're at risk for blood clots or kidney problems, your doctor should give you ALYGLO at the lowest effective dose and infusion rate. Staying well-hydrated before treatment is essential.**
- ALYGLO is not suitable for people who have had severe allergic reactions to immune globulin or those with IgA deficiency and a history of hypersensitivity.
- If you experience any signs of hypersensitivity during the infusion, treatment should be stopped and epinephrine (an emergency medication) should be administered immediately.
- ALYGLO may cause hyperproteinemia, increased serum viscosity, and hyponatremia (low sodium levels).
- Aseptic Meningitis Syndrome (AMS) is a rare condition that can occur after receiving ALYGLO, especially with high doses or rapid infusion. Symptoms usually start within a few hours to 2 days after treatment. If AMS occurs, stopping ALYGLO usually leads to improvement within several days without lasting effects.
- Hemolysis, a breakdown of red blood cells, may occur. Some patients may experience delayed hemolytic anemia due to increased sequestration of red blood cells. Severe hemolysis-related kidney dysfunction or disseminated intravascular coagulation has been reported.
- Transfusion-Related Acute Lung Injury (TRALI) is a rare complication characterized by severe respiratory distress, pulmonary edema, and fever. Patients with TRALI may need oxygen therapy and ventilator support.
- ALYGLO is made from human blood, which may carry a risk of transmitting infectious agents (such as viruses).
- After receiving ALYGLO, some antibodies from the treatment may temporarily show up in blood tests. This could lead to misleading results, so your healthcare provider will consider this when interpreting lab results.
- Common side effects include headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.

Reference: 1. ALYGLO Prescribing Information. GC Biopharma; 2023.

For more information about ALYGLO, talk to your doctor and see Brief Summary of Prescribing Information on next page.

GC Biopharma

Alyglo™
immune globulin intravenous, human-stwk 10% liquid

BRIEF SUMMARY OF PRESCRIBING INFORMATION
Please see full Prescribing Information at ALYGLO.com.

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 ALYGLO. 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. ALYGLO does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction or renal failure, administer ALYGLO 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

ALYGLO is a 10% immune globulin liquid for intravenous injection, indicated for the treatment of primary humoral immunodeficiency (PI) in adults. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskot-Aldrich syndrome, and severe combined immunodeficiency (SCID).

DOSAGE AND ADMINISTRATION

For intravenous use only.

Dose

Table 1 Recommended Dose

Dose	Infusion Number	Initial Infusion Rate	Maintenance Infusion Rate
300 - 800 mg/kg body weight every 21 or 28 days	For the 1st Infusion	1 mg/kg/min (0.01 mL/kg/min)	Double the infusion rate every 30 minutes (if tolerated) up to 8 mg/kg/min (0.08 mL/kg/min)
300 - 800 mg/kg body weight every 21 or 28 days	From the 2nd Infusion	2 mg/kg/min (0.02 mL/kg/min)	Double the infusion rate every 15 minutes (if tolerated) up to 8 mg/kg/min (0.08 mL/kg/min)

Significant differences in the half-life of IgG among patients with PI may necessitate the dose and frequency of immunoglobulin therapy to vary from patient to patient. Determine the proper dose and frequency by monitoring clinical response.

Measles Exposure

If a patient has been exposed to measles, consult with physician to administer an extra dose of IGIV as soon as possible and within 6 days of exposure. A dose of 400 mg/kg should provide a serum level > 240 mIU/mL of measles antibodies for at least two weeks.

If a patient is at risk of future measles exposure and receives a dose of less than 530 mg/kg every 3 - 4 weeks, then the dose should be increased to at least 530 mg/kg. This should provide a serum level of 240 mIU/mL of measles antibodies for at least 22 days after infusion.

Administration

- Monitor vital signs throughout the infusion. Slow or stop the infusion if adverse reactions occur. If symptoms subside, the infusion may be resumed at a lower rate that is comfortable for the patient.
- Ensure that patients with pre-existing renal insufficiency are not volume depleted. For patients at increased risk of renal dysfunction or thrombotic events, administer ALYGLO at the minimum infusion rate practicable, and consider discontinuation of administration if renal function deteriorates [*see Boxed Warning, Warnings and Precautions*].
- After administration, the infusion line may be flushed with either normal saline or 5% dextrose in water.

CONTRAINDICATIONS

ALYGLO is contraindicated in:

- Patients who have a history of anaphylactic or severe system reaction to the administration of human immune globulin.
- IgA-deficient patients with antibodies to IgA and a history of hypersensitivity [*see Warnings and Precautions*].

WARNINGS AND PRECAUTIONS

Hypersensitivity: Severe hypersensitivity reactions may occur[1]. In case of hypersensitivity, discontinue ALYGLO infusion immediately and institute appropriate treatment. Have epinephrine available for immediate treatment of severe acute hypersensitivity reactions.

ALYGLO contains trace amounts of IgA (≤ 100 mcg/mL). Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions. ALYGLO is contraindicated in IgA-deficient patients with antibodies against IgA or a history of hypersensitivity reaction [*see Contraindications*].

Thrombotic Events: Thrombosis may occur following treatment with ALYGLO[1]. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.

Consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including patients with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies. For patients at risk of thrombosis, administer ALYGLO 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 [*see Boxed Warning, Dosage and Administration*].

Renal Failure: Renal dysfunction, acute renal failure, osmotic nephropathy, and death[1] may occur upon use of ALYGLO. Ensure that patients are not volume-depleted before administering ALYGLO. Monitor renal function and urine output periodically, especially in patients who are at higher risk of renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine before the initial infusion of ALYGLO and at appropriate intervals thereafter. If renal function deteriorates, consider discontinuing ALYGLO. In patients who are at risk of developing renal dysfunction, because of pre-existing renal insufficiency or predisposition to acute renal failure (such as diabetes mellitus, hypovolemia, overweight, use of concomitant nephrotoxic medicinal products or age > 65 years), administer ALYGLO at the minimum infusion rate practicable [*see Boxed Warning, Dosage and Administration*].

Hyperproteinemia, Increased Serum Viscosity, and Hyponatremia: Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving ALYGLO. It is critical to clinically distinguish true hyponatremia from a pseudohyponatremia that is associated with or causally related to hyperproteinemia with concomitant decreased calculated serum osmolality or elevated osmolar gap. Such treatment aimed at decreasing serum free water in patients with pseudohyponatremia may lead to volume depletion, a further increase in serum viscosity, and a possible predisposition to thrombotic events[1].

Aseptic Meningitis Syndrome (AMS): AMS may occur with ALYGLO. AMS usually begins within several hours to 2 days following ALYGLO treatment. Discontinuation of treatment has resulted in remission of AMS within several days without sequelae[1].

AMS may occur more frequently with high doses (2 g/kg) and/or rapid infusion of ALYGLO. AMS is characterized by the following signs and symptoms: Severe headache, nuchal rigidity, drowsiness, fever, photophobia, painful eye movements, nausea, and vomiting. Cerebrospinal fluid (CSF) studies frequently reveal pleocytosis up to several thousand cells per cubic millimeter, predominantly from the granulocytic series, and elevated protein levels up to several hundred mg/dL, but negative culture results. Conduct a thorough neurological examination on patients exhibiting such signs and symptoms, including CSF studies, to rule out other causes of meningitis.

Hemolysis: ALYGLO may contain blood group antibodies that can act as hemolysins and induce *in vivo* coating of red blood cells (RBCs) with immunoglobulin, causing a positive direct antiglobulin test (DAT) (Coombs test) result and hemolysis[1]. Delayed hemolytic anemia due to enhanced RBC sequestration, and acute hemolysis, consistent with intravascular hemolysis, have been reported. Cases of severe hemolysis-related renal dysfunction/failure or disseminated intravascular coagulation have occurred following infusion of IGIV.

Hemolysis (cont.):

The following risk factors may be associated with the development of hemolysis following IGIV administration: High doses (e.g., 2 g/kg or more), given either as a single administration or divided over several days, and non-O blood group. Other individual patient factors, such as an underlying inflammatory state (as may be reflected by, for example, elevated C-reactive protein or erythrocyte sedimentation rate), have been hypothesized to increase the risk of hemolysis following administration of IGIV[1], but their role is uncertain.

Closely monitor patients for clinical signs and symptoms of hemolysis, particularly patients with risk factors noted above. Consider appropriate laboratory testing in higher risk patients, including measurement of hemoglobin or hematocrit.

If clinical signs and symptoms of hemolysis or a significant drop in hemoglobin or hematocrit have been observed, perform confirmatory laboratory testing, including direct antiglobulin test. If transfusion is indicated for patients who develop hemolysis with clinically compromising anemia after receiving ALYGLO (immune globulin intravenous, human-stwk), perform adequate cross-matching to avoid exacerbating ongoing hemolysis.

Transfusion-Related Acute Lung Injury (TRALI): Noncardiogenic pulmonary edema [Transfusion-Related Acute Lung Injury (TRALI)] may occur in patients administered ALYGLO[1]. TRALI is characterized by severe respiratory distress, pulmonary edema, hypoxemia, normal left ventricular function, and fever. Signs and symptoms typically appear within 1 to 6 hours following treatment. Patients with TRALI may be managed using oxygen therapy with adequate ventilator support.

Monitor patients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-human leukocyte antigen (HLA) antibodies in both the product and the patient's serum.

Transmissible Infectious Agents: Because ALYGLO is made from human blood, it 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. The risk of infectious agent transmission has been reduced by screening plasma donors and by including virus inactivation/removal steps in the manufacturing process of ALYGLO.

Report all infections thought by a physician possibly transmitted by ALYGLO to GC Biopharma USA, Inc. at 1-833-426-6426. Discuss the risks and benefits of its use with the patient before prescribing or administering this product.

Monitoring Laboratory Tests

- Periodic monitoring of renal function and urine output is particularly important in patients at increased risk of developing acute renal failure. Assess renal function, including measurement of blood urea nitrogen (BUN) and serum creatinine before the initial infusion of ALYGLO and at appropriate intervals thereafter.
- Because of the potential for increased risk of thrombosis with ALYGLO, consider baseline assessment of blood viscosity in patients at risk for hyperviscosity, including those with cryoglobulins, fasting chylomicronemia/markedly high triacylglycerols (triglycerides), or monoclonal gammopathies.
- If signs and/or symptoms of hemolysis are present after an infusion of ALYGLO, perform appropriate laboratory testing for confirmation.
- If TRALI is suspected, perform appropriate tests for the presence of anti-neutrophil antibodies in both the product and patient's serum.

Interference with Laboratory Tests: After infusion of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation. Passive transmission of antibodies to erythrocyte antigens (e.g., A, B, and D) may cause a positive direct or indirect antiglobulin (Coombs) test.

ADVERSE REACTIONS

The most common adverse reactions, observed in ≥ 5% of study subjects, were headache, nausea/vomiting, fatigue, nasal/sinus congestion, rash, arthralgia, diarrhea, muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, and dizziness.

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In an open-label, single-arm, multicenter, non-randomized clinical trial, 33 subjects with primary humoral immunodeficiency received doses of ALYGLO ranging from 319 mg/kg to 817 mg/kg every 21 days or 28 days for up to 12 months.

The passive transfer of antibodies with IGIV administration may interfere with the response to live virus vaccines such as measles, mumps, rubella, and varicella. Immunizing physicians should be informed of recent IGIV therapy so that appropriate measures may be taken.

Twenty-eight subjects (85%) experienced a total of 145 temporally associated adverse reactions (adverse events that occurred during or within 72 hours after the end of an infusion) during the study. The temporally associated ARs were headache (13 subjects, 39%), nausea/vomiting (11 subjects, 33%), fatigue (6 subjects, 18%), nasal/sinus congestion (5 subjects, 15%) rash (4 subjects, (12%), arthralgia, diarrhea (3 subjects, 9% each), muscle pain/aches, infusion site pain/swelling, abdominal pain/discomfort, cough, dizziness (2 subjects, 6% each).

These are presented in Table 2. There were no deaths and no adverse reactions leading to withdrawal from the study.

0008-01-2024 3/2024

Table 2 Adverse Reactions* (ARs) (within 72 hours after the end of an ALYGLO infusion) in ≥ 5% of Subjects

Adverse Reactions (ARs)	No. of Subjects Reporting ARs (Percentage of Subjects) [N[1]=33]	No. of Infusions with ARs (Percentage of Infusions) [N[2]=427]
Headache	13 (39)	32 (7.5)
Nausea/vomiting	11 (33)	20 (4.7)
Fatigue	6 (18)	18 (4.2)
Nasal/sinus congestion	5(15)	5 (1.2)
Rash	4 (12)	4 (0.9)
Arthralgia	3 (9)	4 (0.9)
Diarrhea	3 (9)	3 (0.7)
Muscle pain/aches	2 (6)	7 (1.6)
Infusion site pain/swelling	2 (6)	6 (1.4)
Abdominal pain/discomfort	2 (6)	3 (0.7)
Cough	2 (6)	2 (0.5)
Dizziness	2 (6)	2 (0.5)

*Adverse events that occurred during or within 72 hours after the end of an infusion
[1]Total number of subjects
[2]Total number of infusions

Postmarketing Experience: Because postmarketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions or establish a causal relationship to product exposure. The following adverse reactions have been identified and reported during the post-approval use of marketed IGIV products:

Blood and lymphatic system disorders: leukopenia, hemolysis, pancytopenia; **Immune system disorders:** hypersensitivity (e.g., anaphylaxis), anaphylactic shock, anaphylactic reaction, anaphylactoid reaction, allergic reaction, angioedema, face edema; **Metabolic and nutritional disorders:** fluid overload, (pseudo) hyponatremia; **Psychiatric disorders:** agitation, confusion, anxiety, nervousness; **Nervous system disorders:** coma, loss of consciousness, seizures, (acute) encephalopathy, cerebrovascular accident, stroke, aseptic meningitis, migraine, speech disorder, paresthesia, hypoesthesia, photophobia, tremor; **Cardiac disorders:** myocardial infarction, cardiac arrest, angina pectoris, tachycardia, bradycardia, palpitations, cyanosis; **Vascular disorders:** hypotension, (deep vein) thrombosis, peripheral circulatory failure/collapse, hypertension, phlebitis, pallor; **Respiratory, thoracic and mediastinal disorders:** apnea, Acute Respiratory Distress Syndrome (ARDS), TRALI, respiratory failure, pulmonary embolism, pulmonary edema, bronchospasm, dyspnea, hypoxia, wheezing, cough; **Gastrointestinal disorders:** diarrhea, hepatic dysfunction, abdominal discomfort; **Skin and subcutaneous tissue disorders:** eczema, urticaria, rash (erythematous), dermatitis, pruritus, alopecia, Stevens-Johnson syndrome epidermolysis, skin exfoliation, erythema (multiform), dermatitis (e.g., bullous dermatitis); **Musculoskeletal and connective tissue disorders:** back pain, arthralgia, myalgia, musculoskeletal pain, muscle stiffness, pain in extremity, neck pain, muscle spasm; **Renal and urinary disorders:** acute renal failure, osmotic nephropathy, renal pain; **General disorders and administration site conditions:** injection-site reaction, chills, chest pain or discomfort, hot flush, flushing, flu-like illness, feeling cold or hot, edema, hyperhidrosis, malaise, asthenia, lethargy, burning sensation; **Investigations:** hepatic enzymes increased, oxygen saturation decreased, falsely elevated erythrocyte sedimentation rate, positive direct antiglobulin (Coombs) test.

DRUG INTERACTIONS

Clinical studies have not evaluated mixture of ALYGLO with other drugs and intravenous solutions. It is recommended that ALYGLO is administered separately from other drugs or medications which the patient may be receiving. Do not mix the product.

Transitory rise of the various passively transferred antibodies in the patient's blood after infusion of immunoglobulin may yield positive serological testing results, with the potential for misleading interpretation.

USE IN SPECIFIC POPULATIONS

Geriatric use: In patients over age 65 or in any patient at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse ALYGLO at the minimum infusion rate practicable.

Reference: 1. ALYGLO Prescribing Information. GC Biopharma USA, Inc.; 2023.

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SARS-CoV-2 and COVID-19: Brain Fog

By Terry O. Harville, MD, PhD

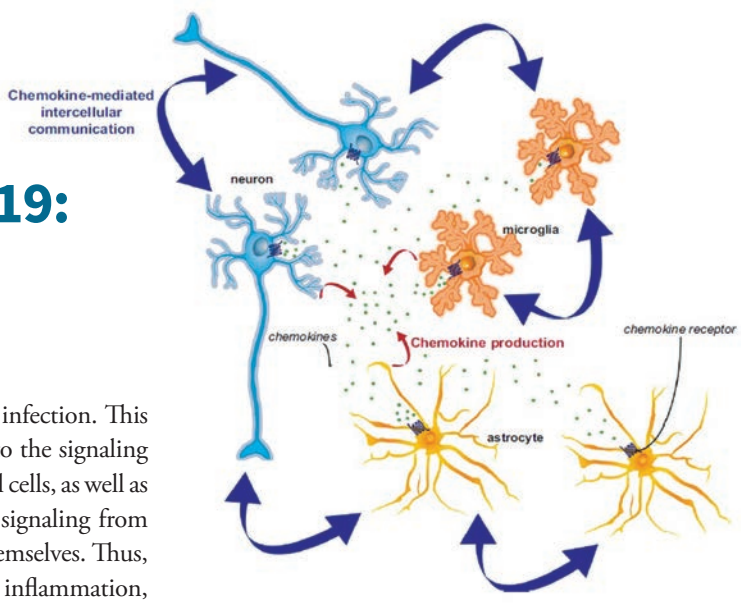

Figure. Reciprocal signaling of inflammatory chemokines between microglial cells, astrocytes and neurons, resulting in an inflammatory state, which can adversely affect brain fog.

IN THE last issue, we discussed brain fog as a consequence of ongoing inflammation after a COVID infection. Further, we mentioned that brain fog can occur after any viral infection. Recently, during the current influenza season, brain fog has been reported as a major complaint in patients after contracting the flu.

There are likely several contributory factors for brain fog in patients with long COVID (or PASC, post-acute sequelae of COVID). Ongoing inflammation appears to be a major factor in all forms of post-infectious brain fog. Microglial cells, which are the main indwelling immune cells within the brain, are bone marrow-derived cells that migrate to the brain and carry out macrophage and immune dendritic cell-type activities. Thus, they are important for the initiation of immune activation and maintenance of the immune response, as are macrophage and immune dendritic cells in the rest of the body's tissues.

Microglial cells (like tissue macrophages) exist in two primary states of activation: M1 and M2. M1 is the state of increased inflammation triggered by an infection. It is characterized by the release of inflammatory chemokines and cytokines, which help initiate and maintain an inflammatory immune response. The goal is to clear the infection and calm it down, but when the process continues, unnecessary inflammation can cause tissue injury. Further, astrocytes are brain-tissue derived to support cells. They are there to help maintain the brain environment and provide support for neuron function. Additionally, they can secrete inflammatory chemokines in response to an infection. This is in response to the signaling from microglial cells, as well as in response to signaling from the neurons themselves. Thus, in a state of inflammation, such as with a viral infection, microglial cells, acting as macrophage and immune dendritic-cell equivalents, will secrete inflammatory chemokines and cytokines, which can signal to astrocytes and neurons to, in turn, reciprocally signal with chemokines. As such, three-way inflammatory signaling is occurring. Further, if an astrocyte or neuron is otherwise directly affected by the viral infection, either could be the initial source of chemokine secretion for activating the microglial cells, and then the other cell type (Figure). If counteractive processes do not occur, this can continue unabated. This ongoing inflammation disrupts neuron function, clinically exhibited as brain fog. Notably, that all can be occurring with the innate components of the immune system (i.e., the initiators of the immune response), which would be trying to attract the adaptive immune system components.

The M2 state of activation of microglial cells is the opposite. Anti-inflammatory cytokines (primarily IL-10 and TGF-β) are secreted to bring about reduced inflammation. Unfortunately, in long COVID, it appears that microglial cells are converted to the M1 state and persist there. Multiple publications support this, and we have unpublished data indicating continued presence of inflammatory chemokines and cytokines in patients with long COVID.

Microclotting is an additional major concern regarding brain function and brain fog (also in other tissues and organs) in patients with long COVID. Microclotting was demonstrated in the brains of patients after COVID infection, regardless of the infection severity.[1] Our finding of anti-ACE2 antibodies may be contributing to this.[2] Microclotting can result in reduced blood flow and disruption of brain function, which can be a serious cause of brain fog, as well as injury to other tissues and organs.

We will further discuss evaluation and treatment of brain fog in the next issue.

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PI and Skin Cancer: Understanding the Risks

By Michelle Greer, RN, IgCN

IMMUNE DEFICIENCIES can be primary or secondary. A primary immune deficiency (PI) is the result of an inherent defect within the immune system. A secondary immune deficiency occurs in response to an external factor, such as a virus or medication, that lowers the immune system and typically resolves with the removal of the cause. There are hundreds of types of PIs, and depending on the component of the immune system impacted, they are treatable but not curable, except with a stem cell transplant, which is not commonly performed.

Components of the Immune System

With multiple components, the immune system's function is to protect against infections and other conditions, including allergies and cancer. This complicated network of cells and organs functions together to identify foreign invaders and remove them from the body. The immune system's function is also to keep itself healthy. So, an immune system defect can result in an autoimmune condition, in which the immune system creates an antibody against a part of the body that should be kept healthy. It is not uncommon for those with a PI to also have an autoimmune disease. Autoimmunity is observed with particular frequency in patients with primary antibody deficiencies such as common variable immunodeficiency (CVID) and selective IgA deficiency. But, combined immunodeficiency disorders and disorders of innate immunity have also been associated with autoimmunity.[1] Depending on the type of PI, the autoimmunity incidence can be up to 30 percent.

PI and Cancer Risk

There is a higher risk of malignancies in people with PI, depending on the type of PI, and the type of malignancy varies. A meta-analysis that looked at the overall and site-specific incidence of cancer in subjects with PI enrolled in the United States Immune Deficiency Network registry compared with age-adjusted cancer incidence in the Surveillance, Epidemiology and End Results Program database concluded an excess incidence of cancer occurred in PI patients. Specifically, the occurrence of lymphoma in PI populations principally drove this increased incidence, while no increased risk of the most common solid tumor malignancies was observed. These data point to a restricted role of the immune system in protecting from specific cancers. The study also found that after lymphoma, there was an increased incidence of skin cancer. In fact, skin cancer was the next most common cancer diagnosis in those diagnosed with CVID.[2]

In two studies in the U.S. and Europe, skin cancer was the second most frequent malignancy after lymphomas, accounting for 15 to 21 percent of all malignancies reported and having a 3.3- to 4.5-fold increased risk compared to the general population.[3] However, the type of skin cancer was not specified.

Disorders of the immune system may result in various cutaneous manifestations, including cutaneous malignancies. In patients with PI, the risk of developing malignant cutaneous neoplasms (tumors) is substantially increased, which may be due to oncogenic viruses that find a suitable microenvironment for tumorigenesis and cancer development.[4] Overall, the literature does point to an increase in some form of skin cancer in PI patients.

Skin Cancer Precautions

So, what precautions can people with PI take in light of this data? The

5 Common Sunscreen Mistakes — And How to Avoid Them

To protect your skin and reduce your risk of skin cancer, following are five common sunscreen mistakes — and how to avoid them:

1) ***Ignoring the label.*** There are a variety of sunscreens on the market. To effectively protect yourself from the sun, the American Academy of Dermatology (AAD) recommends using sunscreens that are broad-spectrum, water-resistant and have an SPF of 30 or higher.
2) ***Using too little.*** Most people only apply 25 to 50 percent of the recommended amount of sunscreen. However, at a minimum, most adults need about one ounce of sunscreen — roughly the amount to fill a shot glass — to fully cover skin not covered by clothing. Depending on your body size, you may need more sunscreen to protect your exposed skin from the sun's harmful rays. Apply the sunscreen 15 minutes before going outdoors, and reapply every two hours while outdoors or after swimming or sweating.
3) ***Applying only in sunny weather.*** Alarmingly, AAD found that only about 20 percent of Americans use sunscreen on cloudy days. However, the sun emits harmful UV rays all year long. Even on cloudy days, up to 80 percent of UV rays can penetrate your skin. To protect your skin and reduce your risk of skin cancer, apply sunscreen every time you are outside, even on cloudy days.
4) ***Using an old bottle.*** The U.S. Food and Drug Administration requires that all sunscreens retain their original strength for at least three years. Throw out your sunscreen if it's expired or you're unsure how long you've had it. In the future, if you buy a sunscreen that lacks an expiration date, write the purchase date directly on the bottle so you know when to toss it out.
5) ***Relying solely on sunscreen.*** Since no sunscreen can block 100 percent of the sun's UV rays, it's important to seek shade and wear sun-protective clothing, including a lightweight, long-sleeved shirt, pants, a wide-brimmed hat and sunglasses with UV protection, when possible. For more effective sun protection, select clothing with an ultraviolet protection factor (UPF) label.

first is to have regular examinations by a dermatologist. In a recent conference session at the Immune Deficiency Foundation, dermatologist Edward Cowen, MD, MHSC, FAAD, recommended visiting a dermatologist at least annually since visible skin problems can be important for the diagnosis and management of health issues. According to Dr. Cowen, parents should seek a pediatric dermatologist for children with PI, and adults with PI should look for a medical dermatologist. In addition, he recommends choosing a provider who will perform a full skin exam, address lesions of concern and make an accurate diagnosis through a biopsy, not just a skin swab.[5]

Aside from an annual examination, PI patients should regularly monitor their own skin and have any changes promptly evaluated. Practicing sun safety is important for the general population, but even more so for those with a PI. This includes wearing a hat, sunglasses, sunscreen with a sun protection factor of 30 or higher, protective clothing that covers the body as much as possible, and staying in the shade. Sunscreen should be applied before going outdoors and reapplied after swimming or sweating. Smoking and consuming alcohol can increase cancer in general, but studies have shown a direct correlation between skin cancer and smoking and drinking, so PI patients are advised to avoid both. Lastly, tanning beds should be avoided.

The Importance of Cancer Awareness

Awareness of the increased risk of skin cancer and taking steps to minimize and get ahead of it is crucial in the overall management of PI. While more specific studies are needed to understand the correlation between PI and skin cancer, the data does suggest there is an increased risk in general, so regular dermatology visits, self-exams, sun safety and good health practices that promote healthy skin are important.

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

MEDICINES

Bivigam, Gamunex-C and Panzyga Lots Withdrawn

Specific lots of intravenous immune globulin (IVIG) and subcutaneous IG (SCIG) have been voluntarily withdrawn by the manufacturers due to a higher rate of allergic/hypersensitivity-type reactions, some of which were considered medically significant. Affected products and lots include:

• Bivigam: NDC number: 69800-6503-1; Lot numbers: 321524 and 321724; Size: 10g; Packaging: 100 ml vial; Expiration dates: 07-01-2027 and 08-31-2027

Reason: This voluntary withdrawal is being conducted due to the potential for an increased rate of allergic/hypersensitivity-type reactions associated with these specific lots. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IG products.

Contact: For technical or clinical questions, contact ADMA Customer Service at Customerservice@ADMAbio.com or call (888) 458-4244.

• Gamunex-C: NDC number: 13533-800-40; Lot number: B01J112733; Size: 40g; Packaging: 400mL vial; Expiration date: 11-08-2027

Reason: This voluntary withdrawal is being conducted as a precautionary measure due to an increased rate of allergic/hypersensitivity-type reactions associated with this specific lot. A small number of the reactions were considered medically significant. Hypersensitivity and anaphylactic/anaphylactoid reactions are a known risk with IG products. This withdrawal is being conducted with the knowledge of the U.S. Food and Drug Administration's Center for Biologics Evaluation and Research.

Contact: For technical or clinical questions, contact U.S. Clinical Communications at (800) 520-2807.

• Panzyga: Lot number: L319C8261; Expiration date: 05-14-2026

Examine your stock immediately to determine if you have any vials from this lot. If you have product from this lot, cease use immediately and return the affected product to the point of purchase to receive replacement product.

Immune Deficiency Foundation. Bivigam, Gamunex-C, and Panzyga Lots Withdrawn, March 11, 2025. Accessed at primaryimmune.org/resources/news-articles/bivigam-gamunex-c-and-panzyga-lots-withdrawn.

RESEARCH

First CVID Patient Begins Leniolisib Clinical Trial

The first patient has been dosed in a Phase II clinical trial evaluating Pharming's leniolisib in common variable immunodeficiency (CVID) patients with immune dysregulation.

The trial is a single arm, open-label, dose range-finding, multi-center study to be conducted in approximately 20 patients 12 years of age and older. It will include patients with a CVID diagnosis, a requirement for evidence of lymphoproliferation and at least one additional clinical manifestation of immune dysregulation, including interstitial lung disease, autoimmune cytopenias or enteropathy. The objectives of the trial are to assess safety and tolerability, pharmacokinetics, pharmacodynamics and explore clinical efficacy of leniolisib in the targeted CVID with immune dysregulation population. The trial has been designed to inform a subsequent Phase III program.

Leniolisib, marketed under the brand name Joenja in the U.S., is an oral small molecule phosphoinositide 3-kinase (PI3K) delta inhibitor approved in the U.S. and several other countries as the first and only targeted treatment of activated PI3K delta syndrome (APDS) in adult and pediatric patients 12 years of age and older. Leniolisib inhibits the production of phosphatidylinositol-3-4-5-trisphosphate, which serves as an important cellular messenger and regulates a multitude of cell functions such as proliferation, differentiation, cytokine production, cell survival, angiogenesis and metabolism.

Pharming Doses First Patient in Phase II Trial of Leniolisib for Common Variable Immunodeficiency with Immune Dysregulation. PharmaBiz, March 22, 2025. Accessed at www.pharmabiz.com/NewsDetails.aspx?aid=176933&sid=2.

RESEARCH

Study Shows Disparities Persist in Testing for IEIs

According to a study published in *The Journal of Allergy and Clinical Immunology: In Practice*, significant racial disparities persist in genetic testing for inborn errors of immunity (IEIs) despite the removal of financial barriers. Barriers outside of financial considerations may be at play in these disparities, said Karen M. Gilbert, PhD, senior research analyst in the department of population medicine at Harvard Pilgrim Health Care Institute, and colleagues.

The retrospective cohort analysis used data from 18,603 patients (61.4 percent female) in the Optum deidentified Clinformatics Datamart (CDM) national claims database, which includes commercial and Medicare Advantage health plans in the United States. The analysis also used data from the 6,681 patients (61.9 percent female) in the navigateAPDS program. Invitae also provided data for 29,579 patients (54.2 percent female) who were tested for IEIs without sponsorship. Additionally, the researchers used a cohort of 46,710 patients (47.5 percent female) who received genetic testing for arrhythmia and cardiomyopathy through the Unlock Cardiomyopathy and Arrhythmia Program as a comparator group.

Most of the patients in the CDM cohort lived in urban areas (n=16,708; 90.4 percent) and in predominantly white neighborhoods (n=14,284; 77.3 percent). Also, most (n=13,357; 71.8 percent) did not receive genetic testing during the study period. The navigateAPDS cohort of patients who received sponsored testing for IEIs included 5,644 patients (87.7 percent) living in urban areas and 5,042 (90.2 percent) self-identifying as white. The Invitae non-sponsored cohort included 23,120 (87.5 percent) patients living in urban areas and 17,800 (82.6 percent) self-identifying as white.

Median Area Deprivation Index scores in the Invitae cohorts included 46 for the cohort of patients with sponsored testing for IEIs and 42 for those who did not receive sponsored testing, indicating greater deprivation. Median ages of genetic testing included 33 years for the sponsored cohort and 14 years for the non-sponsored cohort.

Percentages of white patients included 90.2 percent (89.4 percent-91 percent) in the sponsored cohort and 82.6 percent (82.1 percent-83.1 percent) in the non-sponsored cohort, which the researchers called a significant difference. Percentages of Black patients included 4.3 percent (3.7 percent-4.8 percent) in the sponsored cohort and 8 percent (7.7 percent-8.4 percent) in the non-sponsored cohort. Overall, the researchers said, American Indian and Alaska Native, Asian, Black and Hispanic patients were underrepresented, and white patients were overrepresented in both cohorts relative to the racial and ethnic composition of the U.S. population. American Indian, Alaska Native and Black patients also were underrepresented and white patients also were overrepresented in both cohorts, the researchers said, when rates of IEIs documented as an underlying cause of death were compared between these cohorts and nationwide.

Although 21.3 percent of individuals with IEIs documented as a contributing cause of death were Black, the researchers further noted 4.3 percent of the sponsored cohort and 8 percent of the non-sponsored cohort were Black. By comparison, the researchers said 18.1 percent of the patients in the comparison cohort of patients with cardiomyopathy who were Black was representative of the 18.2 percent of patients who were Black among cardiovascular deaths in the United States.

The researchers concluded that these findings indicate persistent disparities in genetic testing for IEIs among historically marginalized racial and ethnic groups despite sponsored services. IG

Gawel, R. Disparities Persist in Testing for Inborn Errors of Immunity Despite Sponsored Program. Healio, Jan. 31, 2025. Accessed at www.healio.com/news/allergy-asthma/20250131/disparities-persist-in-testing-for-inborn-errors-of-immunity-despite-sponsored-program.

FDA-approved for adult and pediatric patients aged 2 years and older with primary immunodeficiency (PI)

cutaquig®
Immune Globulin Subcutaneous (Human)-hipp,16.5% solution

Count the reasons

to ask your care team about cutaquig

1 hour or less to **complete infusion***

2 or fewer **infusion sites**†‡

3 **flexible dosing** schedule options§

Not an actual patient.

*The estimated infusion duration for a 13 g (78 mL) weekly dose is approximately 45 minutes in an adult patient using 2 infusion sites, if tolerated, not including setup time.
†Depending on your dose and dosing schedule selected.
‡Most infusions only need 2 or fewer infusion sites.
§Every-other-week, weekly, or frequent dosing (2-7 times a week).

Scan to visit **CutaquigInfo.com** to learn more.

INDICATIONS AND USAGE

CUTAQUIG (Immune Globulin Subcutaneous [Human] - hipp) is a 16.5% immune globulin solution for subcutaneous infusion indicated for treatment of primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older.

There are many forms of PI. Certain types of PI are associated with low immunoglobulin G (IgG), which are proteins that help fight infection.

CUTAQUIG 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 that replace the missing antibodies in patients with PI.

CUTAQUIG is given under the skin (subcutaneous). Most of the time, infusions under the skin are given at home by self-infusion or by a caregiver. Only use CUTAQUIG by yourself after you have been instructed on use by a healthcare provider (HCP).

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

See full Prescribing Information for complete BOXED WARNING

- **Thrombosis may occur with immune globulin products, including CUTAQUIG. 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.**
- **For patients at risk of thrombosis, administer CUTAQUIG 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 of hyperviscosity.**

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

CUTAQUIG can cause the following serious reactions:

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

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

What should I know while taking CUTAQUIG?

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

CUTAQUIG can cause serious side effects. If any of the following problems occur after starting CUTAQUIG, contact your HCP or call emergency services. If any of the following problems occur during CUTAQUIG infusion, 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
- 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

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

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

The most common side effects of CUTAQUIG are:

- Infusion site reactions (including but not limited to redness, swelling, itching, fluid in tissue, pain, mass, bruising)
- Headache
- Elevated body temperature

One or more of the following possible side effects may occur at the site of infusion; these may go away within a few hours and are less likely after the first few infusions:

- Mild or moderate pain
- Redness
- Itching

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.

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.

CUTAQUIG® is a registered trademark of Octapharma AG.

Please see brief summary of Full Prescribing Information on following page and Full Prescribing Information, including complete BOXED WARNING and Patient Information and Instructions for Use, at CutaquigInfo.com.

Pfizer | octapharma | Manufactured by Octapharma Pharmazeutika Produktionsges m.b.H.
Distributed by Pfizer Labs, Division of Pfizer Inc.

PP-CQG-USA-0561

March 2023

cutaquig®
Immune Globulin Subcutaneous (Human)-hipp,16.5% solution

CONSUMER BRIEF SUMMARY

(CUTAQUIG: *cute-ah-quig*)

This brief summary highlights the most important information about CUTAQUIG. Please read it carefully before using CUTAQUIG and each time you get a refill, as there may be new information. This Patient Information 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.CutaquigInfo.com.

What is CUTAQUIG?

CUTAQUIG is a ready-to-use liquid solution of immunoglobulin G (IgG), also called antibodies, which protects the body against infection. CUTAQUIG is used to treat adult patients and pediatric patients 2 years of age and older with primary humoral immunodeficiency (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. Regular administration of CUTAQUIG has been demonstrated to help your body to fight bacteria and viruses that cause infections. CUTAQUIG is made from human plasma that is donated by healthy people. CUTAQUIG contains antibodies collected from these healthy people; these antibodies replace the missing antibodies in patients with PI.

WARNING: THROMBOSIS

See full Prescribing Information for complete BOXED WARNING

- **Thrombosis may occur with immune globulin products, including CUTAQUIG. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors.**
- **For patients at risk of thrombosis, administer CUTAQUIG 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 of hyperviscosity.**

Who should NOT use CUTAQUIG?

Do not use CUTAQUIG if you have ever had a severe allergic reaction to immune globulin or other blood products.

Tell your healthcare provider if you:

- Ever had any severe reaction to other immune globulin medicines
- Were told that you have a condition called IgA deficiency
- Have a history of heart or blood vessel disease
- Have had blood clots or thick blood
- Have been immobile for some time

CUTAQUIG can cause serious side effects. If any of the following problems occur after starting CUTAQUIG, contact your HCP or call emergency services. If any of the following problems occur during CUTAQUIG infusion, 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
- 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

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

What should I tell my healthcare provider before using CUTAQUIG?

Talk to your healthcare provider about any medical conditions that you have or have had.

Tell your healthcare provider:

- That you are taking CUTAQUIG before you get a vaccination, as vaccines may not work while you are taking CUTAQUIG.
- About all of the prescription and non-prescription medicines you take, including over-the-counter medicines, dietary supplements, or herbal medicines.
- If you are pregnant, plan to get pregnant, or if you are nursing because CUTAQUIG might not be right for you.
- If you have diabetes. If you need to do glucose testing, your healthcare provider may tell you to use a different way to monitor your blood sugar levels on the day that you receive a CUTAQUIG infusion. Some types of blood glucose testing systems (glucometers) can falsely interpret the maltose contained in CUTAQUIG as glucose. If you are uncertain, ask your healthcare provider which glucose testing system you can use while using CUTAQUIG.

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

- Infusion site reactions (including but not limited to redness, swelling, itching, fluid in tissue, pain, mass, bruising)
- Headache
- Elevated body temperature

One or more of the following possible side effects may occur at the site of infusion; these may go away within a few hours and are less likely after the first few infusions:

- Mild or moderate pain
- Redness
- Itching

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. If you encounter any problems or experience side effects during or after the infusion, contact your healthcare provider. When doing so, keep your treatment diary or logbook with you to be able to give all necessary information.

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.

This brief summary is based on the CUTAQUIG Prescribing Information (October 2021).

CUTAQUIG® is a registered trademark of Octapharma AG.

Pfizer | octapharma®

Manufactured by Octapharma Pharmazeutika Produktionsges m.b.H.
Distributed by Pfizer Labs, Division of Pfizer Inc.

MEDICINES

First Wave Stelara Biosimilar Now Available in U.S.

Korean biopharmaceutical company Celltrion has launched Steqeyma (ustekinumab-stba), a first-wave biosimilar to Stelara (ustekinumab), in the United States following its approval by the U.S. Food and Drug Administration in December 2024. Steqeyma is approved for the same indications as Stelara, including treatment of plaque psoriasis and psoriatic arthritis in adult and pediatric patients, as well as Crohn's disease and ulcerative colitis in adult patients. It is available in both subcutaneous injection and intravenous infusion. FDA approval of Steqeyma was based on the totality of evidence, including the results from a Phase III study, that demonstrated Steqeyma and its reference product are highly similar and have no clinically meaningful differences in terms of safety and efficacy.

"Chronic inflammatory diseases such as plaque psoriasis and psoriatic arthritis place significant burden on patients," said Mark G. Lebwohl, MD, of the Icahn School of Medicine at Mount Sinai, New York. "Biosimilars increase access to essential therapies, while maintaining the same high standards as the reference product. The availability of Steqeyma provides patients and healthcare providers a cost-effective alternative to manage chronic inflammatory diseases." IG

Steqeyma (ustekinumab-stba), a Biosimilar to Stelara (ustekinumab), Now Available in the United States. Celltrion press release, March 13, 2015. Accessed at www.celltrion.com/en-us/company/media-center/press-release/3811.

RESEARCH

Newly Described Protein Offers Promising Target for Treatment of Autoimmune Disease

Researchers at Washington University School of Medicine in St. Louis and the Perelman School of Medicine at the University of Pennsylvania have identified a protein in cells that spurs the release of infection-fighting molecules. The protein, whose role in the immune system had not previously been suspected, provides a potential target for therapies that could prevent overreactive immune responses that are at the root of many autoimmune diseases.

The team made the discovery by studying a rare autoimmune disease called STING-associated vasculopathy with onset in infancy (SAVI), a condition that leads to the immune response attacking tissues in the lungs and limbs of patients, often resulting in death before adulthood. SAVI is caused by changes to a protein in cells called STING, which usually responds to the presence of viral DNA by activating the component of the cell that generates immune proteins. These immune proteins are then released to tell the body's immune system what viral invaders to attack and where to attack them. However, in SAVI, STING is overactive, triggering constant immune activity that damages healthy tissue.

Using immune cells that were sensitive to the disease-causing mutations in STING, the team performed a screen to identify proteins that prevented this sensitivity. The protein ArfGAP2 stood out: It seemed to be strongly connected to the final step when the immune response proteins get released. The team determined that without ArfGAP2, STING could not drive the release of the immune proteins. "It's like a train station and ArfGAP2 is acting as the conductor, directing which molecules are to be shipped out," said researcher David Kast, PhD, an assistant professor in the Department of Cell Biology & Physiology at WashU Medicine. "If STING and ArfGAP2 are not working together, the trains are stopped." The team reasoned that stopping the never-ending "trains" in SAVI's constant immune response could be a means of treating the rare disease. They say it is a promising target for other conditions that similarly lead to excess immune proteins of the same type, perhaps including the "cytokine storms" characteristic of COVID-19 or the brain inflammation linked to immune responses in Alzheimer's disease. IG

Researchers Find Missing Link in Autoimmune Disorder. WASHU Medicine news release, March 18, 2025. Accessed at www.eurekalert.org/news-releases/1077401.

IgNS Immunoglobulin National Society

Advancing Ig Therapy Practice

COMING SOON!

A Patient's Guide to Ig Therapy

The first and only resource **FOR PATIENTS** based on the nationally recognized IgNS Standards of Practice for Clinicians.

- ☑ Ig therapy explained
- ☑ What to expect from your clinician before, during, and after your infusion
- ☑ Adverse reactions explained
- ☑ Strategies to reduce the risk of side effects
- ☑ Tips for effective communication with your healthcare team
- ☑ And much more

Visit us on the web
www.Ig-NS.org

Follow us on social media

IDF WALK FOR PRIMARY IMMUNODEFICIENCY

An initiative of the Immune Deficiency Foundation

Walks located in:

Boston
Milwaukee
Philadelphia
San Antonio
Seattle
St. Louis
Tampa
Coast to Coast

Learn more at **walkforpi.org**

Immune Deficiency Foundation FILMS

compromised.

[life without immunity]

Follow the heart-wrenching yet hopeful stories of those living with a primary immunodeficiency.

A must-watch documentary.

Learn more: idf.primaryimmune.org/watchfilm

ADVOCACY. EDUCATION. RESEARCH.
A COMMUNITY EMPOWERED

Whether you've been recently diagnosed, have been living with a primary immunodeficiency (PI) for years, or just think you might have a PI, the Immune Deficiency Foundation is here to help.

While PI has no cure, there are lifesaving treatments available that can improve your quality of life. Our programs are meant to connect, engage, and empower families to live longer, stronger, healthier lives.

SCAN ME

Immune Deficiency Foundation

primaryimmune.org | idf@primaryimmune.org

RESEARCH

Efgartigimod Monotherapy More Effective Than IVIG in Elderly Patients with Generalized Myasthenia Gravis

Efgartigimod, a neonatal Fc receptor (FcRn) inhibitor, induced greater reductions in myasthenia gravis activities of daily living scores at weeks four and eight compared with intravenous immune globulin (IVIG) in elderly patients with generalized myasthenia gravis (gMG), according to results published by investigators in *Clinical Immunology*.

MG is often treated with therapies such as plasma exchange and IVIG; however, both have been associated with adverse events despite their efficacy. Efgartigimod has emerged as an alternative, particularly for patients with contraindications or who may be at higher risk of severe complications with the intense therapies. Efgartigimod is the first FcRn inhibitor to be approved by the U.S. Food and Drug Administration and works similarly to IVIG by reducing immunoglobulin G levels.

In a single-center, prospective cohort study, elderly Chinese patients with AChR-Ab-positive gMG were enrolled from January 2024 to July 2024. Patients were randomly assigned to receive either efgartigimod or IVIG treatment, and the efficacy of each treatment was observed during hospitalization and post-discharge follow-up. Primary outcomes included the differences in improvements of total scores and sub scores across all muscle groups on the MG-ADL and the percentage of minimal symptom expression in each group at weeks four and eight.

These results suggest superior efficacy in elderly AChR-Ab-positive patients with gMG with efgartigimod compared with IVIG and a preference for efgartigimod in patients who have primary manifestations of limb and respiratory muscle weakness. Importantly, the risk of infection in patients receiving FcRn inhibitors such as efgartigimod appears to be limited based on available data, but vigilance among healthcare providers and pharmacists is still necessary. IG

Halpern, L. Efgartigimod Monotherapy More Effective Than IVIG in Older Patients With Generalized Myasthenia Gravis. Pharmacy Times, March 4, 2025. Accessed at www.pharmacytimes.com/view/efgartigimod-monotherapy-more-effective-than-ivig-in-elderly-patients-with-generalized-myasthenia-gravis.

RESEARCH

New Dried Blood Test Detects Autoimmune Pulmonary Alveolar Proteinosis (aPAP)

Savara, Inc., a clinical stage biopharmaceutical company focused on rare respiratory diseases, announced the launch of the aPAP ClearPath Dried Blood Spot (DBS) test in the U.S. Using a blood sample from a noninvasive finger prick instead of a traditional venous blood draw, the DBS test is a simple, no-cost test designed to help diagnose autoimmune pulmonary alveolar proteinosis (aPAP), a rare autoimmune lung disease caused by antibodies targeting GM-CSF.

Savara partnered with TrilliumBiO, a health solutions provider with a Clinical Laboratory Improvement Amendments-certified lab, to develop and validate the new testing method. "We are happy to introduce a version of aPAP ClearPath that can provide physicians with a tool to help confirm or rule out aPAP with just a few drops of blood," said Matt Pauls, chair and CEO of Savara.

"Having a simplified and reliable diagnostic reduces logistical barriers for both patients and healthcare providers and may help physicians diagnose aPAP earlier, as well as avoid common and lengthy misdiagnoses associated with the disease," said Ali Ataya, MD, associate professor of medicine at the University of Florida Division of Pulmonary and Critical Medicine. IG

Savara Announces U.S. Launch of the aPAP ClearPath Dried Blood Spot Test to Detect Autoimmune Pulmonary Alveolar Proteinosis (aPAP). BioSpace, March 6, 2025. Accessed at www.biospace.com/press-releases/savara-announces-u-s-launch-of-the-apap-clearpath-dried-blood-spot-test-to-detect-autoimmune-pulmonary-alveolar-proteinosis-apap.

RESEARCH

Lower Dose vs. Higher Dose of IVIG Remains Effective in Treating Pediatric ITP

Results of a recent study published in *Therapeutic Advances in Hematology* showed that an initial treatment of 1 g/kg intravenous immune globulin (IVIG) in patients with newly diagnosed pediatric immune thrombocytopenia (ITP) demonstrated comparable effectiveness to the double dose of 2 g/kg without negatively impacting the incidence of chronic disease.

ITP usually resolves itself spontaneously; however, 20 percent of patients will have a chronic course that lasts more than one year. IVIG is utilized as a first-line treatment in new-onset pediatric ITP to lower the risk of bleeding and subsequent severe complications, yet dosing for initial treatment currently varies at 0.4, 0.8 or 1 g/kg body weight per day for between one to five days.

Higher doses of IVIG pose problems: While they can quickly increase platelet counts and reduce the risk of chronic disease, IVIG is expensive, with a median cost of $6,275. In addition, increased platelet counts have been reported as a main risk factor of IVIG-related adverse events (AEs). Therefore, identifying the optimal IVIG dose for pediatric ITP that does not carry an excessive price tag or pose harmful side effects is essential.

In the study, the investigators retrospectively compared short- and long-term treatment response and adverse events of commonly used IVIG dosing regimens in pediatric patients with ITP. Data was collected from Schneider Children's Medical Center of Israel between January 2010 and December 2020. One group of patients received IVIG at 1 g/kg dosage, while the other received IVIG at a dose of 1 g/kg/day over two days, for a total of 2 g/kg.

A total of 446 pediatric patients with newly diagnosed ITP were identified; 168 (37.7 percent) received IVIG as their first-line therapy. Nearly half of the patients treated with IVIG (82, 48.8 percent) received a single dose of 1 g/kg (group 1), while 86 (51.2 percent) were given a total of 2 g/kg (group 2).

Compared to group 1, group 2 had a lower platelet count (mean $5.7 \pm 5.2 \times 109$/L vs. $8.6 \pm 7.7 \times 109$/L, respectively, $p = .005$) and presented a more severe phenotype with bleeding symptoms and bleeding from other sites. Importantly, there was no major difference in the duration of hemorrhagic symptoms or in the scale of bleeding between either group.

Investigators found the average time to reach a platelet count above 50×109/L following treatment was 2.2 ± 1 days in group 1, as compared with 2.9 ± 1.3 days in group 2 ($p = .0015$).

Response was sustained in both groups, with 74.3 percent of group 1 patients and 76.2 percent of group 2 patients ($p = .72$) reaching a sustained response. Interestingly, AEs were slightly more likely in group 2 when compared with group 1 (47.7 percent vs. 32.9 percent, $p = 0.06$). In addition, at the one-year follow-up, 77.8 percent of patients were in remission with no significant differences in remission rates between the two study groups.

These data indicate that a lower dose of IVIG remains effective in treating newly diagnosed pediatric ITP, both in the short-term and long-term. They also strongly suggest a lower dose of IVIG can lead to similar therapeutic benefits without the obstacles of high cost or potential side effects. However, the investigators say future prospective studies are warranted to confirm these findings.

Halpern, L. Lower Dose of IVIG Remains Effective in Treating Pediatric Immune Thrombocytopenia Compared with High Dose. Pharmacy Times, Oct. 3, 2024. Accessed at www.pharmacytimes.com/view/lower-dose-of-ivig-remains-effective-in-treating-pediatric-immune-thrombocytopenia-compared-with-higher-dose.

Important Safety Information

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.

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

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.

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

Get the protection of Ig without the IV

- **NO SERIOUS BACTERIAL INFECTIONS REQUIRING HOSPITALIZATION***
- **CONTINUOUS PROTECTION**
- **NO SERIOUS SIDE EFFECTS†**

IVIg may leave you feeling sick before and after infusions. But Hizentra gives you continuous Ig protection plus the ability to self-infuse where and when you choose after speaking to your doctor. With no serious bacterial infections,* you get more freedom and confidence in everyday moments. It's time to ask your doctor if Hizentra is right for you.

LIVE IN ***STRENGTH***
WITH HIZENTRA

Scan for more reasons to switch

*In a 12-month study, Hizentra delivered low rates of infection with no serious bacterial infections that could potentially require hospitalization, like bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, bacterial meningitis, and visceral abscess.

†In the 12-month study of people taking Hizentra to treat PI, there were no serious side effects related to treatment. Two subjects withdrew from the 12-month study due to nonserious side effects.

Ig, immunoglobulin; IVIg, intravenous immunoglobulin.

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.

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.

CSL Behring

Hizentra®
Immune Globulin Subcutaneous (Human) 20% Liquid

Important Safety Information (continued)

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 accompanying 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.

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.

CSL Behring

RESEARCH

New Treatment for Systemic Sclerosis Fast Tracked by FDA

A new restrospective study established glucocorticoids and intravenous immune globulin (IVIG) as the primary therapeutic agents for treating autoimmune encephalitis (AE). While methylprednisolone is the most frequently utilized glucocorticoid in the management of encephalitis, this study investigated the efficacy of dexamethasone (DEX) in combination with IVIG in the treatment of pediatric AE.

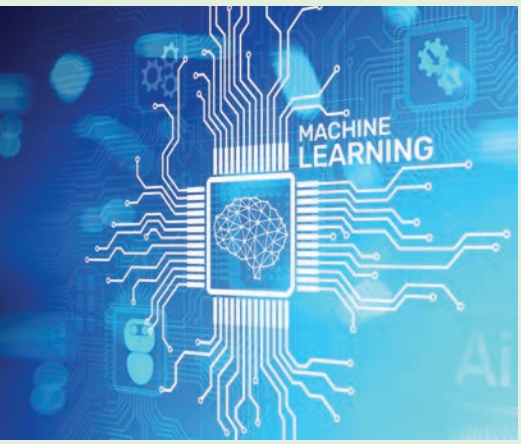
The study included 41 pediatric patients who were diagnosed with AE and were categorized into two groups on the basis of their treatment history. Group A (n=29) comprised children who initially received immunotherapy at other healthcare institutions but were referred to the study for DEX+IVIG combination treatment because of inadequate response to prior therapies. Group B (n=12) consisted of children who were administered DEX+IVIG treatment early in the acute phase of AE at the study's hospital. The therapeutic outcomes of DEX+IVIG treatment in children with nonacute AE (Group A) and acute AE (Group B) were evaluated. The modified Rankin scale (mRS) was used to assess the clinical status of all participants.

Ninety percent of the patients were severely ill prior to DEX and IVIG treatment (mRS = 3.8 ± 1.0). Following treatment, the clinical symptoms of children in both the nonacute stage (Group A) and the acute stage (Group B) significantly improved. At the final follow-up, 90.2 percent of patients (mRS=0-2) exhibited a favorable prognosis, with a complete response rate (mRS=0) of 43.9 percent and a relapse rate of 2.4 percent. Children who experienced relapse were treated with DEX+IVIG, leading to a positive outcome. No severe adverse events were observed during treatment. The results of this study indicated that DEX+IVIG is an effective treatment for children with acute, nonacute and relapsing AE. IG

Zhou, X, Luo, X, He, Z, et al. Efficacy of Dexamethasone Combined with Intravenous Immunoglobulin for the Treatment of Pediatric Autoimmune Encephalitis. *Frontiers in Neurology*, Feb. 27, 2025. Accessed at www.frontiersin.org/journals/neurology/articles/10.3389/fneur.2025.1512908/abstract.

RESEARCH

A New Machine Learning-Based Test Could Diagnose Autoimmune Diseases Faster



Researchers at Stanford Medicine have created a machine-learning method for screening for multiple diseases simultaneously. The method — called Mal-ID for machine learning for immunological diagnosis — can be optimized to detect complex, difficult-to-diagnose autoimmune diseases such as lupus.

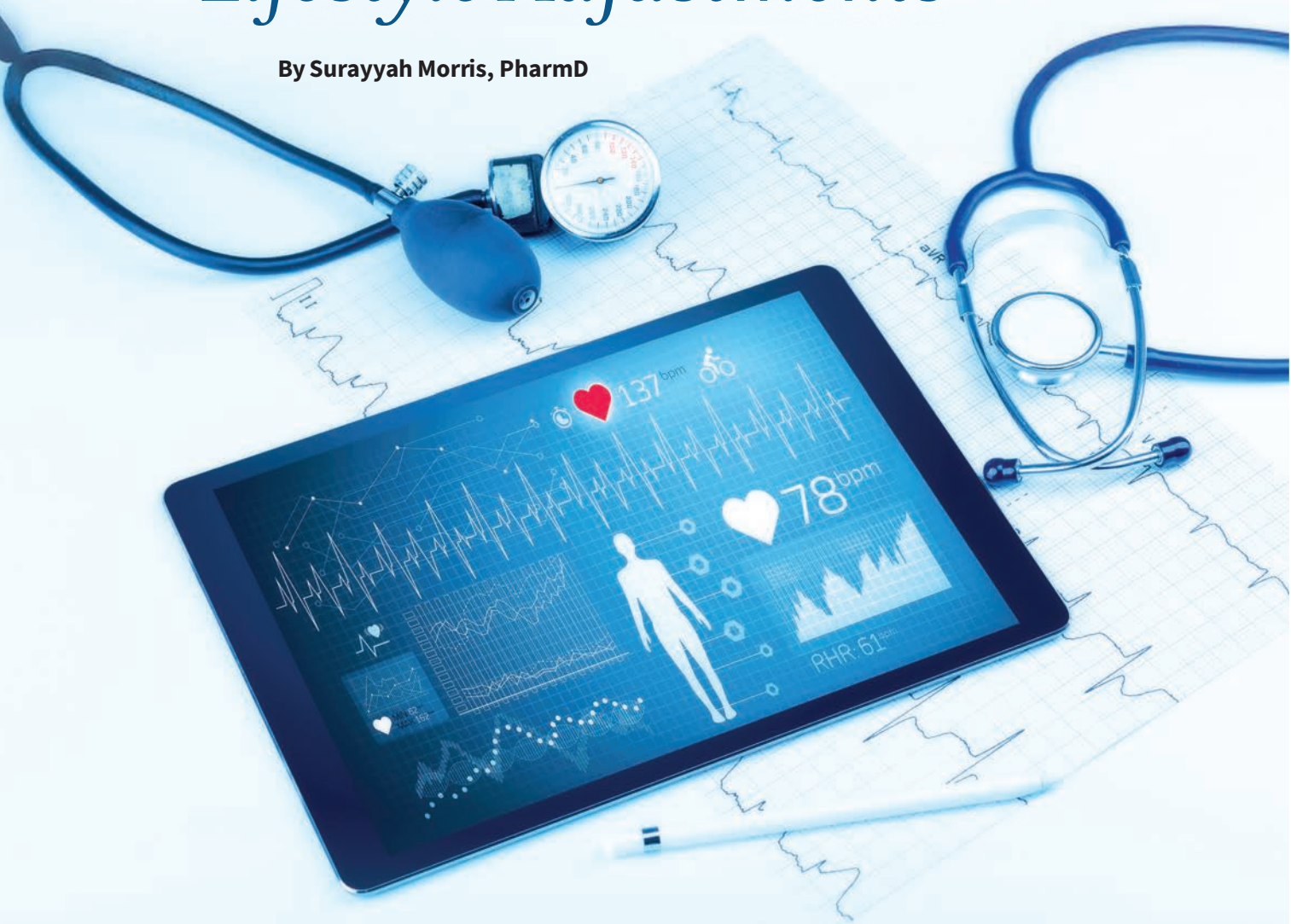
In a study comprised of a mixture of nearly 600 people — some who were healthy and others with infections, including COVID-19 or autoimmune diseases — Mal-ID successfully identified what diseases each person had based only on their B and T cell receptor sequence and structures. Researchers believe Mal-ID could also track responses to cancer immunotherapies and subcategorize disease states in ways that could help guide clinical decision making. And, Mal-ID may also help researchers identify new therapeutic targets for many conditions.

Although the researchers developed Mal-ID on just six immunological states, they believe it could be adapted to identify immunological signatures of additional diseases and conditions such as lupus, which can be difficult to diagnose and treat. "Patients can struggle for years before they get a diagnosis, and even then, the names we give these diseases are like umbrella terms that overlook the biological diversity behind complex diseases," said Maxim Zaslavsky, PhD, one of the lead authors of the study. "If we can use Mal-ID to unravel the heterogeneity behind lupus, or rheumatoid arthritis, that would be very clinically impactful." IG

Tang, B, and Wosen, J. A Newly Developed Machine Learning-Based Test Could Diagnose Autoimmune Diseases Faster. STAT, Feb. 20, 2025. Accessed at www.statnews.com/2025/02/20/machine-learning-immune-cells-test-diagnose-auto-immune-diseases.

Staying Up to Date with Health Screenings and Lifestyle Adjustments

By Surayyah Morris, PharmD



Taking charge of your health with regular health screenings and lifestyle adjustments is an investment in your future.

IN TODAY'S fast-paced world, with a future likely orchestrated by artificial intelligence (AI), it is easy to overlook the importance of maintaining a healthy lifestyle and staying up to date with necessary health screenings. In fact, many elements of technology are making their way into healthcare, which can relieve some stresses, but also create equal or more deficiencies in care. There are just some elements of healthcare that (logically) are not efficient to evaluate through a screen or over the phone. Neither here nor there, the role of health screenings and lifestyle adjustments remains essential in disease prevention, early detection and overall well-being. By staying informed about your health and taking the right steps to improve it, you can significantly increase your quality of life, prevent chronic

diseases and extend your life expectancy. Let's discuss the significance of staying up to date with health screenings, the role of lifestyle adjustments in health and how these elements can work together for a healthier future.

The Importance of Health Screenings

Health screenings are vital tools for early detection of health conditions that may not present noticeable symptoms. Many conditions, including heart disease, diabetes, various cancers and, on the rare occasion, a chronic illness, might develop silently, without any obvious signs of trouble. It is vitally import to listen to your body and recognize significant abnormalities, no matter how small or insignificant they may seem at the time. Early detection through health screenings allows for timely interventions that can often improve the prognosis of disease and effectiveness of treatment. Additionally, some conditions are preventable or manageable if caught early, which highlights the importance of regular check-ups and screenings.

Early detection through health screenings allows for timely interventions that can often improve the prognosis and effectiveness of treatment.

Types of Health Screenings

The types of health screenings you may need depend on factors such as age, gender, family history, lifestyle and environment. Some common health screenings include:

- Blood pressure screening: High blood pressure (hypertension) is a major risk factor for heart disease, stroke and kidney problems. Regular blood pressure checks help detect hypertension early, so lifestyle changes or medication can be initiated before damage occurs to the heart and arteries.
- Cholesterol screening: Elevated cholesterol levels contribute to the development of plaque in the arteries, which can increase the risk of heart disease. Screening for cholesterol levels helps determine whether diet or medication needs to be adjusted to maintain healthy cholesterol levels.
- Diabetes screening: Type 2 diabetes is a growing health concern, and many people are unaware they have it until complications arise. Regular screening for high blood sugar levels can help catch diabetes early and allow for lifestyle modifications that can prevent or manage the condition before it progresses and begins to significantly affect quality of life, physically and mentally.
- Cancer screenings: Cancer screenings, such as mammograms for breast cancer, pap smears for cervical cancer, colonoscopies for colorectal cancer and prostate exams for prostate cancer, are essential for early detection. Catching cancer at an early stage can make it much easier to treat and can significantly improve survival rates.
- Bone density screening: Osteoporosis is a condition characterized by weakened bones that are more prone to fractures than normal. Bone density screening helps identify people at risk for osteoporosis, which allows for preventive measures to be taken before fractures occur.
- Eye and hearing exams: Regular eye and hearing tests help catch developing problems such as glaucoma, cataracts and hearing loss. Early detection can prevent these conditions from worsening.
- Skin cancer screening: Skin cancer is an especially common cancer, but highly treatable if detected early. Regular skin checks for new or changing moles can help detect skin cancer in its early stages, improving the chances of successful treatment.

The Role of Regular Health Screenings in Prevention

The primary benefit of keeping up with health screenings is to prevent disease and encourage healthy habits. Chronic diseases have risk factors that are used to evaluate, mitigate and/or manage because of early detection. By identifying risk factors specifically for the concerns relating to relevant signs and symptoms, health professionals will recommend lifestyle changes or treatments that assist in preventing illness from developing or worsening.

For instance, if your cholesterol level is elevated, health professionals can modify your diet and increase your physical activity to bring those levels back within a healthy range. These are called therapeutic lifestyle changes. These small but significant changes are essential in creating healthy habits and avoiding disease. If your blood sugar levels indicate prediabetes or insulin resistance, you may be

advised to adopt a diet that incorporates more whole foods, minimizes consumption of sugars and carbohydrates, and exercise regularly to prevent the onset of type 2 diabetes. These therapeutic lifestyle changes can be adopted without waiting for signs and symptoms to appear or worsen. You'll lose nothing by making healthy changes to your routine, improving and maintaining a satisfactory life.

While health screenings are critical for detecting and managing diseases, lifestyle choices also play a fundamental role in maintaining good health.

Additionally, screening guidelines are recommended for certain conditions that are typically more treatable when detected early. Once you reach a certain age or satisfy a criteria of risk factors, your providers should inform you and discuss any tests they can initiate to make sure you remain healthy. A regular screening for colorectal cancer, for example, may reveal precancerous polyps, which can be removed before they have a chance to develop into cancer. Early-stage cancers tend to have higher survival rates, emphasizing the importance of regular screenings. This applies to many conditions.

Lifestyle Adjustments and Their Impact on Health

While health screenings are critical for detecting and managing diseases, lifestyle choices also play a fundamental role in maintaining good health. The aforementioned therapeutic lifestyle changes are where this becomes important. Making the most safe and appropriate adjustments to your routine will help you manage any conditions you may already battle, can help prevent further chronic conditions from developing and can improve overall well-being when adopted and practiced regularly. It is widely recognized that lifestyle factors such as sleep, exercise, stress management, diet and avoidance of tobacco and excessive alcohol are crucial for maintaining optimal health.

Diet and Nutrition

You've probably heard 100 times over how your diet should be "healthy" and "nutritious," but what does that really mean? No, it doesn't mean you have to skip meals, take diet pills, rely on supplements or eliminate foods you enjoy. It means fill up on fresh foods and lay off junk food. Once you make the initial dietary adjustments, maintenance and moderation are essential. When those 20 pounds fall off and your blood pressure levels normalize, you can at that point work on maintaining the great improvements you've made, avoiding regression into old unhealthy habits.

Maintaining a balanced, nutrient-dense diet helps keep you at a healthy weight, reduces the risk of chronic diseases and provides the body with essential vitamins and minerals needed to function properly. Your diet should be rich in vegetables, whole grains, lean proteins, fruits and healthy fats to support and help regulate those essential laboratory levels. Additionally, it will be difficult for your body to be afflicted with unwanted issues when it's at its healthiest. As you age, risk factors become more significant, so start implementing positive changes early if you're able. Access to care and resources are sometimes a barrier; however, there are resources widely available for a variety of populations.

Consuming processed foods, genetically modified foods, sugary drinks and excessive amounts of red meat can contribute to the risk of developing chronic illness. Minimizing the consumption of these items is the first suggestion to incorporate these changes. Diets high in sodium and unhealthy fats may contribute to high blood pressure and cardiovascular disease. A diet high in refined sugars can increase your risk of developing type 2 diabetes. By making nutritious food choices and focusing on whole, nutrient-dense foods, you'll significantly improve the status of your health and well-being. Don't forget to drink your water too! Half of your body weight in ounces per day is a great starting point. Make adjustments based on personal circumstances, and don't forget to celebrate additional benefits such as increased energy, more efficient digestion and clearer skin.

Exercise and Physical Activity

Regular physical activity is another foundation of building and maintaining a healthy lifestyle. Exercise helps strengthen

muscles and bones, regulate weight, improve heart health, build physical endurance and especially improve mental health. The Centers for Disease Control and Prevention recommends at least 150 minutes of moderate-intensity aerobic activity per week, along with muscle strengthening on two or more days each week. If that number seems intimidating, break it down into manageable 30-minute sessions over the course of five days. For example, a brisk walk 30 minutes a day for five days with two days of rest. Or join a 45-minute group class three times a week. You could break it down further with a 30-minute exercise routine split into two sessions, or three sessions of 10-minute exercises. The benefit of making any of these changes is flexibility to accommodate your needs.

Furthermore, physical activity releases endorphins, which can improve mood and reduce the risk of depression and anxiety that are often side effects of developing chronic conditions.

Sleep and Rest

Sleep is another critical factor in maintaining good health. Rest (not completely sleeping but not physically active, or sleeping with your eyes open) is essential as well. Poor sleep has been linked to a variety of health concerns, including obesity, heart disease, diabetes and weakened immune function. Noticing the theme here?

The actual number of hours necessary for adequate sleep is debatable, depending on many personal factors and states of health. Generally, you should aim for seven to nine hours of sleep each night to allow your body to rest, recover and repair itself. If your sleep quality is sufficient, you will benefit from allowing yourself the courtesy of great rest and recovery.

Inadequate sleep can impair cognitive function, making it more difficult to focus, retain information and make sound decisions. Prioritizing sleep hygiene, such as keeping a consistent sleep schedule, avoiding screens before bedtime and creating a calm, dark sleep environment, can improve sleep quality.

Stress Management

Chronic stress has detrimental effects on both physical and mental health. Prolonged stress is associated with increased inflammation and a weakened immune system. These contribute to health problems, including heart disease, digestive issues and mental health disorders such as anxiety and depression. The overall outcome of stress on the body is one that may be just as disadvantageous to your well-being as poor food habits and minimal physical activity.

Adopting stress-management techniques, such as meditation, mindfulness, yoga, deep breathing exercises and engaging in hobbies, can help reduce stress levels and improve well-being. Finding healthy ways to manage stress is essential for maintaining long-term health.

Avoiding Harmful Habits

Finally, refraining from harmful habits such as smoking and consuming excessive amounts of alcohol is crucial for maintaining good health. Smoking is one of the most noteworthy leading causes of preventable diseases, including lung cancer, respiratory disorders and heart disease. Quitting smoking is one of the best things you can do for your health.

Excessive alcohol consumption is linked to liver disease, cancer and mental health issues, among a slew of other likely unfavorable outcomes. Limiting alcohol intake to mild to moderate levels, as recommended by health professionals, can reduce the risk of these conditions and a variety of other potentially damaging events.

Essential Components of a Healthy Lifestyle

Staying up to date with health screenings and making necessary lifestyle adjustments are essential components of achieving and maintaining an optimal state of health while actively preventing chronic conditions from surfacing. With regular annual health screenings, early detection of health conditions allows for timely interventions with more positive outcomes. At the same time, making lifestyle changes, such as adopting a healthy diet, exercising regularly, managing stress and getting enough sleep, can significantly improve overall well-being and prevent the onset of diseases.

Taking charge of your health through screenings and lifestyle adjustments is an investment in your future. By staying proactive about your health, you can live a longer, healthier life and reduce the risk of chronic conditions. The key is to make health a priority and incorporate both screenings and lifestyle changes into your routine.

The all-encompassing approach to a disease-free, managed-disease or overall healthy state of being should be the goal. IG

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Cutaneous Cues: What Your Skin May Be Trying to Tell You

Your skin is the largest organ in your body, and it has a lot to say about your health. Therefore, it is important to pay close attention to it, especially if you have a primary immune deficiency.

By Rachel Maier, MS

YOUR SKIN communicates nonverbal messages all the time. A glowing tan reveals you spent time in the sun; goosebumps say you're cold, frightened or excited; stretch marks indicate a recent pregnancy or weight loss. Your skin also gives you clues that distress or disease is happening somewhere else in your body. For example, dry skin can indicate dehydration or diabetes; flushed skin can signal you are overheated or have taken too much of a certain medication; and mottled skin can indicate poor circulation or melasma.

When something about your skin changes, pay attention. Your skin may be saying something simple, but it could be telling you something much more important.

Skin Changes vs. Skin Diseases

Skin changes all the time. Some changes are normal, natural and do not pose a danger to your health (although sometimes, they may feel uncomfortable). For example, acne usually breaks out during adolescence; freckles may appear after spending extended amounts of time outside; and aging skin usually develops fine lines and wrinkles. These messages signal changes are happening in your body, but they usually are not a cause for concern.

However, some changes in your skin are not normal. Things like hives; atopic dermatitis (eczema); new growths or moles; redness, swelling or pain; changes in color or texture; or pus-filled blisters may indicate an underlying condition that needs medical attention. If your skin develops patches of discolored skin; open sores, lesions or ulcers; itchy, painful rashes; red, white or pus-filled bumps; unusually scaly or rough skin; or moles that change shape, color or size, make an appointment with your doctor.[1]

Your doctor may order one or more lab tests, including blood tests, biopsies and skin cultures to help identify the cause. Blood tests look for autoantibodies, bacteria or viruses;[2] biopsies use a needle, punch or cutting sheath to remove a small piece of skin that is analyzed for skin disorders, infections or cancers;[3] and skin cultures use a swab, needle or syringe to collect a sample of skin to look for germs that may be causing an infection.[4]

Noninfectious Skin Conditions

Noninfectious skin conditions are common and usually harmless. They often can be tolerated with comfort care at home, but some may require medical intervention. However, many noninfectious skin conditions can point to an underlying issue, so it is a good idea to talk to your medical provider about them. Here is a snapshot of the most common noninfectious skin conditions:

• *Eczema.* This chronic condition causes inflammation, redness and irritation of the skin. Also called atopic dermatitis, symptoms include red, dry patches of skin; rashes that ooze, weep or bleed when scratched; or thickening and hardening of the skin. During childhood, a red, thickened rash that may ooze or bleed is most common on the elbows, knees, neck and ankles. In teens and adults, the most common symptom is a red to dark brown scaly rash, which may bleed or crust when scratched, that appears on the hands, neck, elbows and knees, skin around the eyes and ankles and feet. Eczema is not contagious; an interplay of genes, the immune system and the environment produce this often painful condition. Those with asthma, allergies or hay fever are prone to eczema. Bacterial skin infections can develop in those with eczema, usually from scratching and infecting an irritated area.[5]

• *Psoriasis.* Psoriasis is a chronic, often painful skin disease characterized by rashes that appear as dandruff-like plaques or scaly patches on the skin, usually on the knees, elbows, trunk and scalp. It is an autoimmune disease without a known cure, and people who have it are at risk for developing skin infections.[6]

• *Granulomas.* Granulomas are small clusters of immune cells that form when the immune system protects itself from something harmful or foreign such as bacteria, a fungus, a virus or even splinters or sutures. Granulomas are more common in people with chronic infections or inflammation, but anyone can get them. These masses are not usually dangerous on their own, but instead may point to a chronic condition such as chronic granulomatous disease (CGD), sarcoidosis or an infection. Granulomas can form anywhere on the body, but they usually appear on the skin as raised, red ring-shaped lesions.[7]

• *Telangiectasias*. This is a big word for a simple condition: broken capillaries. Commonly called "spider veins," telangiectasias are damaged capillaries that are visible just beneath the skin. They appear as red or purple web-like clusters that resemble tree branches or spider webs. They can form anywhere, but they typically develop in the legs or face. Telangiectasias are common in autoimmune conditions such as scleroderma, dermatomyositis and lupus, and links between telangiectasias and primary immune deficiencies have been found.[8,9]

• *Hives.* Also called uticaria, hives are raised, red or skin-colored itchy bumps that can appear after exposure to allergens (food, medicine, latex, pet dander, pollen), insect stings or bites, infections or even physical stimuli (pressure, cold/heat, exercise, sun exposure). Hives can appear anywhere and often change shape, move around and disappear and reappear over short periods of time. They can be either acute (short-lived) or chronic (long-term). Antihistamines usually resolve the symptoms of hives by blocking the effect of histamine (the chemical released by the immune system in response to a foreign protein). Hives are not dangerous on their own, but when they are accompanied by swelling of the throat or other symptoms of anaphylaxis, immediate emergency care is required.[10]

Many noninfectious skin conditions can point to an underlying issue, so it is a good idea to talk to your medical provider about them.

• *Vasculitis.* Vasculitis is an autoimmune disease that causes inflammation in blood vessels, which means blood vessels swell and thicken and can be seen beneath the skin. It's an internal problem that sometimes manifests with rashes or bumps on the skin.[11] Swelling makes it difficult for blood to flow through the blood vessels, which can damage organs or other tissues.

Skin Infections

Infections happen when pathogens get into the body and start multiplying. When your skin is scratchy and itchy, it can break and let germs enter your body. Some skin infections are topical, but others go deep into the skin. The most common pathogens to cause skin infections include:[12]

• Bacteria: cellulitis, impetigo, boils, staphylococcal infections
• Viruses: shingles (herpes zoster); chicken pox; molluscum contagiosum; warts; measles; hand, foot and mouth disease; herpes simplex
• Fungi: athlete's foot, yeast infection, ringworm, nail fungus, oral thrush, diaper rash
• Parasites: lice, bedbugs, scabies, cutaneous larva migrans

Symptoms of skin infections vary depending on the type and cause of the infection, and whether you have a weakened immune system. However, common symptoms include redness on pale skin or purple/darkened areas on dark skin; lesions that are flat or raised, bumpy or wart-like; itching; and pain and tenderness and skin that is warm to the touch. Symptoms of severe infection include pus, blisters, skin sloughing/breakdown, dark areas that can indicate necrosis (tissue death), pain and discoloration or widespread swelling. People who are older, have poor circulation, have diabetes, are malnourished, have excessive skin folds, must stay in one position for a long time (such as those who are paralyzed), have an immune system disease or are immunocompromised have an increased risk of skin infections. If you have a PI, you are at heightened risk for skin infections.[12]

Special Considerations for People with PI

The skin has a lot to say about everyone's health, but if you have a PI, you should pay particularly close attention to what your skin says. PI weakens your immune system, which makes it harder to fight off pathogens, and immune dysfunction can sometimes cause your body to mistakenly attack its own healthy cells (as in autoimmune skin diseases). As a result, you may tend to suffer from a wide variety of skin conditions. Allergic disorders, skin infections, autoimmune conditions, autoinflammation and cancer are often seen in PI.

According to Edward Cowen, MD, senior clinician head at the National Institutes of Health Dermatology Consultation Service, visible skin problems can be important for diagnosing and managing health issues in PI patients. In fact, skin manifestations are often one of the first signs that point to a PI diagnosis.[13] According to the International Patient Organisation for Primary Immunodeficiencies, "Up to 70 percent of people with a [PI] exhibit skin manifestations (such as bacterial, fungal [e.g., candidiasis], viral infections [e.g., molluscum and warts] or eczema), and these signs may be among the primary presenting symptomatology of a [PI]."[14]

If you have a PI, you should monitor your skin every day, prioritize sun protection and see a dermatologist at least once a year. Of primary concern: skin cancer. "One in three people of European descent will develop basal cell carcinoma, and the rate is higher in those with PI." People with PI are also more susceptible to squamous cell carcinoma (an aggressive form of skin cancer).[15]

Annual visits with a dermatologist can help identify skin cancer, as well as the following additional common skin conditions in PI:

• *Dermatitis (skin inflammation)*. Dermatitis is one of the most common noninfectious skin manifestations in PI. Notably, PI patients who have eczema tend to develop food allergies, asthma and rhinoconjunctivitis (hay fever).[13] Dermatitis is itchy; scratching itchy skin can break the skin, which can lead to infections on the skin or in the bloodstream.

• *Autoimmune skin conditions.* Psoriasis, lupus, scleroderma, dermatomyositis, Behcet's disease, pemphigus and pemphigoid are common in PI patients because immune system dysfunction sometimes causes the body to attack healthy skin cells.[16]

• *Bacterial infections*. Staphylococcus aureus-induced skin infections are the most common skin infections reported in people with PI, especially in those with leukocyte adhesion defects (LAD), chronic granulomatous disease (CGD), severe congenital neutropenia and hyper-IgE syndrome (HIES).[12] Some bacterial infections are pyogenic, or pus-producing. (Pus is a sign of an immune response to an infection.) PIs such as CGD, LAD and HIES may present with pyogenic infections; infections may manifest as folliculitis (inflammation of follicles), abscesses (a localized collection of pus surrounded by inflamed tissue), furuncles (boils) or impetigo (red sores around the face that ooze and develop honey-colored crusts).[13]

• *Erythroderma*. This is a condition with severe skin irritation causing redness of the skin and/or scaling involving more than 90 percent of the total body surface. Almost half of erythroderma in infancy is due to PI.[17]

• *Alopecia*. Alopecia (hair loss) is the third most common skin condition in patients with PI.[17]

• *Fungal infections*. Fungal infections in PI patients are linked with combined T- and B-cell immunodeficiencies such as severe combined immunodeficiency (SCID). In babies, SCID may present with persistent yeast infections in the mouth (thrush) and/or on a baby's bottom.[17]

• *Viral infections*. Herpes zoster, herpes simplex and human papillomavirus are typical in neutropenia and hypogammaglobulinemia due to deficiency or defects in CD4+ T cells and NK cells. Warts may indicate combined immune deficiency or WHIM syndrome.[17]

Listen to Your Skin

Some skin conditions are short-lived, minor irritations; others are chronic, extensive skin diseases that need medical attention and ongoing management. Some are noninfectious and only require comfort measures, while others are infectious and require treatment (antibiotics, antivirals, antifungals or antiparasitics) or even hospitalization. One of the best things you can do to take care of your skin is to pay attention to what it is trying to tell you, especially if you have a PI, and talk to your doctor when you notice something new. Equally important: Prioritize sun protection. The best way to guard against skin cancer is to take precautionary measures to prevent it. See our product guide for sun protection recommendations (p.70). IG

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Nurturing in Nature

No matter where you live, your five senses can help you harness the emotional and physical benefits of nature.

By Amy Scanlin, MS

IF TIME SPENT in nature seems nurturing, it should. The outside world reconnects us with our internal selves, reducing anxiety and rates of depression, increasing positive feelings and providing health benefits that improve both quality and quantity of lifespan. Nature, in so many ways, not only feels good, it is good, acting as a powerful, no-cost medicine, one that is accessible to all. "Within the natural world, we feel connected in a way we cannot describe," says human performance coach and author Harvey J. Martin in his book, *Without Words, Mastering the Art of Being*. "Nature wraps its arms around us to keep us safe."

But, how? How can something as simple as being in green space be healthy? And, how may we better harness its healing benefits?

Nature's Protective Benefits

Nature's potential to positively affect emotional and physical well-being is well-documented. And those positive benefits can be enjoyed in just a few minutes of exposure. Reduced stress, improved sleep, reduced blood pressure and improved mindfulness are just some of the many benefits of time spent outdoors. Because it is so effective, nature is sometimes referred to as "vitamin N."

Time spent in nature is also being studied for its potential impact on the immune system by reducing inflammation and improving markers like TNF alfa, interleukin 6 and natural killer cells, says David Perlmutter, MD, in his book *Brain Wash*.[1]

While the mechanisms by which time spent outdoors leads to better health isn't fully understood, it is near universally agreed that nature offers healing and restorative powers. One reason for this may be that those who spend more time outdoors tend to be more active. Parks are often crisscrossed by trail systems, and swing sets beckon one to relive childhood enjoyment. Activity helps to promote a host of benefits, similar to those enjoyed while spending time outdoors. But, when combining activity and nature, one receives a power boost of health benefits.

Instead of asking which activities can be performed outside, Dr. Perlmutter says people should ask which activities *can't* be done outside. Activity doesn't have to be limited to walking or biking. It can include reading, doing homework or preparing dinner on a grill. It's all about getting creative, getting outside and thinking outside the box.

Another theory for nature's powerful healing is its ability to regulate circadian rhythms. Daylight is beneficial, particularly at dawn and dusk when the light absorbed resets the internal clock. At dawn, the rising sun signals the day is beginning, and at dusk, the waning sun cues it is time to wind down. Conversely, artificial light in the evenings has the opposite effect, causing circadian confusion and making falling asleep and sustaining quality sleep a challenge.

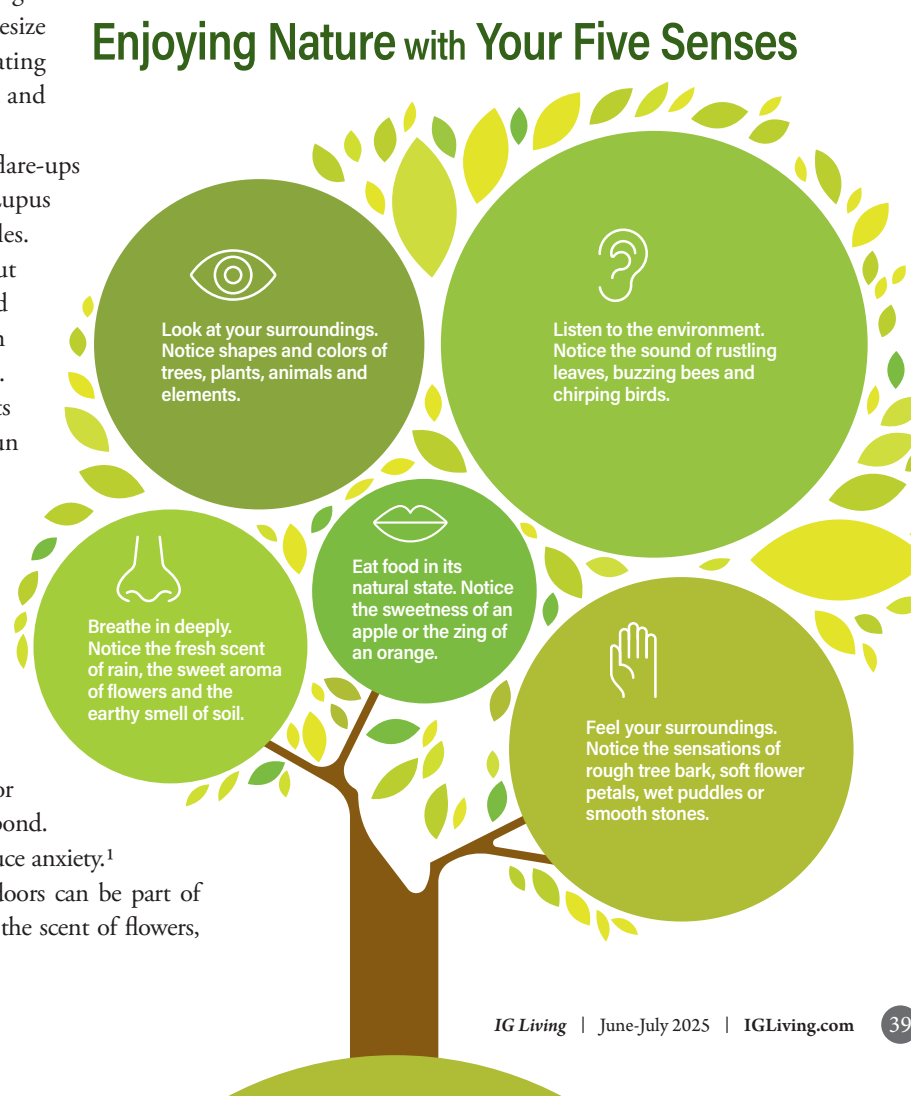
Carefully managed sunlight exposure may also provide protective health benefits. For instance, scientists are studying why those who live at higher latitudes with less year-round sunlight tend to have a higher incidence of multiple sclerosis. Sunlight exposure also helps the body to synthesize vitamin D, which is critical for regulating positive emotion and boosting serotonin and calcium for protective bone health.

But, sunlight exposure can also trigger flare-ups for some with autoimmune diseases. Lupus and rheumatoid arthritis are two examples. Additionally, enjoying the sun without adequate protection poses a very real and dangerous risk of skin damage and skin cancer, as well as damage to the eyes. Healthcare specialists can help patients find the best individualized balance of sun exposure and levels of protections.

The Five Senses

Enjoying nature with all five senses is a great way to reap its many benefits. Look around and see the trees, flowers, birds and streams. Take it all in; take photos and commit it to memory. Then listen — to the birds, the wind rustling through the trees, the babbling brook or spouting water fountain in the nearby pond. Listening to the sounds of nature can reduce anxiety.[1] Even children laughing as they play outdoors can be part of the experience. Next, inhale the fresh air, the scent of flowers, fresh cut grass or loamy moss. Nature provides a respite from environmental toxins ever present in modern life when so much time is spent indoors. Citrus, cypress and cedar scents in particular are beneficial, according to Dr. Perlmutter.

In today's busy world, experiencing the sense of touch while in nature may be less intuitive, but "grounding," or placing one's bare feet to the earth is, for many, an important connection. A small-scale study that looked at whether transmissions of very low level electrical connectivity might function similarly to immune system defenses determined that skin to earth contact is empirically beneficial.[2] The theory is that by shifting from the sympathetic to parasympathetic nervous system, grounding may have potential to reduce inflammation, improve immune response and have a positive effect on chronic and autoimmune diseases. "The complexity that lives inside of us needs the diversity that nature supplies," says Martin. "Green spaces release vibrations that impact our



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 red 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 is found in your body naturally. It's the first part of your two-part infusion. It temporarily opens the space under your skin (the subcutaneous space), allowing a larger amount of IgG to reach your subcutaneous tissue and be absorbed into your bloodstream.

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, fatigue, nausea, fever, and 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 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).

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minds and bodies." Though not scientifically proven in large-scale studies, just removing one's shoes and stepping outside can be an interesting opportunity for self-study. Just remember to find a safe place in a transparent, grassy area or even a sandy beach.

Nature is also applicable to the fifth sense, taste. Adding whole foods to one's diet, particularly vegetables, fruits and grains, provides a cascade of positive health benefits thanks to bountiful micronutrients contained therein. Improved gut health, reduced hormone fluctuations, better weight management and more are important tangential benefits of tasting and enjoying foods produced by mother nature.

Enjoying nature with all five senses is a great way to reap its many benefits.

Finding Nature

The average American spends 93 percent of his or her time indoors or inside a vehicle.[3] That's not a good sign for the state of the nation's health. But, nature isn't hard to find or enjoy. In fact, it can be experienced anywhere, even in the most urban environments where access would appear to be limited. Hospital inpatients recovering from surgery heal faster when they can see nature through their window rather than a brick wall.[4] Those same benefits hold true for everyone.

Of course, many may think that nature can be enjoyed only when in sprawling parks or looking at towering trees. But, nature can be equally enjoyed in one's own back yard, in pocket city parks and container gardens. In fact, adding greenery inside one's own home can also provide benefits. Studies show that patients with plants in their hospital rooms have lower heart rates, need less pain medication and are able to leave the hospital earlier, says Dr. Perlmutter. The same holds true for viewing photos of plants.[5]

The benefits of nature are compounded when one cultivates the plants themselves. Known as horticulture therapy,[6] working with plants, both outdoors and indoors, reduces anxiety and depression and improves well-being. The reason for this may be the satisfaction of working with one's hands, the joy in helping a living thing or any combination of these and other benefits.

Mindfulness

Mindful enjoyment of green space, also known as attention restoration therapy,[7] allows one to better reap its benefits. Mindfulness means putting down the phone and unplugging from the podcast and returning focus to the five senses of sight, sound, smell, touch and taste. Though nature's benefits can be gleaned just from simple exposure, health returns are far greater when one is fully present. By being mindful of the natural world all around, attention is refocused, the mind begins to settle and positive emotions follow.

In fact, EEG (a medical test that measures the electrical activity of the brain) patterns of those exposed to nature show a correlation with greater relaxation. And patients receiving cognitive behavioral therapy show far lower rates of depression when their sessions are conducted outside versus in a hospital or office setting.[8]

Nature offers powerful mechanisms of healing and nurturing the mind and body. Its positive effects are available to everyone, regardless of where one lives, one's economic level or one's ready access to green space. Just stepping outside, bringing home a potted plant or even looking at photos of nature's amazing bounty are all therapeutic places to start.

And, returning to mindfulness during one's time in nature will only offer added benefits. Nature is ever present, and when one takes it all in, it gives back in spades. IG

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Plant Forward:
How to Add More Plant-Based Foods to Your Diet

A myriad of options exist for easily transitioning to more plant-based everyday meals, but starting small will help to make long-lasting change.

By Emily Cooper, RDN

THE INTEREST in and popularity of plant-based diets has been around throughout human history. Many religions such as Buddhism, Jainism and Seventh-day Adventist follow a vegetarian diet. The Greek philosopher Pythagoras touted the benefits of a vegetarian diet, so much so that the vegetarian diet was widely known as the Pythagorean diet up until the 1800s.

Nowadays, the presence of plant-based foods and beverages can be seen at nearly every food store or restaurant in the United States. In fact, the plant-based foods market in the U.S. grew 29 percent from 2017 to 2019, and it was worth an estimated $8.1 billion in 2023. People are looking for plant-based options for a number of reasons — from ethical and religious considerations, to rising food costs, personal health or environmental concerns. Whatever your reason, there are many easy ways to add more plant-based foods to everyday meals.

What Does Plant-Based Mean?

Plant-based is not really a one-size-fits-all term or diet. It can mean something a little different for everyone. According to Merriam-Webster's dictionary, the definition of plant-based is "made or derived from plants" *or* "consisting primarily or entirely of foods derived from plants." Some of the most common plant-based foods are made with fruits, vegetables, beans, legumes, nuts and seeds.

Here are some common terms used in the plant-based conversation, and how they are all a little bit different:

- Vegetarian: a diet that avoids many, but not all, animal-based products. This includes avoiding meat, poultry, seafood and sometimes eggs or dairy products.
- Vegan: a diet that avoids all animal-based products, including eggs, dairy products and even honey.
- Plant-forward: a diet that includes animal products, but in smaller quantities, putting the emphasis on plant-based foods first.
- Whole-food, plant-based: a diet that both minimizes processed foods and promotes meals built around plant-based foods. It can include animal products, but in limited amounts.

Incorporating more plant-based foods into your diet means increasing your intake of foods that come from plants while also reducing your intake of foods that come from animals (sometimes, without actually eliminating those foods). The specifics of how you do that are up to you.

What Are the Benefits of a Plant-Based Diet?

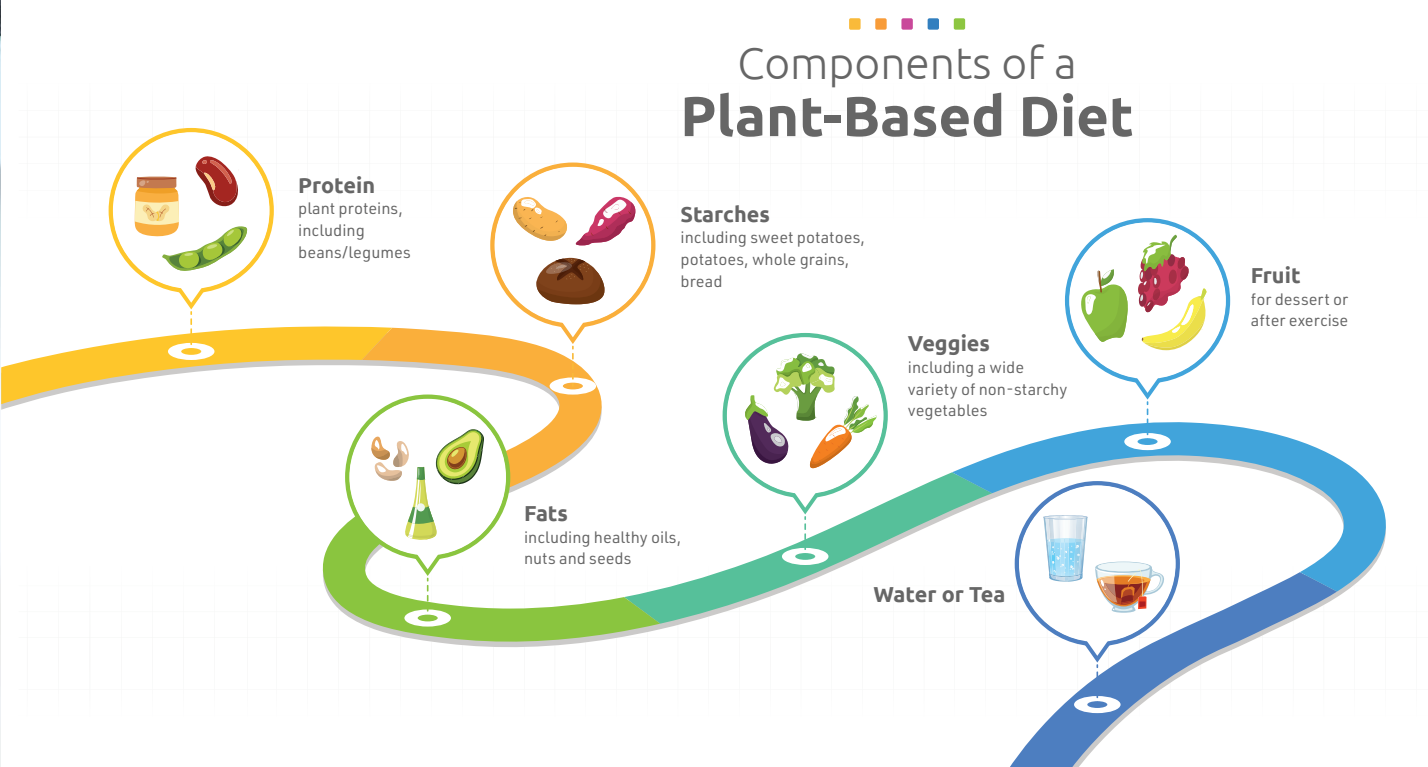
Just as the term plant-based isn't one size fits all, the benefits of this way of eating aren't either. They can differ whether you are eating some animal-based foods or none at all. But there are some common benefits that can be achieved by simply adding more plant-based foods to your daily life. Some of these include helping to lower blood pressure and cholesterol, losing or maintaining weight and helping to lower A1C levels.

Whatever it means to you and your health goals, there are plenty of ways to add more plant-based foods to your day. Finding the foods you enjoy and a way of eating that works for you is key to making it a permanent part of your lifestyle. Here are some ways to add more plant-based foods to every meal, and some simple swaps you can add to your day.

Breakfast

Adding more vegetables and fruits first thing in the morning is a great way to start the day off right. It can help you kickstart good habits for the rest of the day, give a little energy boost and keep digestion regular. Here are some easy ways to add more to your breakfast routine.

Mix eggs and veggies. If eggs are a breakfast staple in your household, add veggies to them. This can add more volume, color and nutrition to your breakfast plate. Try making a veggie omelette: Broccoli and cheddar or spinach and feta are tried-and-true, veggie-centric omelette ideas. Experiment with different combinations to find what you like best. You can also



simply add chopped veggies to scrambled eggs, or just enjoy them on the side if sunny side up eggs are more your style.

Make a tofu scramble. Swap out eggs for tofu: Simply crumble extra-firm tofu in your pan, and saute until the excess water evaporates. Add your veggies and favorite seasonings (a little bit of turmeric gives that familiar yellow color), and cook until heated through.

Try a smoothie. If you're on-the-go, a smoothie is a simple and portable breakfast option that you can fill with plant-based foods. Instead of dairy-based milks, use plant-based milks such as soymilk or almond milk. Smoothies are an easy way to get a serving of veggies, too. Try adding a handful of spinach or steamed and cooled zucchini or cauliflower before blending with the rest of your smoothie ingredients. Experiment with different fruits (and veggies too) for different flavor combinations. You can even take advantage of what produce is in season to maximize the flavor and nutrition of these fruits and vegetables. For an extra nutritional boost and added staying power, try adding in your favorite peanut or nut butter, chia seeds or ground flax. These are full of healthy fats and fiber, which will help to make a more filling and satisfying smoothie.

Whether an appetizer or main meal, starting with a base of leafy greens is a simple way to get in more veggies.

Lunch

There are plenty of plant-based options for your afternoon meal. The added nutritional boost from plants can help fight off the midday slump, limit mindless snacking and help you stay alert and focused.

Start with a salad. Whether an appetizer or main meal, starting with a base of leafy greens is a simple way to get in more veggies. This includes greens like baby spinach, arugula, chopped romaine lettuce and mixed greens. If you're enjoying a salad as a main meal, add some filling ingredients such as colorful vegetables or even fresh fruits; a serving of plant-based protein like cooked tofu or canned beans; healthy fats like chopped nuts or sliced avocado; and a drizzle of your favorite dressing. If you're serving salad on the side, enjoy it before your main meal to get your veggies in first. If you're not a fan of salads, you can swap it out for a vegetable soup instead. Make your own, or look for canned vegetable soups that are lower in sodium.

Make a veggie sandwich. If sandwiches and wraps are more your style, bring the salad to them! You can make a satisfying sandwich by pairing fresh vegetables such as classic lettuce and sliced tomatoes or even leftover roasted vegetables with flavorful sandwich spreads such as hummus, mashed avocado or plant-based mayo. Sandwiches and wraps are also portable, which makes them a great option when you're on the go or if you have limited time during the afternoon.

Dinner

Your evening meal is another opportunity to add more plant-based foods to the day. Adding these fiber-rich foods can help you stay full and satisfied until the morning, and will help you get a restful night's sleep.

Keep frozen vegetables on hand. A quick way to add more plant foods to your meals is with frozen vegetables. They take just minutes to prepare, or they can be added directly when cooking dishes like soups, a stir fry or pasta. Keep a variety of options in your freezer such as chopped spinach, peas, mixed vegetables and different veggie blends. You can even find pre-cooked grain options like brown rice or quinoa to make for a quick side dish or base of a meal. Make sure you look for options without extra sauces. This helps you control how much salt you add to meals, and it also makes them more versatile for different recipes.

Go meat-free once a week. Designate one night per week for a meatless dinner. This can help you prioritize plant-based options, and it will encourage you to try new recipes. Opt for recipes with plant-based proteins such as beans, lentils, edamame or tofu in place of meat or seafood. Or, you can simply make familiar meals without the meat and add more vegetables instead (as in a stir fry). Start with making meals you already know and love in a meatless version. This can make the transition easier and less daunting.

Snacks

Adding plant-based options to meals isn't your only option. Snacks can also be an opportunity to add more

fruits, veggies, whole grains and nuts to your day. They can also help give you an energy boost and stave off hunger until your next meal.

Make fruits and vegetables visible. Something as simple as keeping a bowl of fruit on your countertop or storing chopped vegetables in the front of your refrigerator can be a powerful nudge when it's time for a snack. Having healthy options prepped and ready to go ahead of time means you are more likely to reach for them when you get hungry. Dedicate 10 to 15 minutes on the weekend to chop vegetables and wash and store fruits. This way, when the week gets busy, you already have healthy options to grab for a snack or use to make meals. Alternatively, you can buy a few options that are pre-made from the grocery store. These tend to be more expensive than prepping them on your own, but they can save a lot of time, especially when life gets busy.

Include snacks with healthy fats. Having fruits and vegetables at the ready is helpful, but pairing them with healthy fats significantly increases their staying power. Healthy fats are satisfying, meaning they'll help keep you feeling full for longer than having fruits or vegetables on their own. Some ideas include having an apple with peanut butter or a handful of almonds, pairing chopped vegetables with mashed avocado or an oil-based dressing, or eating whole-grain pretzels with hummus. Healthy fats like these are plant-based on their own, so enjoying them with fruits or vegetables is extra credit.

Simple Swaps

There are more and more plant-based versions of traditional animal-based products on the market each and every day. If you are looking to make the switch, here are some simple ways you can make it happen.

Instead of cow's milk, try plant-based milk. A lot of milk alternatives are available now, from almond and rice milks all the way to banana milk or flax milks. If you're looking to swap out dairy milk for a plant-based option with comparable nutrients, try soy milk. It has a nutrition profile similar to cow's milk, such as protein, calcium and vitamin D, but it also has a little extra fiber from the soybeans. A lot of other milk alternatives are low in calories, but they don't offer a lot of extra nutrition. If you have a soy allergy, look for another higher protein option like pea milk or a fortified almond milk. Opt for unsweetened flavors to limit the amounts of added sugar.

Instead of eggs, try ground flax. This doesn't go for scrambled or sunny side up eggs in the morning, but ground flax can be a good substitute for eggs in baked goods. It is also known as a flax egg. To make one egg, mix one tablespoon of ground flax with three tablespoons of water, and let it sit for five minutes, or until thickened. It works best in baked goods such as quick breads, brownies, cookies and even pancakes. While a flax egg doesn't have as much protein as a chicken egg, it is a natural source of fiber and healthy fats.

Instead of chicken or beef broth, try vegetable broth. If you use a lot of chicken or beef broth in your cooking, swapping it out for a vegetable broth is a super easy swap to make for a plant-based option. While the flavor won't be exactly the same, vegetable broth can be a flavorful alternative for soups, stews and other dishes. Try cooking sides like rice or quinoa in vegetable broth instead of water for added flavor. Look for a reduced-sodium variety to limit the amount of sodium you are adding to dishes.

Plant-Based Protein Sources

These foods tend to be high in fiber, vitamins, minerals and other important nutrients:

- Beans and legumes
- Broccoli
- Chickpeas
- Edamame
- Lentils
- Nut butter
- Nuts and seeds
- Oats
- Peas
- Quinoa
- Sorghum
- Soymilk
- Spinach
- Tempeh
- Tofu
- Veggie patties

Make Long-Lasting Changes

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EMILY COOPER, RDN, is a nationally recognized registered dietitian, health writer and recipe developer based in New Jersey. She is the author of *Mediterranean Diet on a Budget* and the website sinfulnutrition.com.

Diagnosing and Treating CVID

CVID may be the most common type of severe antibody deficiency or primary immunodeficiency, and an earlier diagnosis allows for more effective treatment.

By Jim Trageser

ALTHOUGH COMMON variable immune deficiency (CVID) may be the most common type of severe antibody deficiency or primary immune (PI) disorder (perhaps as common as one in 10,000 to one in 50,000 persons), the underlying genetic causes remain largely unknown. Possibly, 10 percent can have a genetic cause identified.[1] Environmental factors are also thought to have significant roles in causing or triggering CVID.[2] For example, infection with Epstein-Barr virus may precipitate the development of CVID in some patients.

CVID was one of the early PIs to be discovered. Charles Janeway Sr., MD, submitted an article to *Transactions of the Association of American Physicians* in 1953 describing a male patient who repeatedly suffered from infections.[3] Dr. Janeway referred to this patient's condition as "agammaglobulinemia" based on low levels of immunoglobulins (or antibodies) in the serum from the blood. Agammaglobulinemia had been used a year earlier to describe a patient with X-linked agammaglobulinemia (XLA), but anyone with low serum immunoglobulin levels can be defined as having

agammaglobulinemia, with CVID being one type of this disorder.[4]

Typically, CVID results in frequent/recurrent bacterial and viral infections of the respiratory system. (Indeed, physicians are taught to consider antibody deficiency, such as CVID, in a patient with recurrent sinopulmonary infections.) Additionally, patients with CVID are at higher risk of developing autoimmune disorders. Unfortunately, since T lymphocyte function can also be adversely affected in patients with CVID, there can be greater risks of developing cancer. In particular, lymphomas, which can be driven by the Epstein-Barr virus, are a major issue. The good news is that the use of immune globulin (IG) replacement therapy, either intravenously (IVIG) or subcutaneously (SCIG), at appropriate dosing levels, provides protection from infections for most patients with CVID, and can also provide benefits regarding autoimmunity and prevention of disease-associated complications.

What Is CVID?

CVID is a group of conditions with similar clinical features for which the immune system does not produce enough antibodies. Specifically, it is associated with a reduced to absent serum immunoglobulin G (IgG), along with reduced to absent serum levels of IgA and/or IgM.[5] Additionally, serum IgE tends to be absent or near-absent in patients with CVID. Occasionally, during the evolution of CVID, the serum IgM may be normal or even become elevated, and then subsequently decline as CVID fully declares itself. In the past, serum IgG of less then 400 mg/dL was considered the hallmark of diagnosis. More recently, the serum IgG level merely needs to be below the range of normal for age. Further, in the past, CVID was diagnosed when the blood B lymphocyte count was less than 200 cells/mcL. More recently, it was recognized that one of the "variabilities" in CVID is that the B lymphocyte count can be essentially absent (as found in XLA), low, normal or even elevated for age. In any case, the B lymphocytes in CVID fail to produce appropriate levels of needed antibodies.[2]

CVID may be the most frequently diagnosed severe PI with antibody deficiency (thus the inclusion of the word "common" in its name).[1] Both males and females are equally affected, and there does not seem to be any difference among ethnic groups — although it is slightly more prevalent in Northern Europe than in other geographic regions.[2] Approximately 80 percent of CVID cases are diagnosed in adults (thus, the previously used terms of "acquired agammaglobulinemia" or "acquired hypogammaglobulinemia" to describe this condition, both of which were abandoned in the 1980s when HIV-associated "acquired immunodeficiency syndrome" or "AIDS" came into use to avoid confusion), even though it can occur at any age.[2] CVID is less likely to be diagnosed in patients under the age of 4 years, since immune systems develop and mature at different rates in young children, making the diagnosis more difficult.[4]

The "variable" in CVID indicates the variability of symptoms and severity in patients. Some patients have greater T lymphocyte dysfunction, making them more akin to the condition known as combined immunodeficiency, rather than a more pure antibody deficiency (such as with XLA).

CVID is a group of conditions with similar clinical features for which the immune system does not produce enough antibodies.

Some 25 percent of patients with CVID develop autoimmune manifestations. These patients may have enlarged lymph nodes (lymphadenopathy) and enlarged spleens (splenomegaly). Most commonly, they will produce rogue antibodies that attack their own cells and tissues. Most typically, blood cells are the targets and result in cytopenias, including red blood cells, resulting in anemia; platelets, resulting in thrombocytopenia; and white blood cells, resulting in leukopenia. Other manifestations of autoimmunity include, but are not limited to, thyroid disease, inflammatory bowel disease and rheumatoid arthritis.[4] Some patients have septic arthritis (actual infection of the joints), most commonly in the hip due to mycoplasma. Another 20 percent of patients exhibit gastrointestinal issues, some of which are infection-related and others autoimmune-related.[4]

Granulomatous disease is another serious condition in patients with CVID. This occurs when small clusters

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 this and adjacent page of this advertisement and Brief Summary of Prescribing Information.

FDA approved for chronic inflammatory demyelinating polyneuropathy (CIDP) in adults to improve neuromuscular disability and impairment

- **80% treated with 1g/kg and 92% treated with 2g/kg of PANZYGA saw improvement in arm and/or leg impairment***
- **With the PANZYGA Co-Pay Program, eligible patients may pay as little as $0 for PANZYGA†**
  - Patients must have commercial insurance to be eligible
  - Patients are not eligible if they are enrolled in a state or federally funded insurance program

*Depending on the ongoing therapy dose.
†Eligible, commercially insured patients may pay as little as $0 for PANZYGA and may receive a maximum benefit of $12,500 per year or the cost of patient's co-pay in a 12-month period (whichever is less) for claims received by the program. Terms and conditions/eligibility requirements apply. See full Terms and Conditions at PanzygaCoPay.com.

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

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

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 U.S. Food & 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 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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PP-PAN-USA-0927

April 2024

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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of immune cells (granulomas) form in response to the inflammation of an infection. If large numbers of granulomas form, they can interfere with the normal function of that tissue. If left untreated, the granulomatous disease can cause tissue injury, most often in the lungs (granulomatous lymphocytic interstitial lung disease, GLILD), skin, liver, spleen and digestive tract (with the appearance of inflammatory bowel disease such as Crohn's disease).[6,7]

Certain cancers — particularly non-Hodgkin lymphomas, non-melanoma skin cancers and gastric cancers — are found at higher rates in patients with CVID than in the general population.[5,6] T lymphocyte dysfunction may have a role in failure to find and deal with developing cancers.[8]

What Causes CVID?

There is no singular specific underlying cause of CVID. Mutations in at least 13 genes have been determined to produce the clinical features of CVID. These include the gene for the protein CD19 associated with B lymphocyte development and activation, the ICOS gene and the TNFRSF13B gene, the latter two involving T lymphocyte activation and interaction with B lymphocytes.[2] Further, some 20 percent of patients with CVID have a close family member with an IgA deficiency, which may be due to IGAD2, which involves the same gene, TNFRSF13B, as occurring in some patients with CVID.[2]

Symptoms and Progression of CVID

Frequent, recurrent and/or severe bacterial and viral respiratory infections in the ears, sinuses, bronchi and lungs are the primary indicators of CVID.[4] The so-called encapsulated bacteria, such as pneumococcus, Hemophilus and Moraxella, are the primary bacterial infections of the respiratory system. Any respiratory virus can be problematic. The gastrointestinal norovirus has plagued patients with CVID. Repeated episodes of shingles may occur due to reactivation of the varicella virus. Other symptoms can include gastrointestinal tract problems, enlarged lymph nodes, painful joints and clubbed fingers or toes (due to compromised pulmonary function).[6]

If left untreated or undertreated, CVID can result in chronic bronchitis (chronic infection of the airways, which is difficult to eradicate). Chronic inflammation can also occur, which can exacerbate arthritis and autoimmune disease symptoms, including inflammatory bowel disease (especially when granulomata are present). Alopecia areata (the loss of hair in open round patches) or alopecia universalis (the total loss of all hair on the body and scalp) are other autoimmune/chronic inflammation risks. Chronic inflammation may also injure mucosal tissues with a risk for bowel cancers. Dysfunction of T lymphocytes can result in further risk of cancer occurring. Unfortunately, these risks increase as patients become older.

Diagnosing and Treating CVID

Based on the number, recurrence rate, type and severity of infections, an antibody deficiency such as CVID should be suspected. Further, if autoimmune manifestations are present, this adds to the credence that CVID could be present. Initial testing for antibody deficiency should include analyses of the quantitative serum levels of the immunoglobulins IgG, IgA, IgM and IgE (IgE is frequently absent, or near-absent, in patients with CVID).[6] Complete blood and platelet counts are needed to determine if cytopenias (as noted above) are present. Further, testing for autoimmunity or other issues found from the patient interview and physical examination should also be performed.

If any of the screening tests are abnormal (for example, low IgG with low IgA and/or low IgM), or the suspicion of CVID is high, further testing for the ability of the patient to make antibodies should be performed.[9] These involve checking for the capability to make antibodies to the polysaccharide antigens from pneumococcal bacteria and to make antibodies to the diphtheria and tetanus toxoid protein antigens. These are performed by collecting serum from the patient (pre-immunization serum) and then immunizing with the pneumococcal polysaccharide and the dT vaccines. Four weeks after the immunizations, serum is obtained from the patient (post-immunization serum). Both sera are sent to specialized laboratories to determine the antibody levels. Specific amounts of the antibodies and the changes from the pre-immunization to the post-immunization are reviewed. An inadequate increase in antibody levels indicates the immune system is failing to work normally, which provides the necessary evidence to make the diagnosis of CVID.[9]

Occasionally, patients are "borderline" on test results. That is, the test results are not sufficiently abnormal to confirm the diagnosis of CVID. This becomes a dilemma for the patient and the healthcare providers. These borderline results should not be dismissed and interpreted as CVID is absent. Indeed, the clinical status of the patient should have a major

impact on further evaluations and the treatment plan. For example, genetic studies may be useful for identifying the known genetic risk factors found in approximately 10 percent of patients with CVID. Otherwise, for the patient who is responding well to occasional antibiotic treatment, after discussion and planning with the patient, the approach of antibiotic treatment as needed could be continued with retesting in six months to a year, repeated until a definitive diagnosis is made. For the patient requiring essentially constant antibiotic usage, a trial of IG replacement therapy should be negotiated with the patient and the third-party payer. The rationale is to prevent further complications, such as bronchiectasis, which not only increases the patient's morbidity and risk for mortality but also increases the cost of care.

Unfortunately, it takes on average about nine years from the onset of symptoms to the diagnosis of CVID.

The development of CVID in someone is an evolving process. Early test results may not be too abnormal, thus delaying the diagnosis. For example, IgA may be lost, then subclasses of IgG, then total IgG, before the loss of IgM. As noted above, the IgM level may be normal or even increase prior to decreasing as CVID evolves, and this increase can result in separate concerns about the development of lymphoma. This can then add to further emotional distress and potential additional testing, which may not be otherwise necessary. Due to all this, unfortunately, it takes on average about nine years from the onset of symptoms to the diagnosis of CVID. Thus, repetitive testing should be performed on any continuously ill person, regardless of prior test results, until a diagnosis can be achieved.

IG replacement therapy is the primary treatment for CVID. Patients receive 400 to 600 mg/kg (typically beginning with 500 mg/kg, and increasing as needed to prevent infections and deal with autoimmune manifestations) intravenously every three to four weeks.[10,11] Alternatively, patients may receive SCIG.[6] SCIG may be infused in a variety of regimens, in part depending on the product used. In any case, the total monthly dose is adjusted according to parameters associated with the product being used and divided into the number of infusions to be given in a month. Some SCIG products are infused subcutaneously twice a week, once a week or once every two weeks, and a facilitated SCIG infusion product is infused once a month. It is critical to note that once IG replacement infusions begin, they should not be paused for any non-medically necessary reason.

Patients on IG replacement therapy may have additional testing performed to monitor treatment. This depends on the symptoms and protocols being implemented.

Despite IG replacement therapy, some patients continue to require antibacterial or antifungal antibiotics and may require antiviral treatments. Other conditions, such as autoimmune diseases, may be treated with conventional therapies that any patient may receive.

Patients with CVID should be closely monitored by their healthcare providers, with a minimum of annual visits. During these visits, additional testing, such as X-rays, CT scans and pulmonary function testing, may be performed to monitor the pulmonary system status. Further testing such as X-rays/CT scans of the sinuses may be helpful. Separately, patients with gastrointestinal symptoms may require more frequent endoscopies than the general public. Patients for which there may be greater concern about the development of lymphoma may have the specialized PET/CT scan performed for identifying potential lesions. Patients are encouraged to keep track of their own weight, fevers, respiratory symptoms and gastrointestinal symptoms, and report any significant changes for treatment adjustments.

Because a diagnosis of CVID can be emotionally draining, mental health counseling may be recommended. This may take the form of joining a support group with other patients with CVID.

CVID Research

There are about five dozen active or recently concluded studies involving CVID on the clincaltrials.gov website. These range from improved diagnostic tools to using certain antibiotics to address chronic infection/inflammation of the digestive system. One interesting study to be conducted at Duke University plans to examine how

patients with CVID respond to the COVID-19 vaccine. Another, from France, is determining how many patients with CVID will develop GLILD. Scientists continue to try to determine the genetic causes of CVID, while other researchers work to determine what environmental factors may trigger CVID.

Looking Ahead

A cure for CVID likely awaits researchers discovering the root causes of this group of disorders, with the individual treatments required for each. Until then, an earlier diagnosis with effective treatment and ongoing monitoring provides the best option for patients with CVID to help keep them safe and maintain a high quality of life. Resources regarding CVID include the Immune Deficiency Foundation (primaryimmune.org) and the Jeffrey Modell Foundation (info4pi.org).

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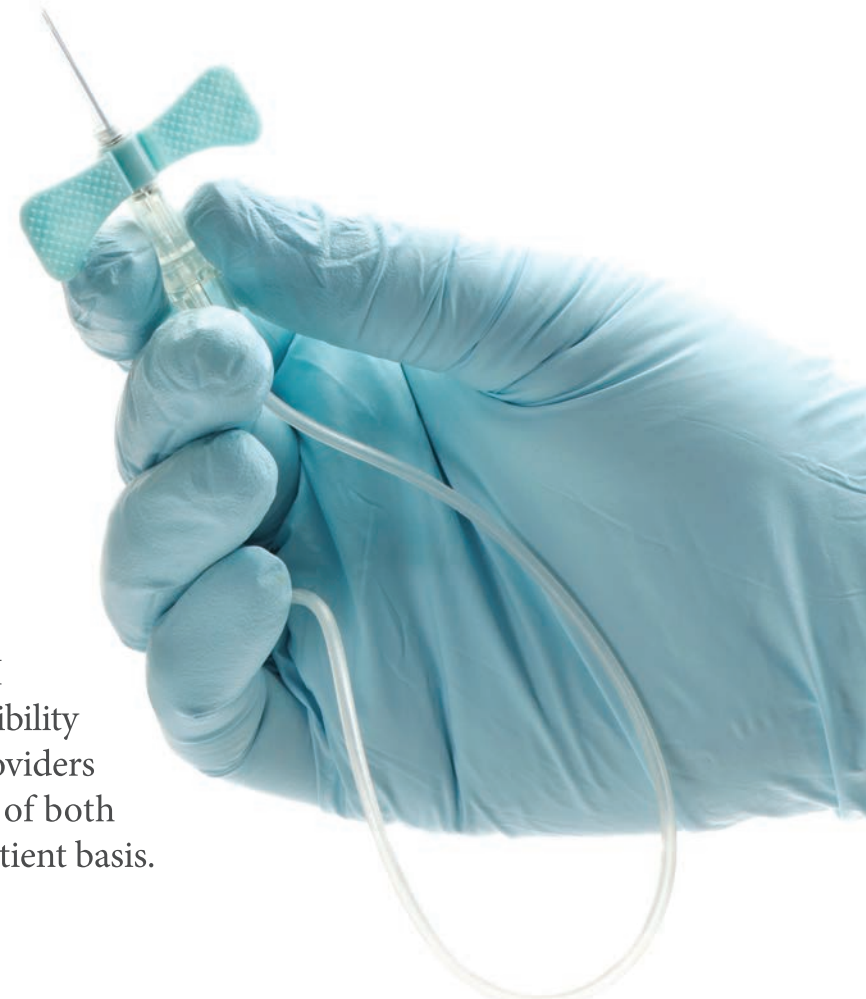
JIM TRAGESER is a freelance journalist in the San Diego, Calif., area.

Current Misconceptions About SCIG Therapy



SCIG can be a good option for PI patients due to its convenience, flexibility and safety; however, healthcare providers should discuss the pros and cons of both IVIG and SCIG on a patient-by-patient basis.

By Kelvin Shaw, MD, Brent Rutland, MPH, MBA, and Jasmin Bosshard, MS

SUBCUTANEOUS IMMUNE globulin (SCIG) therapy is a popular treatment option for patients with primary immunodeficiency disorders (PI) and is well-established as an alternative to intravenous IG (IVIG) therapy. SCIG provides benefits such as the ability to self-administer at home and schedule treatments when convenient, as well as a reduced rate of adverse events. Yet, despite these advantages, a large percentage of PI patients are still treated with IVIG[1] because of their health profile (physically or mentally), risk profile and personal situation.

Misconceptions surrounding SCIG may be a reason for the low percentage of PI patients on SCIG therapy. Here, we aim to address these misconceptions and provide accurate, evidence-based information to help patients and caregivers make informed decisions about treatment options. Healthcare providers should let patients know about the pros and cons of SCIG and IVIG, and offer training and support to help patients and caregivers become comfortable with administering SCIG at home.

Current Misconceptions

Misconceptions surrounding SCIG can lead to confusion among patients and healthcare providers. Following are four identified common misconceptions associated with SCIG therapy for the treatment of PI:

Misconception 1: SCIG is not effective. Studies have shown that SCIG and IVIG are equally effective in preventing infections and maintaining immunoglobulin levels in patients with PIs.[2,3] In fact, some studies have shown that SCIG is associated with a lower incidence of serious bacterial infections compared to IVIG.[3,4] Whereas IVIG infusions are administered by a healthcare professional at inpatient or outpatient infusion suites, physicians' offices or at home, SCIG is typically administered at home, while facilitated SCIG may also be administered at home or in-office by a nurse, depending on insurance coverage and preference.[5] At-home administration can be more convenient for some patients and their caregivers,[2,6] while also limiting patient contact with others. Therefore, SCIG is a safe and effective alternative to IVIG for patients with PIs.

Misconception 2: SCIG is associated with many injection site reactions. Injection site reactions can occur with both SCIG and IVIG; however, some studies have shown that the overall incidence of injection site reactions is similar between the two treatment options,[2,7] while some studies report more injection site reactions with SCIG.[8] Regardless of the initial frequency of SCIG injection site reactions — swelling/bumps — these reactions are mostly minor[9] and are seldom a cause of discontinuation.[10] Injection site reactions can often be managed with simple measures such as rotating injection sites and using warm compresses. Patients who self-administer SCIG at home can also benefit from training and support from healthcare providers to help them manage injection site reactions.

While injection site reactions with SCIG are usually mild and easily managed, serious systemic reactions are more common with IVIG.[11,12] Therefore, it is important to recognize that a proper training regimen improves outcomes with SCIG.[13]

Misconception 3: SCIG is difficult to administer. Many patients find that self-administration of SCIG at home is easy, effective and well-adapted to their needs. Some studies report that up to 90 percent of patients can self-administer SCIG without assistance.[14] In addition, many healthcare providers offer training and support to help patients and caregivers become comfortable with administering SCIG. Indeed, adequate support by trained professionals is important for SCIG self-administration success.[15]

Misconception 4: SCIG is very expensive for the healthcare system. While the cost of SCIG can vary depending on factors such as dosage, frequency of administration and insurance coverage, studies have shown that SCIG can be cost-effective compared to IVIG due to factors such as reduced hospital visits and lower incidence of adverse events.[2] From a healthcare system perspective, IVIG is more time-consuming[1] for healthcare professionals, patients and caregivers and, therefore, is a more healthcare resource-intensive option (especially due to healthcare professional assistance during infusions and the use of infrastructure). On the other hand, the ability to self-administer SCIG at home can also lead to cost savings in nursing.[14]

Lastly, the ability to avoid disruptions to school[16] or work[17] is also an important advantage associated with SCIG.

Studies have shown that SCIG and IVIG are equally effective in preventing infections and maintaining immunoglobulin levels in patients with PIs.

How Clinicians Can Help Guide Patients' Decisions

While SCIG offers several benefits over IVIG, there are some considerations physicians should keep in mind when guiding their patients to make "their" best choice:

1) Patient preference. Patient preference should be a key consideration when choosing between IVIG and SCIG. Patients consistently report higher satisfaction and better quality of life with SCIG therapy compared to IVIG.[11,12,16,18-26] The ability to self-administer treatment at home, which provides greater convenience and flexibility,[18] is one of the main reasons patients prefer SCIG therapy. A study by Gardulf et al. found that 97 percent of patients preferred SCIG over

IVIG, citing the ability to administer treatment at home as the primary reason.[27] However it should be mentioned that there can be reasons such as a patient's personal or medical situation that requires only healthcare professional-assisted IVIG treatment. Indeed, some patients prefer to be treated in the hospital because they are more comfortable with having a medical professional present. And, some patients want to keep their treatment separate from their home life.

2) Medical history. The patient's medical history and current health status should also be considered when choosing between IVIG and SCIG. For example, patients with scar tissue or other skin conditions that may make subcutaneous injections difficult may not be good candidates for SCIG. Limited manual dexterity may also make IVIG a better option for some patients. Conversely, patients with a history of severe reactions to IVIG may not be able to tolerate the medication with this treatment modality. These patients may benefit from switching to SCIG. Lastly, the flexibility to easily alter doses and frequencies may make SCIG a better option for patients prone to adverse events, especially systemic adverse events.

3) Treatment goals. The goals of therapy should be considered when choosing between IVIG and SCIG. If the goal is to increase immunoglobulin levels rapidly, then IVIG may be the preferred option, at least initially. However, if the goal is to maintain steady-state immunoglobulin levels over a long time, then SCIG may be more efficacious.

The Role of Healthcare Providers

Misconceptions regarding the benefits of SCIG may contribute to its underutilization among patients with PIs. However, healthcare providers can educate patients and caregivers proactively about their options to dispel these misconceptions and provide accurate evidence-based information. By doing so, patients can benefit from the convenience, flexibility and safety of SCIG therapy, which can improve results by improving treatment adherence, quality of life and overall treatment outcomes. It is the responsibility of healthcare providers to ensure patients have access to all available treatment options and that they receive the education and support necessary to make informed decisions about their care.

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Profile: Mathilda von Guttenberg

By Trudie Mitschang

MATHILDA VON GUTTENBERG studies neuroscience at the University of California Los Angeles (UCLA) with a research specialization in psychoneuroimmunology. The 22-year-old's fascination with the study of the mind-body connection for people living with chronic illness stems from her own journey with common variable immune deficiency (CVID). When she's not doing research, applying for PhD programs, taking classes or working, Mathilda enjoys spending time outdoors and reconnecting with nature through photography, hiking, skiing, swimming and horseback riding.

Trudie: For those unfamiliar with the term, how would you define psychoneuroimmunology?

Mathilda: Psychoneuroimmunology is "an attempt to decipher the bidirectional communication between the brain and the body." In simple terms, it studies how our thoughts, emotions and stress can influence our immune function and overall health, answering questions such as "What is the connection between a person's physical and mental health?" The mind-body connection influences so much of our health, and for people living with long-term conditions, it's not just the physiological, it's the psychological.

Trudie: Tell us a bit about your CVID diagnosis.

Mathilda: Growing up, I struggled with recurring respiratory infections and gastrointestinal issues that kept me constantly ill and on antibiotics. I struggled to gain weight and was often too weak to take part in everyday activities. I remember my mother taking me to countless specialists for answers. Eventually, I was just stamped as an unlucky kid, while some doctors even dismissed my health issues as "phantom symptoms." Thankfully, my parents never gave up trying to get a diagnosis. That advocacy paid off, and we finally found an immunologist who discovered I had CVID. I was 12 years old by the time I was finally diagnosed, and my levels were dangerously low.

Trudie: What was your initial treatment plan?

Mathilda: Subcutaneous immune globulin (SCIG) therapy provided some relief from infections, but also caused side effects such as headaches and joint inflammation. After five years, I switched to a different product with a lower concentration of immunoglobulin G, which alleviated the adverse reactions.

Trudie: What was it like growing up with a chronic illness?

Mathilda: Taking care of my body was something I had to worry about from a very young age. I missed school a lot and didn't socialize much because I was constantly weighing whether a weekend of fun was worth the risk of getting sick. I was also hesitant to disclose my condition, which made me feel even more isolated.

The hardest part about a primary immunodeficiency (PI) such as CVID, in my opinion, is that it is often invisible. While I was relieved people couldn't immediately tell I was struggling, it was exhausting to face disbelief and stigma when I did try to explain. I had to fight for school accommodations, and I felt like I was constantly justifying my needs.

I spent much of my teen years learning as much as I could about my condition. I was forced to connect the dots that the doctors wouldn't, as well as answer my own questions to a certain extent. Even back then, I wanted to understand the science behind it.

Trudie: What drew you to a career in neuroscience?

Mathilda: As I got older, I developed a genuine love for subjects such as biology and chemistry; they just made sense to me. I wanted to find a way to turn that passion into something meaningful. By 10th grade, I started exploring career paths in the medical field. Years of dealing with repeated illnesses and uncertainty sparked a deep curiosity about how psychological and biological factors interact to shape health outcomes. What truly captivated me about neuroscience, though, is how beautifully it brings together so many fields of thought — bridging psychology, biology, philosophy and more.

Trudie: You've focused your research

on mindset and physical health. Tell us about that.

Mathilda: People with chronic conditions often face a double burden — the physical impact of their illness itself and the toll that living with a chronic condition takes on their mental health. This, in turn, can create a vicious cycle in which deteriorating mental health worsens physical symptoms. We often talk about this in terms of mindset — how the relationship with a condition and symptoms can directly influence physical health, even showing up in blood markers, immune responses and other physiological indicators. I genuinely believe there's a critical connection here, especially based on my own experiences. As a teenager, I struggled with mental health, not just because of living with a chronic condition, but likely also due to the effects of a dysregulated immune system. Over time, my focus has evolved to explore how stress, resilience and the biopsychosocial dynamics of illness shape mental health outcomes for people with chronic conditions. I started asking questions such as, "What determines our ability to adapt in the face of adversity?" and "Why do some people navigate health challenges more effectively than others?" These questions have guided my research interests, helping me to understand the intricate connections between the mind and body in managing chronic illness.

Trudie: You talked about your research on mindset. What has shaped your capacity to adapt to adversity?

Mathilda: What truly shaped my ability to adapt was my curiosity. I've always wanted to understand how things work, especially my own body and mind. The more I learned about how stress and mindset can influence immune function, the more empowered I felt. It turned my condition into something I could approach scientifically instead of something that just controlled my life. I started to see resilience not just as pushing through challenges, but as reframing them — finding ways to gain back some control and make sense of what I was going through. That shift in perspective is what really helped me cope, and it's a big part of why I'm so passionate about researching the mind-body connection now. I want to help others find that same sense of agency and understanding in managing their own health challenges.

Trudie: What are your long-term career plans?

Mathilda: If there's one thing I've learned, it's that plans rarely unfold the way you expect. When it comes to my long-term career, I try to keep an open mind. I'm passionate about advancing research in this field, but I also care deeply about science communication and health policy. My hope is to build a career that allows me to integrate all these aspects — conducting meaningful research while also making complex scientific information accessible to the public and helping shape policies that improve care. Ultimately, I want my work to have a real impact, both in the lab and beyond.

Trudie: Are you involved in any advocacy work?

Mathilda: I'm currently leading a project at UCLA in collaboration with the Center for Accessible Education. Our goal is to identify the unique stressors faced by this population and develop personalized stress profiles for students with long-term conditions. By understanding their specific challenges, we hope to create more tailored accommodations and support systems that can improve their quality of life and help prevent stress from further impacting their health.

Trudie: What do you wish healthy people understood about invisible illness?

Mathilda: Just because someone appears fine on the outside doesn't mean they aren't fighting a difficult battle. And, just because you carry it well doesn't mean it isn't heavy. What I wish most is that healthy people would approach these situations with genuine curiosity and empathy. A simple act of acknowledgment — believing someone without needing proof and validating their experiences — can be incredibly powerful. Sometimes, knowing that someone sees and believes what you're going through is enough to lighten the weight you carry, if only a little.

Trudie: What advice do you have for other young people living with PI?

Mathilda: Remember that your condition is just one part of who you are; it doesn't define you. It's easy to feel overwhelmed or even trapped by all the appointments, medications and symptoms, but finding something outside of your illness that you're passionate about can make a world of difference. Also, don't be afraid to advocate for yourself. I know it can feel exhausting to constantly explain your needs or correct misconceptions, but no one understands what you're going through better than you do. Surround yourself with people who listen, believe you and are willing to learn. Finding a supportive community — even if it's just one or two people — can help you feel less alone. Finally, be kind to yourself. Living with a chronic condition isn't easy, and it's OK to have bad days. IG

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

Reconnect with game night

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.

Register for a community educational program created for people living with PI—*My Life, My Story.*

Learn more about what it's like to infuse CUVITRU from clinical nurse educators and other patients like you.

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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Fitting *PI* Into Your Life, Not Your *Life* Into PI

By Michelle Searle

WHEN LIVING with primary immunodeficiency (PI), it's easy to feel like the condition dictates what is and isn't possible. At last summer's Immune Deficiency Foundation (IDF) national conference, I attended a session on mental health and PI. During the discussion, I raised my hand and shared a belief that has shaped my own experience: It's not about fitting your *life* into your PI, but rather fitting *PI* into your life. That shift in perspective has been a guiding force in how I've pursued my dreams and lived my life despite the challenges that come with this illness.

From a young age, I dreamed of moving to Italy. Throughout college, I took every opportunity to prepare for that goal, including studying the language, immersing myself in the culture and mapping out a plan to make the move a reality. (If you would like to hear more details about how I moved to another country and managed my PI, I've written previous columns about it.) Some people may have hesitated to follow their dream of moving to another country, thinking about the logistical challenges of managing a chronic illness in a foreign country. However, not moving was never an option for me. I had already decided I was going to live in Italy, and that meant I would simply have to figure out how to manage my PI there.

There were, of course, hurdles. I had to find a new immunologist, navigate a different healthcare system and determine how I would get my medications and supplies in a new country. But these were just details to figure out — not reasons to give up on my dream. If anything, PI made me a stronger problem solver. It taught me how to plan ahead, advocate for myself and handle unexpected challenges with resilience. Because of PI, I became more adaptable, resourceful and determined to create the life I wanted.

This mindset shift — from seeing PI as an obstacle to recognizing it as a part of my life that I manage — has helped me in more ways than one. Over the years, I've attended many PI events, and I've often heard people say they couldn't even think of doing or trying something because of their chronic illness. They were trying to fit their life into their PI. Instead of focusing on what I can't do because of PI, I focus on what I can do because of it. Living with a chronic illness has given me a deep appreciation for my health and well-being, a strong sense of empathy for others facing medical challenges and a level of independence I may not have otherwise developed.

One of the most valuable lessons PI has taught me is the importance of community. I have connected with others who share similar experiences, and those relationships have been incredibly meaningful. Whether it's through patient advocacy groups, online communities or friendships formed at conferences, knowing I am not alone has been a source of great strength. These connections remind me that while PI presents challenges, it also brings opportunities to support and be supported by others who truly understand. These connections also show me all I can do and accomplish even while living with PI.

Additionally, living with PI has helped me cultivate a deep sense of gratitude. Because I know what it's like to struggle with my health, I don't take the good days for granted. Every experience, big or small, feels more meaningful. I cherish my ability to travel, pursue my passions and build a fulfilling life because I know how hard I've worked to make it happen.

For anyone struggling with PI, I encourage you to ask yourself: What do you want your life to look like? What dreams do you have that feel out of reach? Instead of thinking about what PI might take away, think about what it has taught you — your resilience, your ability to adapt and the strength you have to navigate challenges. Your goals don't have to be put on hold because of your condition. They may require adjustments, but they are still within reach.

Fitting PI into your life doesn't mean ignoring its realities. It means acknowledging them, planning for them and then moving forward anyway. It means understanding that PI is a part of you, but it doesn't define you. If I had let my condition dictate my choices, I wouldn't be where I am today. Instead, I chose to chase my dreams, PI and all, and I hope others will find the courage to do the same. Ask yourself: Are you fitting *PI* into your life, or are you fitting your *life* into PI? 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.

Finding Purpose Through Volunteering

By Megan Ryan

LIVING WITH chronic illness or pain can be a challenging journey, often accompanied by feelings of isolation, frustration and a loss of purpose. Amid these difficulties, I've found a powerful opportunity for personal growth and fulfillment through volunteering. Engaging in volunteer work has provided me with a renewed sense of purpose, connection and empowerment. While I no longer work full time, volunteering with organizations that find connection such as Undies for Everyone, which provides children living in poverty or crisis with new underwear, is a rewarding and meaningful experience.

Chronic illness or pain can disrupt many aspects of life, including careers, relationships and daily routines. These disruptions can lead to a sense of purposelessness, as you may feel limited in your ability to contribute to society or pursue goals. Yet, volunteering offers a pathway to rediscovering purpose and making a meaningful difference in the lives of others.

For individuals with chronic illness or pain, one of the most significant benefits of volunteering is the ability to reframe your limitations. Rather than focusing on what you cannot do, volunteering allows you to focus on your strengths and abilities. By identifying activities that align with your skills and interests, you can find ways to contribute meaningfully, even with health constraints.

The act of contributing to a cause or community can foster a sense of accomplishment and self-worth, counteracting the feelings of helplessness that can accompany chronic illness.

Volunteering can be a powerful source of empowerment. By taking an active role in helping others, you can regain a sense of control and build self-efficacy. The act of contributing to a cause or community can foster a sense of accomplishment and self-worth, counteracting the feelings of helplessness that can accompany chronic illness.

While the benefits of volunteering are clear, individuals with chronic illness or pain may face unique challenges in finding suitable opportunities. It is important to choose activities that align with your abilities and health conditions. Organizations may offer flexible volunteer roles, including remote or virtual opportunities, that can accommodate varying levels of physical or mental capacity. Many organizations need volunteers to write thank-you notes to donors, which can often be done from home. If you have specific expertise or skills from a professional background, those can often be put to work. Or sometimes, it is just completing tasks essential to an organization's mission such as shelving food at a food bank or walking dogs for an animal rescue.

Following are some tips for volunteering while living with chronic illness or pain:

- Start small: Begin with a small commitment, and gradually increase involvement as your health allows.
- Communicate clearly: Be open and honest with a volunteer coordinator about any limitations you may have.
- Focus on your strengths: Choose activities that align with your skills and interests.
- Celebrate your contributions: Recognize and celebrate your accomplishments, no matter how small.

By providing opportunities to find purpose, build connection and foster empowerment, volunteering can help you navigate the challenges of chronic illness and live a more fulfilling life. Remember, even small contributions can make a big difference. By embracing the power of volunteering, you can rediscover your purpose and create a positive impact on the world around you. IG

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.

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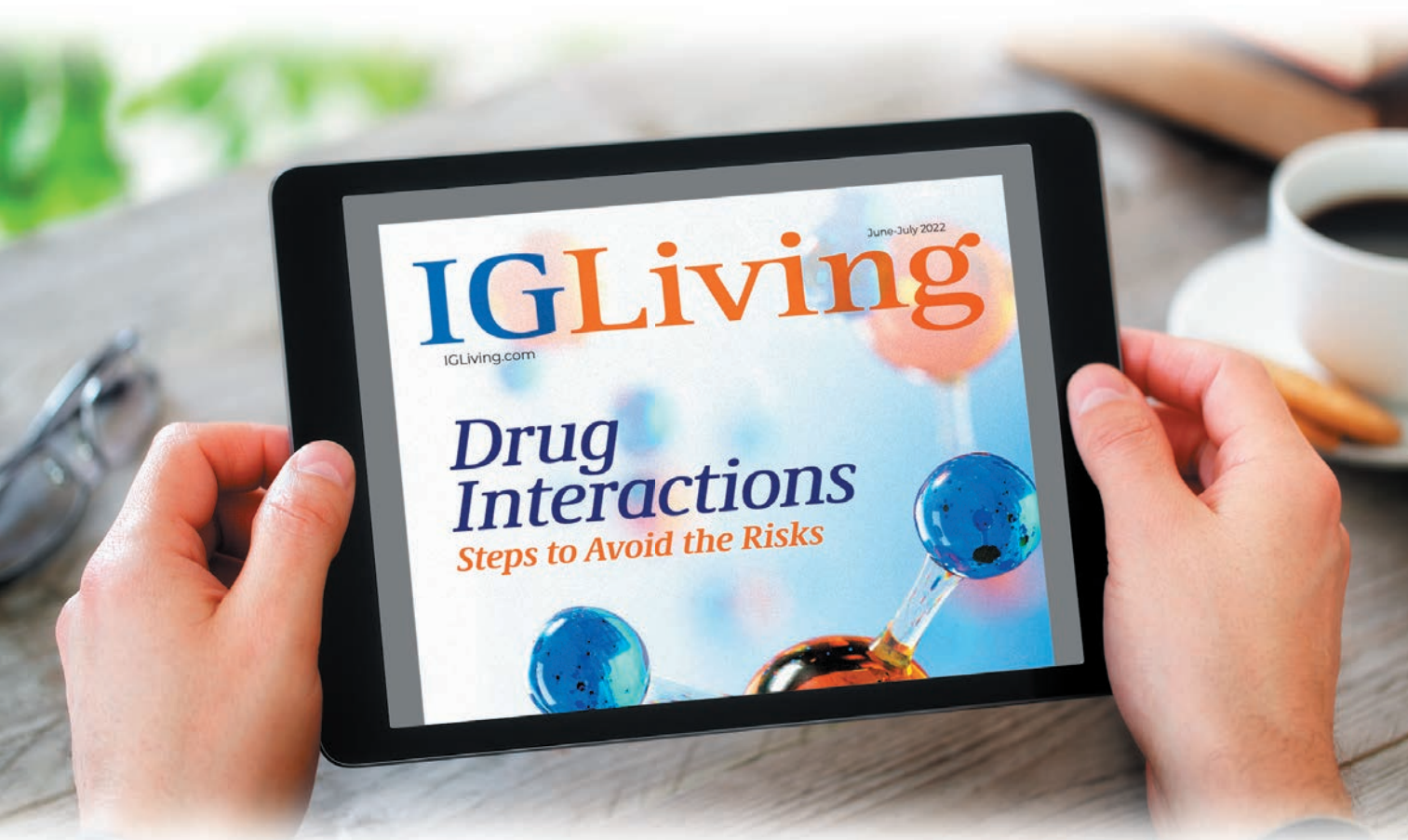

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Helping Kids Cultivate a Healthy Body Image

By Jessica Leigh Johnson

THESE DAYS, it seems children and teens face increasing pressure to meet unrealistic and harmful expectations about what they should look like. Strict societal standards surrounding beauty, body build, shape and weight can make it difficult for anyone, especially children, to feel comfortable in their own skin, while the quest for the ideal body or appearance can threaten confidence and compromise physical and mental health.[1]

Simply stated, the term "body image" is the way in which people view their own bodies. It is part of a person's overall self-image. In general, children who have a healthy body image have positive feelings about their bodies. They're comfortable with how they look, and they're satisfied with their physical abilities, how their bodies move and the rate at which their bodies are growing. Having a healthy body image boosts kids' confidence and self-esteem, while children who don't feel good about their bodies or their appearance have a poorer self-image.[2]

Children and teens who think negatively about their bodies not only suffer from lower self-esteem, but they are also at an increased risk of depression, substance abuse, eating disorders and unhealthy body weight (being underweight or overweight). In some cases, teenagers with an unhealthy body image might choose to engage in risky behaviors, such as ignoring schoolwork or participating in illegal behaviors, that could affect their future opportunities or lead to trouble with the law.[1]

Because of the many changes that take place during puberty, the topic of body image really comes into focus during the adolescent years. But surprisingly, the development of a healthy body image in children can start as early as infancy and toddlerhood, so it's imperative that parents engage in open and honest communication with their children from a young age to foster a healthy body image.[1]

Set a Good Example

One of the most powerful influences on children's body image is the way in which their parents act and speak about their own bodies. What are their beliefs about dieting and weight? Do they get down on themselves if they miss a workout? Parents must remember that even if they think their words and attitudes pertain only to them, their children are watching and listening, and they may eventually mimic their behavior.[3]

As parents, our words and actions can actually be harmful to our children's body image. If we're constantly asking if our clothes make us "look fat" every time we get dressed, that's what our children are going to remember. To a certain degree, parents need to model being comfortable with their bodies and show outward appreciation for what their bodies allow them to do.[4]

Other unhealthy behaviors to avoid include:

- Making comments that link being thin to being attractive, popular or healthy.[3]
- Comparing your body to other people's bodies.[3]
- Criticizing other people, including family members, for the way they look.
- Pushing children and teens to achieve beyond their abilities in school, sports or other activities.[3]
- Not taking part in activities with your children, such as having your photo taken or swimming/going to the beach, because of how you perceive your body.[1]
- Skipping meals or punishing yourself for eating something considered unhealthy.[1] For example, making comments about how "bad" you've been if you eat a cookie, or saying things like, "This is going straight to my thighs," is not helpful at all.[4]

Body Image in Growing Children

A healthy body image develops over time, starting in infancy and evolving as kids grow and go through puberty.[2] At each and every stage, parents can help support their child's healthy body image.

Starting in grade school, children may become more aware of their own bodies as they compare themselves to others. Although it may seem obvious, parents should remember to compliment their children for the things they do, and not simply for how they look; try to focus on something other than their height, weight, body size or body shape. Mention the child's personality, achievements in school, activity level and other healthy lifestyle choices. Praise them for the things that make them different from other people.[3]

Parents can also help their kids incorporate movement into their daily routine. Getting into the habit of some form of exercise can set children up for a life that prioritizes healthy movement. Have kids experiment with different kinds of sports and activities until they find something they enjoy. Leading a more active lifestyle will help them recognize that being in good physical shape isn't just about "looking good"; it also gives kids more stamina to do the things they like to do.[4] Exercise is also an effective mood booster and a great way to blow off stress and anxiety.

But just like with attitude and positive talk, parents need to be a model for an active lifestyle, too. This can mean involving children in the parents' activities, such as inviting them to go on the parents' daily walk, or simply saying to the child, "I'm heading to the gym," or "I'm going for a jog," to show them that being active is an essential part of living.[4]

Body Image in Teens and Young Adults

During adolescence, it can be difficult to maintain a healthy body image not only because of major physical and emotional changes that take place, but also the many social pressures that occur during this phase of life.[1] Adolescents often become extremely concerned about their bodies and their weight. The opinions of their peers matters more than ever, and it doesn't help that they are exposed to unrealistic media images of the "ideal body" on a daily basis.[3]

Parents may be at a loss as to how they can help their adolescent child develop a healthy body image with everything that is working against them. One thing that is effective, though, is listening to the child's concerns and acknowledging the reality of their feelings. They can let teenage children know that at times they have had not-so-positive feelings about their bodies, too, and while they have dealt with similar thoughts and feelings, it wasn't the focus of their life; it didn't stop them from being who they wanted to be, or doing the things they wanted to do.[4]

Another part of fostering a positive body image, especially in girls, involves limiting their exposure to the most body-obsessed parts of pop culture, including what they watch on TV and who they follow on social media. It won't be possible to shield them from every influencer who is vying for their attention, trying to impress upon them what the "perfect" figure looks like (or the perfect lips, or the perfect eyebrows, etc.), especially as they grow older and more independent. But if parents are in the room when their teens are watching certain shows or scrolling through reels on social media, they shouldn't be afraid to speak up and point out how foolish the behaviors are that they are witnessing. It's totally OK to make comments like, "Man, that woman is really obsessed with her looks. Isn't that sad? She has so much more to offer."[4]

Accepting Our Bodies as Who We Are

Most people don't love every single thing about their appearance, but for the most part, we accept it as part of who we are and what makes us different from everyone else. If parents find that their children are struggling with an unhealthy body image, they should first be sympathetic and offer a listening ear. They might also consider talking to their children's primary care provider or a mental health professional who can provide children with the tools necessary to stand up against social pressure and start to feel good about their bodies.[1] IG

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Protecting Your Skin from the Sun

By Rachel Maier, MS

LOVE TO SOAK up the sun? You might want to protect your skin with more than just sunscreen before you spend lazy afternoons by the pool this summer. As wonderful as those warming rays may feel, they contain ultraviolet (UV) radiation that damages your skin. Sunscreen is a fantastic first step, but keeping your skin safe and healthy involves more than remembering to reapply every 80 minutes.

Why Is Sunlight Harmful?

Sunlight isn't *all* bad. It helps your body produce vitamin D, an important nutrient your bones need to stay strong; it boosts your mood by increasing serotonin levels; and it helps improve sleep by regulating your circadian rhythm. However, exposure to any amount of sunlight that results in sunburn compromises your skin's health. The sun's UV rays damage the DNA in skin cells, producing genetic mutations that can lead to premature aging and skin cancer. UV rays can also damage the eyes, causing cataracts, macular degeneration, corneal sunburns and eye or eyelid cancers.[1]

How to Protect Yourself

A trio of sunscreen, shade and protective clothing guard against the harmful effects of the sun's UV rays:

Sunscreen: No matter what sunscreen you prefer (spray, cream, stick), look for broad-spectrum, sun protection factor (SPF) 30 (or higher) and water resistance. Broad spectrum means the sunscreen protects against both UVA and UVB rays. The SPF number is a measure of how much UV radiation it takes to produce a sunburn on protected skin (e.g., skin with sunscreen applied to it) relative to the energy required to produce a sunburn on unprotected skin. And don't forget your lips need protection too! Make sure to use lip balm with SPF 30 or higher.

Shade: Seek out a shaded park bench; lounge beneath a pop-up canopy made of fabric with UV protection factor of 30 or higher while at the beach; wear a wide-brim hat (bonus if it is made of UV-protected materials) when a shade structure isn't available; and make sure to wear sunglasses with 100 percent UV-protected lenses, which filter out all harmful UV radiation.[1] In fact, UV rays can penetrate clouds, so sunglasses are a good idea on overcast days as well.

Protective clothing: Look for specialty clothing pieces made with fabrics that carry a UV protection factor (UPF). UPF measures the amount of UV radiation that can penetrate the fabric and reach your skin. UPF 50+ blocks 98 percent of the sun's rays. Coolibar sun protection clothing was the first clothing line to receive the Skin Cancer Foundation's (SCF's) Seal of Recommendation, which is given to products that meet the foundation's criteria for safe and effective sun protection when used as directed.

Prioritize Sun Safety All Year

Everyone — no matter your skin tone — should prioritize sun protection. Fair skin tones burn more easily than dark skin tones, but darker skin tones can still become damaged by overexposure to the sun. People with all skin tones should wear broad spectrum sunscreen that is at least SPF 30 or higher; reapply sunscreen after swimming or every two hours; and avoid direct sunlight during peak hours (10 a.m. to 2 p.m.) because the sun's rays are the strongest during that time. And remember: The sun's rays can cause damage all year, whether it is a cloudy winter morning or a hot summer afternoon. Use a daily moisturizer with SPF 30 or higher; wear sunglasses regardless of the weather; and check out the shopping guide for other great products to help protect your skin this summer and all year long.

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

Cetaphil Daily Facial Moisturizer

Daily sun protection doesn't have to leave your skin greasy: This nourishing lightweight facial moisturizer absorbs quickly, leaves a matte finish and contains broad spectrum SPF 35 to protect against damaging UVA and UVB sun rays. Bonus? Its unique blend of antioxidants protects against surface free radical damage. Dermatologist tested and clinically proven to be gentle on sensitive skin, it is hypoallergenic, non-comedogenic, fragrance-free, paraben-free and oil-free, and it received the SCF Seal of Recommendation. *$15.99; www.cetaphil.com/us/moisturizers/daily-facial-moisturizer-spf-35/302994113002.html*

I-Sea Polarized Sunglasses

Family-owned and operated in California, I-SEA Sunglasses handcrafts exclusive, limited-batch sunnies with polarized, 100 percent UV-protected lenses at low prices. Designed to flatter any and all face shapes, these sunglasses are stylish and affordable.

Start at $28; i-sea.com/collections

Shopping Guide for Sun Protection

Coolibar Sun Protective Clothing and Hats

For more than 20 years, Coolibar has been innovating UPF 50+ fabrics and making UPF clothing guaranteed to block 98 percent of UVA/UVB rays. From tees and tunics to swimwear and shawls, Coolibar offers a variety of options to keep you and your family protected from the sun, no matter where life takes you. Its UPF sun protective clothing, sun hats and sun protective swimwear provide the highest UV protection available to keep the whole family cool, comfortable, sun safe — and looking great! It has the SCF Seal of Recommendation.

Child pieces start at $29; adult pieces start at $59; www.coolibar.com

Cetaphil Sheer Mineral Sunscreen Face Drops

This ultra-lightweight sunscreen dries with a matte finish, making it ideal for application under makeup or for daily wear by itself. Formulated with antioxidant vitamin E to help defend against surface free radicals, it has 100 percent mineral active SPF 50 and reflects UVA/UVB rays to protect skin and prevent sunburn. It blends quickly into the skin without leaving a greasy residue and is water-resistant for up to 80 minutes. It has the SCF Seal of Recommendation.

$14.99; www.cetaphil.com/us/sunscreens/sheer-mineral-sunscreen-face-drops-spf-50/302994110001.html

GCI SunShade Rocker

Rock, relax and stay cool under the sun! The SunShade Rocker is your all-in-one outdoor comfort solution, featuring patented spring-action rocking technology and an adjustable SPF 50+ sun shade that rotates front to back for ultimate sun protection.

$90; gcioutdoor.com/collections/rockers/products/sunshade-rocker

Burt's Bees Sun Care Coco Loco Lip Balm

Infused with zinc oxide, this SPF 30, coconut-scented lip balm provides the benefits of mineral sunscreen without the typical whitening appearance and is also water-resistant for up to 80 minutes. It protects and nourishes lips to leave them feeling richly moisturized and soft. It has the SCF Seal of Recommendation.

$4.79; www.burtsbees.com/product/coco-loco-spf-30-lip-balm

octagam® 10%

Immune Globulin
Intravenous (Human) 10%
Liquid Preparation

For the treatment of dermatomyositis (DM) in adults

Reach further with OCTAGAM 10%

The first and only IVIg
FDA approved for DM

Not actual patient
IVIg=intravenous immunoglobulin.

INDICATIONS AND USAGE

OCTAGAM 10% is indicated for the treatment of chronic immune thrombocytopenic purpura (cITP) in adults and dermatomyositis (DM) in adults. For patients with cITP, it is used to rapidly increase the platelet count in the blood to help control or prevent bleeding. For patients with DM, it helps improve muscle function and skin rash.

OCTAGAM 10% is a liquid medication that contains Immunoglobulin G (IgG). OCTAGAM 10% is made from human plasma donated by healthy people. OCTAGAM 10% is given through the vein (intravenously) in a hospital, infusion center, or at home.

IMPORTANT SAFETY INFORMATION

- Do not use OCTAGAM 10% if you have had a severe allergic reaction to IgG or other blood products or have deficiencies of immunoglobulin A (IgA) with antibodies to IgA.
- OCTAGAM 10% can cause the following:
  - Blood clots in your heart, brain, lungs or other areas of your body
  - Kidney problems, or kidney failure
- Tell your healthcare provider (HCP) if you have an allergy to corn. OCTAGAM 10% contains a type of sugar that is made from corn.
- OCTAGAM 10% can cause the following serious side effects. Contact your HCP if you experience the following:
  - Swelling in your mouth or throat, hives/itching, breathing problems, wheezing, fainting, tightness in your chest, or dizziness. This could be a serious allergic reaction.
  - Decreased urination, swelling in your legs, sudden weight gain, or breathing problems, which could mean kidney failure
  - Pain and/or swelling of an arm or leg with warmth in the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens with deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body; these could be signs of a blood clot.
  - Yellow skin or eyes, dark-colored urine, fatigue, or increased heart rate, which could be signs of a blood problem.
  - Headache, stiff neck, drowsiness, fever, sensitivity to light, painful eye movements, or nausea and vomiting, which could mean an inflammation of the membranes covering your brain or spinal cord
  - Trouble breathing, chest pain, blue lips, arms or legs, and fever, which could be related to a lung problem. This typically occurs 1 to 6 hours following infusion.

OCTAGAM 10% helped patients achieve greater improvement in DM symptoms compared to placebo

In a clinical trial, 95 adults with dermatomyositis (DM) were split into two groups. Group 1 was given OCTAGAM 10% and Group 2 was given placebo. Patients in both treatment groups could continue taking their other medications while they were part of the trial. The clinical trial looked at how patients improved in DM muscle and skin symptoms. Researchers measured 3 levels of symptom improvement after 16 weeks: minimal, moderate, and major.*

*Symptoms were measured on a 100-point scale as measured by the Total Improvement Score (TIS), with 0 being worsening or no improvement and 100 being the most improvement. An improvement of at least 20 points was considered minimal; at least 40 points was considered moderate; and at least 60 points was considered major.

79%
At least minimal improvement
vs 44% placebo
(primary endpoint)

68%
At least moderate improvement
vs 23% placebo
(secondary endpoint)

32%
Major improvement
vs 8% placebo
(secondary endpoint)

Patients treated with OCTAGAM 10% saw
symptom improvement in 35 days†

†Based on measuring median time to (at least) minimal improvement.

Most common drug-related side effects

In a clinical study, more than 5% of patients had the following side effects:

Headache: 42%; **Fever:** 19%; **Nausea:** 16%; **Vomiting:** 8%; **Chills:** 7%; **Musculoskeletal pain:** 7%; **Blood pressure increased:** 6%

Eligible patients may pay as little as $0 with the OCTAGAM 10% Co-Pay Program‡

May reduce out-of-pocket costs by up to $12,500 per calendar year.

‡Terms and conditions apply. See full Terms and Conditions at **Octagam10CoPay.com**

Pfizer IGuide™ is committed to providing access solutions for patients prescribed OCTAGAM 10%.

Call 1-844-448-4337, Monday through Friday, 8 AM to 8 PM ET, or visit www.PfizerIGuide.com

Common side effects include headache, fever, nausea, vomiting, increased blood pressure, chills, musculoskeletal pain, dyspnea, infusion site reactions, and increased heart rate.

If you use a blood glucose monitor, check with your HCP to ensure that your monitor and test strips are acceptable to use while you are receiving OCTAGAM 10%.

These are not all of the possible side effects with OCTAGAM 10%. Tell your HCPs about any side effects that you have that cause concern or don't go away.

Talk to your doctor or visit OctagamInfo.com to learn more

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 U.S. 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.

Please see Brief Summary of full Prescribing Information on following page and full Prescribing Information, including complete BOXED WARNING, at OctagamInfo.com

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Immune Globulin
Intravenous (Human) 10%
Liquid Preparation

CONSUMER BRIEF SUMMARY

This brief summary highlights the most important information about OCTAGAM 10%. Please read it carefully before receiving OCTAGAM 10% 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 (HCP) about your medical condition or your treatment. If you have any questions after reading this, ask your HCP. For more information, go to OctagamInfo.com/Octagam-10.

What is OCTAGAM 10%?

OCTAGAM 10% is a liquid medication that contains Immunoglobulin G (IgG). OCTAGAM 10% is used to treat chronic immune thrombocytopenic purpura (cITP) in adults and dermatomyositis (DM) in adults.

OCTAGAM 10% is made from human plasma donated by healthy people. For patients with cITP, it is used to rapidly increase the platelet count in the blood to help control or prevent bleeding. For patients with DM, it helps improve muscle function and skin rash.

OCTAGAM 10% is given through the vein (intravenously) in a hospital, infusion center, or at home by a trained HCP.

WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- **Thrombosis may occur with immune globulin intravenous (IgIV) products, including OCTAGAM 10% liquid. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IgIV products, including OCTAGAM 10% liquid. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IgIV products containing sucrose. OCTAGAM 10% liquid does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer OCTAGAM 10% liquid 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.**

Who should NOT use OCTAGAM 10%?

Tell your HCP if you:

- Have had a severe allergic reaction to IgG or other blood products
- Have deficiencies of immunoglobulin A (IgA) with antibodies to IgA

What should I know before receiving OCTAGAM 10%?

OCTAGAM 10% can cause the following:

- Blood clots in your heart, brain, lungs or other areas of your body
- Kidney problems, or kidney failure

- Tell your HCP if you have an allergy to corn. OCTAGAM 10% contains a type of sugar that is made from corn.
- If you use a blood glucose monitor, check with your HCP to ensure that your monitor and test strips are acceptable to use while you are receiving OCTAGAM 10%

OCTAGAM 10% can cause the following serious side effects. Contact your HCP if you experience the following:

- Swelling in your mouth or throat, hives/itching, breathing problems, wheezing, fainting, tightness in your chest, or dizziness. This could be a serious allergic reaction.
- Decreased urination, swelling in your legs, sudden weight gain, or breathing problems, which could mean kidney failure.
- Pain and/or swelling of an arm or leg with warmth in the affected area, discoloration of an arm or leg, unexplained shortness of breath, chest pain or discomfort that worsens with deep breathing, unexplained rapid pulse, or numbness or weakness on one side of the body; these could be signs of a blood clot.
- Yellow skin or eyes, dark-colored urine, fatigue, or increased heart rate, which could be signs of a blood problem.
- Headache, stiff neck, drowsiness, fever, sensitivity to light, painful eye movements, or nausea and vomiting, which could mean an inflammation of the membranes covering your brain or spinal cord.
- Trouble breathing, chest pain, blue lips, arms or legs, and fever, which could be related to a lung problem. This typically occurs 1 to 6 hours following infusion.

What are the possible or reasonably likely side effects of OCTAGAM 10%?

Common side effects include headache, fever, nausea, vomiting, increased blood pressure, chills, musculoskeletal pain, dyspnea, infusion site reactions, and increased heart rate.

These are not all the possible side effects with OCTAGAM 10%. Tell your HCP about any side effects that you have that cause concern or do not go away. If you encounter any problems or experience side effects during or after the infusion, contact your HCP. When doing so, keep your therapy tracker with you to be able to give all necessary information.

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.

This brief summary is based on the OCTAGAM 10% Prescribing Information (March 2022).

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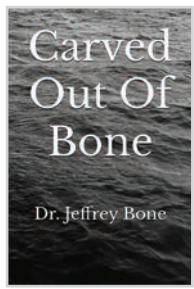


Carved Out Of Bone: Poems of Chronic Pain and Illness, Vol. II

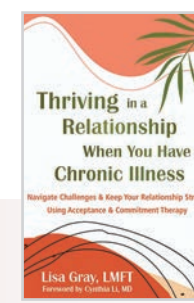
Author: Dr. Jeffrey Kitts Bone
Publisher: Independently Published

Dr. Jeffrey Bone's second poetry collection offers an intimate exploration of the challenges faced by individuals living with chronic conditions. Drawing from his experiences as a psychologist and a patient with common variable immune deficiency, Dr. Bone combines vivid imagery and raw emotion to capture the complexities of living with ongoing pain, illness and the accompanying emotional toll. The poems reflect themes of vulnerability, resilience and the often-overlooked narratives of those managing invisible illnesses. By weaving personal insight with universal truths about the human condition, Dr. Bone crafts a poignant and empowering collection.

Thriving in a Relationship When You Have Chronic Illness: Navigate Challenges and Keep Your Relationship Strong Using Acceptance and Commitment Therapy

Author: Lisa Gray, LMFT
Publisher: New Harbinger Publications

Grounded in evidence-based acceptance and commitment therapy (ACT), this grief-informed guide offers powerful skills to help chronic illness patients and their partners adjust to a chronic illness diagnosis, communicate effectively and protect their bond at each stage of the journey for a lasting and healthy relationship. Included are positive coping strategies to help manage difficult emotions such as anger, sadness and grief; promote intimacy and understanding; and identify what truly matters to move forward in life with values closely aligned.



New and Useful Reading

Tend to Your Spirit: Mindful Living with Chronic Illness

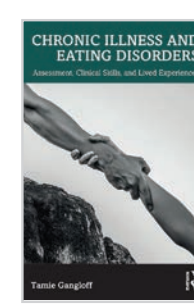
Authors: Florence Caplow and Julianne Lepp
Publisher: Skinner House Books

Tend to Your Spirit offers tools to help readers practice self-compassion and self-care. With candor and vulnerability, spiritual leaders Julianne Lepp and Florence Caplow, both of whom live with long-term illness, offer insights and practices that can benefit anyone facing the emotional impact of a new or ongoing condition. Structured metaphorically around the four seasons, each chapter is devoted to a particular aspect of life with chronic illness, such as grief, hope, perseverance, anger, comfort and finding connection. Interviews and quotes from people with chronic illness of all ages and backgrounds help readers feel less alone.

Chronic Illness and Eating Disorders: Assessment, Clinical Skills, and Lived Experiences, 1st Edition

Author: Tamie Gangloff
Publisher: Routledge

This book explores the intricacies of those with chronic illness and how it can lead to disordered eating. Chapters cover lifelong and acquired illnesses and conditions, visible and invisible disabilities, sports injuries, chronic pain, grief and more. The author examines how each of these conditions can affect appetite, body image and overall perception of food and health. Treatments such as eye movement desensitization, reprocessing therapy and cognitive behavioral therapy are discussed alongside mindful approaches such as body neutrality.



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
- The Stiff Person Syndrome Research Foundation: stiffperson.org

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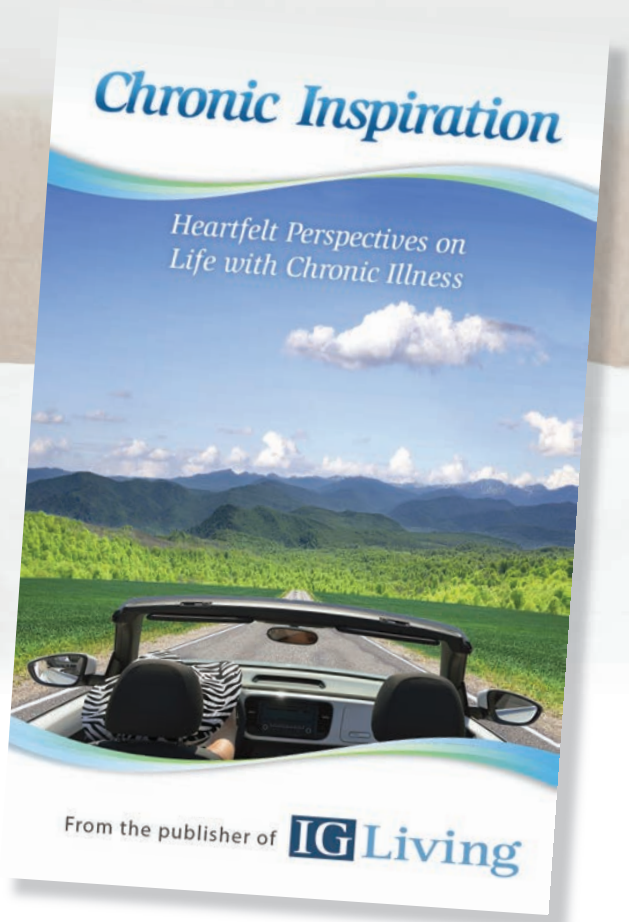

"You can lament what is lost to you, whether it's opportunity, a person or your health, but clinging to anger is no way to experience life." — Rebecca Zook in "Life Lessons," excerpted from *Chronic Inspiration*.

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.

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— Jenny Gardner

IG Living

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

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