IGLiving

August-September 2024

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PI & Mental Health

How to Navigate Chronic Illness on Your Own

Managing College Life with a Chronic Illness

Exercise: An Important Part of Disease Management

Understanding the Plasma Donation Process

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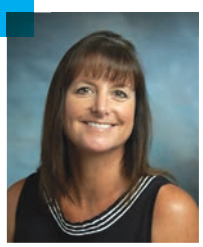
About IG Living
IG Living magazine brings together patients, advocates and caregivers in the immune globulin (IG) community.

IG Living, (ISSN 1949-4548), published bimonthly, is a community service provided by FFF Enterprises, 44000 Winchester Road, Temecula, CA 92590, (800) 843-7477 x1362, fax (951) 699-9655.

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

Coping Strategies Ease the Chronic Illness Burden



IF YOU'VE BEEN diagnosed with an illness that requires immune globulin treatment, you most likely have a lifelong chronic illness that can cause you to be overwhelmed by the responsibilities of managing appointments, insurance and financial stressors, all while juggling life responsibilities and experiencing physical discomfort. Unfortunately, this can lead to chronic illness burnout, unless you take the time to apply strategies to help you cope with your situation.

One of the major effects of chronic illness burnout is the impact it can take on your mental health. In fact, studies show that more than 20 percent of individuals diagnosed with a primary immunodeficiency (PI) have been diagnosed with at least one psychiatric disorder compared to those without PI. We examine the relationship among PI and psychiatric disorders, as well as how to lessen its burden in our article "Navigating the Psychological Landscape of Primary Immune Deficiencies: Empowering Patients and Families" (p.22). It's now known that a combination of immune-related conditions (i.e., having a PI and an autoimmune disorder), gender (females are more likely to be affected by psychiatric disorders) and pregnancy often are factors that can worsen mental health outcomes. But these can be combatted with supportive strategies such as support groups, physical activity, diet, sleep and more.

Having a support system to deal with your chronic illness can also ease the burden. Unfortunately, not everyone has the support of family and friends and, instead, must deal with their chronic illness journey alone. If that is the case for you, we offer some strategies to help you manage on your own in our article "Thriving Alone: Strategies for Navigating Chronic Illness on Your Own" (p.26). It can help to first acknowledge and accept your feelings, followed by educating yourself about your condition, advocating for yourself, structuring how you deal with life in a way that's right for you, utilizing smart technology, seeking professional help when needed, and treating yourself with kindness and understanding.

If you're a young adult heading off to college, managing campus life, classes and your chronic illness might seem impossible. But, rest assured, it is doable with an "I CAN" attitude. As we explain in our article "Coping with Chronic Illness at College" (p.32), the "I CAN" acronym stands for 1) Investigating by learning about your rights, responsibilities and resources, 2) Communicating with the school about your needs, 3) Asking for accommodations and 4) Nurturing healthy habits.

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, MS

IGLiving

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

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At **FFF Enterprises**, we understand the critical nature of your work. Every transaction you make provides essential plasma products for patients in need. That's why we are dedicated to being your reliable supplier of safe and effective plasma products, including immune globulin (IG), hyperimmune globulin, coagulation, and albumin therapies.

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  - *IG Reimbursement Calculator*
  - *IG Reference Charts*
  - *IG Living, a magazine dedicated to the IG community*

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Remembering the Meaning of Chronic

By Abbie Cornett, MBA

SOMETIMES, patients with a chronic illness such as primary immunodeficiency (PI) forget the true meaning of "chronic." I am a prime example of this. After years of relative health, I began to believe that my condition had somehow disappeared. Logically, I knew I had not been miraculously cured, but illogically, I felt as if I was somehow free from my illness.

However, over the past year, my health has taken a downturn. I've found myself sick and on antibiotics every five weeks. This change has taken me aback: I seemingly forgot that chronic means forever.

Living with a chronic illness requires accepting it is lifelong and needs ongoing management and adaptation.

A chronic condition is one that lasts 12 months or more and either places limits on self-care, independent living and social interactions, or results in the need for ongoing intervention with medical products, services and special equipment (or both).[1]

This reality hit me hard. Even more surprising were the feelings and doubts that resurfaced. I keep asking myself, "What did I do wrong?" All the old questions and self-blame came rushing back.

Living with a chronic illness requires accepting it is lifelong and needs ongoing management and adaptation. Here are some strategies to help:

1) *Accept reality.* Understand chronic means forever. Accepting this is not about resignation or giving up hope; it is about acknowledging your reality, preparing for ups and downs and finding ways to live *your* best life.

2) *Get the medical help you need.* Regular medical care is essential. Get routine check-ups, stay on top of prescribed treatments and seek medical advice promptly when needed.

3) *Take care of yourself.* Recognize you chronic illness is not your fault. Seek support from mental health professionals, join support groups or talk to friends and family to help manage your feelings.[2] Practice self-care: Eat a balanced diet, get regular exercise, ensure adequate sleep and avoid stress.

4) *Set realistic goals.* Set realistic, achievable goals; they provide a sense of purpose and accomplishment. Celebrate small victories and recognize progress.

5) *Stay educated.* Understand the nature of your illness, potential complications and new treatments or therapies. Knowledge empowers you to make better decisions about your health and manage your condition more effectively.[3]

6) *Be kind to yourself.* There will be days when it feels like everything is going wrong, and it's easy to be hard on yourself. Remember you are doing your best under difficult circumstances. Be kind to yourself and allow yourself to feel and process your emotions.

7) *Adapt and adjust.* Flexibility is key. Your condition may change over time; being able to adapt and adjust your lifestyle, treatment plans and coping strategies is important. This might mean making changes to your daily routine, work schedule or social activities.

8) *Find joy and meaning.* Do something you enjoy — a hobby, spending time with loved ones or simply enjoying nature. It will make a difference in your overall well-being.

Living with a chronic illness is filled with ups and downs, stability and setbacks. It is challenging, but these strategies can help you better manage your health and live a fulfilling and meaningful life. It's about finding balance between accepting the chronic nature of your illness and not letting it define your life. You can still find ways to thrive, seek joy and maintain a sense of normalcy amid the challenges. Now, I just need to remind myself to practice what I preach. IG

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3. Koumadoraki, A. 6 Benefits of Patient Education and How to Educate Patients. LearnWorlds, Sept. 21, 2022. Accessed at www.learnworlds.com/patient-education.

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.

Can You Say "No"?

I'm getting better at it. I am a huge people pleaser. But I can't help others if I don't prioritize my health.

Yes, but it took a while to get to the point where my health came first.

Do You Know How to Manage Medication Side Effects?

I learned that if my body suffers side effects from a treatment or medication, it is time for a different therapy. Myasthenia gravis is hard enough. Adding other issues to that is not an option for me.

I have negative side effects from my intravenous immune globulin infusions. We have had to break it into three days, first because it's such a big dose, but also because I need so much Benadryl and Zofran. It's a really rough time every four weeks. I wish there was a better way than having to have so much steroids and Benadryl pumped into my system.

I do subcutaneous immune globulin (SCIG) two times weekly due to my need for a high dosage. The steroids caused too much anxiety and depression. Also, they lower your immune system, which none of us need. So when the SCIG came out well over 10 years ago, I got on board and have had minimal side effects. By doing it this way, I'm never so "depleted" of immune response. I used to dread being to week three, as I knew I'd be in rough shape. I had some welts initially, but that is very minimal now. I'm so grateful to be at home in my own environment as well!

Does Chronic Illness Lead to Loneliness?

If you let it. At times, it does feel loneliness takes over me. But I have a support team: my best friend, my admission nurses, my chemo port nurses who administer intravenous immune globulin to me, the hospital volunteer who brings me snacks and sudoku puzzles. I visit the zoo, parks and beaches. Window shopping is always fun. I've learned to overcome my struggles.

Absolutely. Having a chronic illness, particularly one that is very disabling, can be extremely isolating. Knowing that there is literally no one else on the planet who experiences exactly what you experience is quite lonely, too.

It can, but we have to reach out to others to prevent this.

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.

Can Prolonged Use of IVIG Cause Large Granulocyte Lymphatic Leukemia?

I have chronic inflammatory demyelinating polyneuropathy, and I have been treated with intravenous immune globulin (IVIG) for almost two years. I now have an elevated lymphocyte count at 74 percent and a neutropenia count of 1.04. My doctors are thinking it may be large granulocyte lymphatic leukemia, and I am wondering if this could be caused by my prolonged use of IVIG. Is that possible?

Abbie: I spoke with Leslie Vaughan, RPh, CSP, IgCP, and Michelle Greer, RN, IgCN, chief operations officer and executive vice president of sales, respectively, at Nufactor, a specialty infusion company, and they said they are unable to find anything that would support IVIG as the cause of elevated lymphocytes. They did say there is information on transient neutropenia following high-dose IVIG, but it generally resolves within 14 days of IVIG administration.

What Are the Pros and Cons of Ports for IG Treatment?

I was diagnosed with an IgG deficiency, and it was suggested I begin treatment with immune globulin (IG) via a port. I am wondering if you have any articles on the pros and cons of this, or anything else that could be beneficial?

Abbie: Before you make any decision about having a port, it's crucial to discuss your treatment plan thoroughly with your treating physician. He or she can provide personalized guidance based on your medical history, specific condition and treatment needs.

There are advantages and disadvantages of having a port. Ports eliminate the need for multiple needle sticks, which can be particularly beneficial for individuals who experience anxiety or discomfort from frequent venous access. For patients with compromised peripheral veins due to repeated needle sticks or medications, a port provides a reliable and easily accessible route for administering medications and fluids. Ports can also streamline the administration of IG therapy, potentially reducing the time needed for infusions and improving overall treatment experience.

However, ports pose a risk of infection since they provide a direct conduit for organisms into the bloodstream. Proper sterile techniques must be followed during port access to minimize this risk. Ports require a surgical procedure for placement, which carries inherent risks and may cause scarring. Additionally, the vein into which the port is placed may be sacrificed, limiting future venous access. Ports can also lead to complications such as thrombosis and infection, requiring prompt medical attention and possibly hospitalization.

Ultimately, the decision to use a port for IG therapy is a personal one that should be made in consultation with your physician.

» 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.

How Thinking About Death Can Improve Your Life

By Mairead McConnell, PhD

HAVE YOU ever heard the phrase "Live like you are dying"? It refers to the approach of living life as if you have limited time, including taking advantage of opportunities, cherishing loved ones and making the most of every moment. While this may seem like an impractical way to live one's daily life, there are psychological benefits to living with this perspective. And it is also realistic: We all have finite time.

Death is an undeniable reality of life. And yet, most people in our Western culture cope with death by avoiding or denying it. This tendency is understandable: The uncontrollability, uncertainty and permanence of death make it quite scary for many of us to face. For those living with illness, whether chronic or life-threatening, death anxiety can be even more present and challenging to manage.

While it may be uncomfortable at first, thinking about your own death and even planning for the end of your life — no matter how far away it may be — can provide benefits to both you and your loved ones in the present and future.

Clarify your values. When we live our lives as if we have unlimited time, we can begin to lose sight of the bigger picture and lose focus on what matters most. The demands of daily life force us into autopilot, where we are operating out of habit rather than from true alignment with our values. Consider trying this simple thought experiment: Imagine you are watching your own funeral. Imagine the people you hope would attend. What would you like to hear them say about you? What kinds of words would you like people to use to describe you and your life? What do you hope they remember most vividly about you? Now, return to the present moment. What is one step you can take today to live more aligned with that description and to be that person by the time you die?

How important is it? Life is full of challenges, inconveniences, difficult decisions and disappointments. It is normal to experience these, and also normal to have feelings about them, from impatience or anxiety to frustration or anger. These are all normal parts of life, and yet, thinking about death can actually help put these moments into perspective. Next time you notice yourself struggling with a decision or feeling anxious about something relatively small, ask yourself: How important will this be to me at the end of my life? When I look back years from now, how much will this matter? If it is something that won't matter to you years down the road, notice that feeling and give yourself permission to let it go.

Say it now. Relationships are among the most precious things we have in this life. It is truly never too early or too soon to tell the people in your life how you feel about them, so consider telling them what they mean to you. You can choose to write it in a card or a letter or tell them over the phone; even a simple text message will do. It is also never too early to share your wishes for the end of your life and after you are gone. Families who have discussed these topics in advance experience less conflict and distress, and are able to focus on grieving and celebrating their loved one's life rather than guessing what they would have wanted.

"There's no time like the present." That phrase may be a cliché, but it is also true. Life is always busy, and there are always reasons not to do something, but life does not last forever. If you can manage to do it now, go for it! Book the long-awaited trip; take the class you keep thinking about; call the friend you haven't talked to in years but keep meaning to catch up with. Most people regret waiting too long or until it is "too late" to do the things they want to do. It is rarely too early. Now is a great time.

If you struggle with overwhelming death anxiety or would like to address these topics more deeply, consider searching for a therapist using Psychology Today's therapist finder tool. You can select "existential" as the type of therapy to find providers who specialize in processing death and mortality.

If this topic interests you, consider visiting endwell.org. Endwell is a social movement aimed at helping people live and die better by making the end of life an integrated part of life.

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.

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.

panzyga®
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 a registered trademark of Octapharma AG.

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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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?

PANZYGA is a liquid medicine for infusion that contains immunoglobulin G (IgG), which are proteins that help fight infection. PANZYGA is used to treat 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 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.

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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.**

Who should NOT use PANZYGA?

Tell your healthcare provider 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

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
- 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 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

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. If you encounter any problems or experience side effects during or after the infusion, contact your healthcare provider. 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 PANZYGA Prescribing Information (February 2021).

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SARS-CoV-2 and COVID-19: Why Does Our Immune System Have a Problem with This Virus? Part 2

By Terry O. Harville, MD, PhD

VIRUSES ARE inert. They do not have metabolic activity, thus as a viral particle, they are technically not alive. Instead, they are a form of parasite and depend on living cells to provide them with the resources to reproduce. Therefore, for viruses to function, they must have a pathway to enter into a cell. Frequently, these pathways are common components found on the surfaces of cells, which may not have specific separate functionalities that could be interfered with.

For example, influenza virus binds to a common, modified sugar polymer found on the surface of most cell types, known as "sialic acid." Fortunately, in general, this interaction does not result in other disruptions of cellular function. However, when the influenza virus binds to the sialic acid receptor, it does induce the cell to undergo "endocytosis," a process whereby the virus is engulfed and brought into the cell. Once there, processes then allow for the viral RNA to be released, whereupon it can be translated into proteins that replicate the viral RNA and produce proteins for assembly of new viral particles. Other enveloped viruses may bind to a cell surface receptor, which then allows for fusion of the viral membrane with the cell membrane, and thereby release of the viral nucleic acid contents into the cell for transcription of DNA viruses or translation of RNA viruses, with subsequent protein production and viral replication.

Unfortunately, some viruses utilize important cell surface components as their receptors for entry into cells. As mentioned in my last column, HIV binds to CD4, which is a critical protein expressed on helper T lymphocytes, as well as on a variety of other cell types with important immune functions, including monocytes/macrophages, some forms of dendritic cells, microglial cells, Kupffer cells and renal tubular epithelial cells. Thus, all these cell types can be infected with HIV and act as reservoirs of the virus, allowing for the virus to remain present and not be eradicated in an individual, even if the CD4 T lymphocytes can be replaced.

On the surface of HIV is a protein known as GP120. A specific portion of this protein is known as the V3 loop. The V3 loop specifically binds to CD4, thus initiating the entry into CD4 T lymphocytes, which is where and how immune difficulties arise. If an antibody is generated against the V3 loop, the antibody looks like CD4 (the intended binding target for the V3 loop). While this can then be a blocking or neutralizing antibody, it can also be a target for new antibody production. The new antibody is known as an anti-idiotypic antibody, and it will look like the V3 loop and bind to CD4. This then negates the benefit, since this can interfere with CD4 T lymphocyte function, can possibly kill CD4 T lymphocytes or may even better help HIV enter into CD4 T lymphocytes by helping to bridge HIV particles with the CD4 T lymphocytes (as well as the other immune cells that express CD4). This concept also applies to SARS-CoV-2 (SARS2).

SARS2 has a spike protein on the viral surface, with a specific region known as the receptor binding domain (RBD). As a reminder, vaccines developed for dealing with SARS2 use the spike protein or RBD as the major antigens for antibody production of so-called neutralizing antibodies. The RBD binds specifically to a cell-surface protein, ACE2, for entry into cells. Therefore, as described above, an immunologic dilemma occurs. An antibody generated against the RBD, to act as a blocking or neutralizing antibody, will have a configuration that looks like the ACE2 protein. Then, the anti-idiotypic antibody generated against it will look like the RBD, and it will bind to ACE2. This can then disrupt the function of ACE2 and result in a multitude of problems in patients. I and colleagues were the first to describe this issue.[1,2]

In the next column, I will discuss these concepts in detail regarding SARS2.

References

1. Arthur, JM, Forrest, JC, Boehme, KW, Kennedy, JL, Owens, S, Herzog, C, Liu, J, and Harville, TO. Development of ACE2 Autoantibodies After SARS-CoV-2 Infection. *PLoSONE*, 16(9):e0257016. Accessed at journals.plos.org/plosone/article?id=10.1371/journal.pone.0257016.
2. Harville, TO, and Arthur, JM. Anti-Idiotypic Antibodies in SARS-CoV-2 Infection and Vaccination. *The New England Journal of Medicine*, 386(5): Feb. 2, 2022 Accessed at www.nejm.org/doi/full/10.1056/NEJMc2119443.

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

Diagnosing and Treating Stiff Person Syndrome

By Michelle Greer, RN, IgCN

STIFF PERSON syndrome (SPS) is a rare autoimmune neurological condition of the central nervous system. It was previously named stiff-man syndrome but was updated over the years because SPS can affect either sex, and in fact, it affects women more than men. It can begin at any age but symptoms typically emerge between 30 and 40 years. It is also known as Moersch-Woltman syndrome, since it was first described in 1956 by Frederick Moersch, MD, and Henry Woltman, MD.

Types of SPS

There are three types of SPS: classic, variants and progressive encephalomyelitis with rigidity and myoclonus (PERM).

• *Classic:* Classic SPS is the most common clinical form, present in 70 to 80 percent of SPS patients. It is associated with anti-glutamic acid decarboxylase (anti-GAD) antibodies.[1] GAD is the enzyme that catalyzes the production of GABA, a major neurotransmitter of the central nervous system.[2] Antibodies against GAD can interfere with the signal for the body and muscles to relax. GAD is found in the nervous system and the pancreas; as such, these antibodies are also found in other neurological and autoimmune conditions, particularly type 1 diabetes, as well as pernicious anemia, vitiligo and autoimmune thyroid disease.

• *Variants:* Several clinical variants of SPS have been described and include stiff limb syndrome, jerky SPS, cerebellar variant, SPS with epilepsy and dystonia.[1] There is also a variant that is associated with various forms of cancer in which the SPS manifests prior to the cancer diagnosis.

Like other rare autoimmune neurological conditions, SPS is challenging to diagnose because of the rare incidence and insidious symptoms that can be indicative of many conditions.

• *PERM:* This is the most severe and rare form of SPS. It can involve the brain stem, spinal cord and the autonomic nervous system, and therefore, it can result in breathing problems, trouble with gait and vertigo. Antibodies against glycine receptors have been noted. Glycine receptors play a role in neurotransmission, motor control and pain control.

SPS Symptoms

The primary symptoms of SPS are muscle rigidity and spasms that can be achy or painful. Symptoms can begin as mild and be as common as a sore back. The main area for muscle rigidity and spasms are the trunk and abdominal region; however the legs and arms can also be affected. The rigidity can fluctuate without a clear cause. Over time, it can affect posture, and depending on the type of SPS, it can affect gait and balance. Spasms can occur anywhere and last minutes or hours. They can be triggered by a loud or sudden noise such as a door slamming or thunder, as well as changes in temperature or some sort of physical stimulus. Stress can also be a trigger.

Because symptoms are somewhat unpredictable, people with SPS frequently have anxiety and fear about being out and about because symptoms might be

triggered in a public environment where they don't have as much control over sensation, noise and stress.

Diagnosing SPS

Like other rare autoimmune neurological conditions, SPS is challenging to diagnose because of the rare incidence and insidious symptoms that can be indicative of many conditions. Typically, a neurologist would be the specialist to perform a full neurological assessment, as well as an EMG to measure muscle activity. If SPS is suspected, blood work might be done to look for the presence of anti-GAD. A lumbar puncture might also show anti-GAD, as well as protein in the cerebral spinal fluid, which may be indicative of an immune response. Much of the workup involved in neurological conditions can be as much to rule out other conditions as it is to confirm a diagnosis.

Table. Medications That Treat SPS

Medication	Purpose	Examples
Benzodiazipines	Enhance GABA (the antibody anti-GAD inhibits); enhancing GABA allows the muscles to relax; these medications also improve anxiety and insomnia	Xanax Valium Ativan Klonopin
Muscle relaxants	Treat muscle spasms, reduce muscle stiffness	Baclofen Lioresal
Pain relief/ GABA analogue	Improve neuropathic pain by affecting GABA signals	Gabapentin Other anticonvulsants
Immunosuppressants	Suppress the immune response and activity of anti-GAD	Imuran CellCept
Intravenous immune globulin (IVIG)	Exact mechanism of action unknown; works to suppress the immune response and activity of anti-GAD (Since all health plans have medical policies that outline approval criteria for IVIG in various conditions, it is common to require trials of the above medications to obtain authorization for IVIG)	Asceniv Bivigam Gammagard Gammaked Gammaplex Gamunex-C Octagam Panzyga Privigen

Treating SPS

Once a diagnosis of SPS is confirmed, a treatment plan is determined. A neurologist, preferably one who specializes in immune-mediated neuromuscular conditions, should be managing the treatment plan. Because of the nature of the condition, the treatment plan might consist of medications, physical therapy and/or psychological care through therapy and counseling. There is no cure for SPS. Treatment is aimed at symptom management and promoting optimal functioning.

Medications can include benzodiazipines, baclofen, pain relief/GABA, analogue/immunosuppressants and intravenous immune globulin (Table).

Physical therapy may be required depending on the extent of the impact on muscle function and mobility. In addition to traditional physical therapy, activities such as yoga, stretching, water aerobics and chiropractic treatments can help manage symptoms and improve pain and function. Additional interventions such as acupuncture and acupressure may help. Meditation and breathwork can also assist with relaxation.

Since SPS can lead to anxiety, and anxiety can be a trigger for onset of or an increase in SPS symptoms, it's important to manage anxiety. In addition to some of the medicines used to manage the symptoms of SPS, it's important to implement nonmedicinal interventions. Counseling and therapy can help manage stress and anxiety, as well as meditation, prayer and breathwork. Some newer activities include qigong, a form of exercise that uses a combination of gentle movement, calm breathing and meditation that together can reduce stress and anxiety.

Opt for the Best Healthcare Team

As with any chronic condition, understanding, managing and living with SPS can be frustrating and overwhelming. It's important to get the best healthcare team and get on top of the symptoms to enhance function and control pain and anxiety. IG

References

1. Muranova, A, and Shanina, E. Stiff Person Syndrome. *StatPearls*, Jul. 10, 2023. Accessed at pubmed.ncbi.nlm.nih.gov/34424651.
2. Vianello, M, Tavolato, B, and Giometto, B. Glutamic Acid Decarboxylase Autoantibodies and Neurological Disorders. *Neurological Sciences*, 2002 Oct;23(4):145-51. Accessed at pubmed.ncbi.nlm.nih.gov/12536283.

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

MEDICINES

Hizentra Vials to Be Discontinued and Replaced with Prefilled Syringes

CSL Behring is discontinuing all sizes of Hizentra vials in the U.S. by the end of September 2024. The company is advising that all appropriate vial patients should be transitioned to Hizentra prefilled syringes (PFS), and new Hizentra patients should be started on PFS. Customers, providers and patients will receive a final Hizentra vial discontinuation notification once all Hizentra vial inventory has been exhausted.

The following Hizentra Product SKUs are being discontinued:

- Hizentra 1g/5mL vial 44206-0451-01
- Hizentra 2g/10mL vial 44206-0452-02
- Hizentra 4g/20mL vial 44206-0454-04
- Hizentra 10g/50mL vial 44206-0455-10

After discontinuation of these product SKUs, the following available product SKUs will be available:

- Hizentra 1g/5mL PFS 44206-0456-21
- Hizentra 2g/10mL PFS 44206-0457-22
- Hizentra 4g/20mL PFS 44206-0458-24
- Hizentra 10g/50mL PFS 44206-0455-25

"CSL Behring believes it is in the best interest of Hizentra patients to simplify their infusion process, offering them a simple, convenient and ready-to-use option in Hizentra prefilled syringes that eliminates the need for a vial transfer," said Richard Dudek, vice president of healthcare systems. "CSL Behring is committed to putting patients' needs first, and to delivering innovative, lifesaving medicines to patients."

For additional questions, individuals should contact their CSL Behring associate director of corporate accounts. For any medical/clinical questions, contact CSL Behring's medical information team at (800) 504-5434.

CSL Behring Letter to Customers Titled "Notice: Hizentra Vials to Be Discontinued – All Hizentra Patients to Transition to Prefilled Syringes Hizentra® [immune globulin subcutaneous (human) 20% liquid] Vial SKUs, April 2024.

RESEARCH

Study Reveals Genetic Cause of SCID and Omenn Syndrome

Researchers from Newcastle University, the Wellcome Sanger Institute, the Great North Children's Hospital and their collaborators were able to link mutations in the NUDCD3 gene to severe combined immunodeficiency (SCID) and Omenn syndrome — rare and life-threatening immunodeficiency disorders. These mutations prevented the normal development of diverse immune cells needed to combat different pathogens. According to the researchers, the findings open opportunities for early diagnosis and intervention for these conditions.

In the study, researchers studied 11 children across four families, two of whom had SCID while the other nine had Omenn syndrome. All had inherited mutations that disrupted the function of the NUDCD3 protein, which had not previously been linked to the immune system. Using detailed studies of patient-derived cells and mouse models, the team demonstrated that NUDCD3 mutations impair a crucial gene-rearranging process called V(D)J recombination, essential for generating the diverse T cell receptors and antibodies needed to recognize and fight different pathogens.

Mice engineered with the same NUDCD3 mutations had milder immune problems, but the human patients faced severe, life-threatening consequences. Two patients did survive, however, after receiving a stem cell transplant — reinforcing the importance of early diagnosis and intervention.

While newborn screening methods can flag T cell deficiency, knowledge of the specific genetic cause increases confidence in the diagnosis of SCID and Omenn syndrome and informs the choice of curative therapy. Currently this remains out of reach for at least one in 10 affected families.

"For babies born with high-risk immunodeficiencies, early detection can mean the difference between life and death," said Gosia Trynka, author of the study at the Wellcome Sanger Institute and science director at Open Targets. "These diseases leave newborns essentially defenceless against pathogens that most of us can easily fend off. The identification of this new disease gene will help clinicians to make a prompt molecular diagnosis in affected patients, meaning they can receive life-saving treatments more quickly."

Genetic Cause of Rare Childhood Immune Disorders Discovered. Wellcome Trust Sanger Institute, May 24, 2024. Accessed at www.sciencedaily.com/releases/2024/05/240524171437.htm.

MEDICAL DEVICES

Next-Generation Plasma Collection System Given 510(k) Clearance by FDA

The Rika Plasma Donation System (Rika), the next-generational plasma collection system with the individualized nomogram, iNomi, that can determine the plasma collection volume needed from the donor on the day of collection has been granted 510(k) clearance by the U.S. Food and Drug Administration (FDA). The indication for the 510(k) clearance is for the collection of source plasma with or without saline compensation. Rika is designed and developed to be used in plasma collection centers. Additionally, the device was designed specifically for the comfort and safety of the donor by providing alerts and visual cues to help guide the operator. Designed by Terumo BCT, Rika is just one example within a broad suite of medical devices that can collect, separate and process the blood and cells of donors.

Rika is an automated blood component collection system that uses centrifugal force to properly separate the whole blood into plasma and its remaining cells. Collection takes approximately 35 minutes or less while ensuring there is no more than 200 mL of blood outside of the donor's body at one time, using an advanced control system to guide the providers operating the device. Additionally, iNomi uses each individual donor's characteristics (height, weight and hematocrit levels) to determine the amount of plasma that needs to be collected.

FDA granted Rika 501(k) clearance following results from various testing methods, including clinical trials, performance testing and software testing. In both performance and software testing, Rika utilized its individual nomogram to demonstrate its abilities and performed to its requirements by meeting the needs of its user.

Further, Terumo BCT conducted a prospective, open-label, multicenter study to ensure the collection volume of plasma collected using Rika met the individualized nomogram for plasma donations. The trial enrolled a total of 124 plasma products across two United States sites, and the primary end point was the proportion of plasma products with an acceptable plasma collection volume (determined by the individualized nomogram). According to the results, the investigators observed a procedure success in all procedures (CI 95% 0.976). Additionally, there were no new safety signals observed in the study, and all procedure-emergent adverse events (AEs) were anticipated and previously reported as potential AEs during apheresis donation (as indicated in consent forms). Additionally, there were no serious AEs or unanticipated adverse device effects reported during the study's duration.

"Terumo Blood and Cell Technologies (BCT) continues to innovate for the plasma industry, setting new standards and expanding patient access to care," said Antoinette Gawin, president and CEO at Terumo BCT. "As the need for plasma increases, the Rika ecosystem, now including iNomi, is poised to help meet the demand while offering a potentially more comfortable and efficient experience for plasma donors." IG

McGovern, G. FDA Grants 510(k) Clearance for Rika Plasma Donation System. Pharmacy Times, May 10, 2024. Accessed at www.pharmacytimes.com/view/fda-grants-510-k-clearance-for-rika-plasma-donation-system.

DIAGNOSTIC

Machine Learning Tool Identifies Undiagnosed CVID

A research team from University of California, Los Angeles (UCLA) Health has developed a machine learning model capable of identifying undiagnosed common variable immune deficiency (CVID) by analyzing electronic health record (EHR) data.

PheNet, a machine learning algorithm that identifies patients with CVID from their EHRs learns phenotypic patterns from verified CVID cases and uses this knowledge to rank patients by likelihood of having CVID. According to the researchers, PheNet could have diagnosed more than half of their patients with CVID one or more years earlier than they had been diagnosed. When applied to a large EHR dataset, followed by blinded chart review of the top 100 patients ranked by PheNet, the researchers found that 74 percent were highly probable to have CVID. They externally validated PheNet using more than six million records from disparate medical systems in California and Tennessee.

The researchers say that "as artificial intelligence and machine learning make their way into health care, we show that algorithms such as PheNet can offer clinical benefits by expediting the diagnosis of rare diseases." IG

Johnson, R, Stephens, AV, Mester, R, et al. Electronic Health Record Signatures Identify Undiagnosed Patients with Common Variable Immunodeficiency Disease. *Science Translational Medicine*, Vol. 16, No. 745. Accessed at www.science.org/doi/10.1126/scitranslmed.ade4510.

RESEARCH

Study Shows Interferon Combinations Affect Symptoms of Lupus and Its Treatment

Researchers from Johns Hopkins Medicine revealed that certain combinations of antiviral proteins are responsible for symptoms and affect treatment outcomes for patients with lupus; they suggest the findings could lead to changes in how clinicians treat patients with the condition.

In clinical trials for lupus treatments designed to suppress interferon I, researchers observed that patients' conditions failed to improve, despite genetic testing showing high interferon I levels prior to treatment. The team predicted that two other interferon groups, interferon II and interferon III, could be the reason for poor treatment responses in lupus patients.

Looking at different combinations of interferon I, II and III and their overactivity, researchers took 341 samples from 191 lupus patients to determine the activity of the three interferon groups, using human cell lines engineered to react to the presence of each group to analyze the samples.

They found that most participants fell into four categories: increased interferon; combination of increased interferons I, II and III; combination of increased interferons II and III; and normal interferon levels.

Next, the team made several associations between these interferon combinations and lupus systems. For example, in patients with elevated levels of interferon I, lupus was mainly associated with symptoms affecting the skin, while those with elevated levels of interferon I, II and III showed severe presentations of lupus such as organ system damage.

Eduardo Gómez-Bañuelos, assistant professor of medicine at Johns Hopkins University School of Medicine, explained: "These interferon groups are not isolated; they work as a team in lupus and can give patients different presentations of the disease." Evaluating patients' elevated interferon combinations will offer a better understanding of how they may respond to treatments, said Gómez-Bañuelos, which would allow clinicians to group them into clinical subtypes of lupus. IG

Brogan, J. U.S. Study Reveals Interferon Combinations Cause Lupus Symptoms and Affect Treatment. PharmaTimes, May 15, 2024. Accessed at pharmatimes.com/news/us-study-reveals-antiviral-protein-combinations-cause-lupus-symptoms-and-affect-treatment.

RESEARCH

Cabaletta to Launch Phase I/II Clinical Trial of CAR T-Cell Therapy for SSc Patients

The U.S. Food and Drug Administration (FDA) has cleared Cabaletta Bio's request to begin clinical testing of CABA-201, a cell therapy for adults with hard-to-treat systemic sclerosis (SSc). CABA-201 is a CAR T-cell therapy that targets CD19, a protein found on B cells involved in various autoimmune diseases and blood cancers. It modifies a patient's own immune T cells with a chimeric antigen receptor, called CAR, which is designed to recognize and eliminate disease-driving B cells. It also harbors 4-1BB (also called CD137), a protein involved in T-cell survival and activation.

Cabaletta plans to launch an open-label (meaning there is no placebo arm) Phase I/II clinical trial to evaluate CABA-201's ability to eliminate disease-causing B cells throughout the body, with the goal of slowing or halting active inflammatory disease progression. The trial will enroll SSc patients with severe skin manifestations or organ involvement despite treatment with immune-suppressing medications. It will recruit two groups of six SSc patients, ages 18 to 70: one with severe skin manifestations and the other with organ involvement (heart, lungs, kidneys), regardless of skin manifestations.

FDA also gave Cabaletta the green light to test its CAR T-cell therapy

in people with other autoimmune diseases such as lupus and myositis (muscle inflammation). Phase I/II trials of CABA-201 in lupus and myositis are ongoing, following the same dosing regimen to be used in SSc patients; three-month data is expected early in 2024. IG

Bryson, S. FDA Clears Way for Phase 1/2 Trial of CAR T-Cell Therapy in SSc Patients. Scleroderma, Oct. 3, 2023. Accessed at sclerodermanews.com/news/fda-clears-scleroderma-clinical-trial-caba-201-cell-therapy.

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.

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.

0008-01-2024 3/2024

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Giheung-gu, Yongin-si
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Navigating the Psychological Landscape of Primary Immune Deficiencies: Empowering Patients and Families

While living with PI can affect mental health, strategies to address both psychological and physical health can lessen the burden.

By Abbie Cornett, MBA

LIVING WITH a primary immune deficiency (PI) disorder is a multifaceted journey that encompasses not only the physical manifestations of the condition but also significant emotional and psychological challenges for patients and their families. PIs are rare and complex immune system disorders characterized by an increased susceptibility to infections, autoimmunity, autoinflammatory diseases and other health complications. While the medical aspects of PI often require specialized care and treatment, the psychological impact of living with a chronic illness can be equally profound. Coping with the relentless nature of these health issues can lead to chronic stress, anxiety and depression, affecting every aspect of a patient's life.

The impact of chronic illness on mental health cannot be overlooked and must be addressed alongside immune issues for patients to truly thrive. Unfortunately, the mental health side of patients' health is often disregarded as less important than their physical health. This oversight can leave patients feeling isolated and unsupported in managing their emotional well-being.

Thankfully, the importance of addressing mental health alongside physical health is gaining recognition. Ongoing research reveals that immune system disruptions in PI can significantly affect mental well-being. By understanding and treating both aspects, healthcare providers can offer more effective care.

The Link Between Physical Health and Mental Health

The connection between PI and mental health is complex and involves both psychosocial and biological factors. Living with a chronic illness such as PI involves persistent health challenges, frequent infections and the need for continuous medical treatment. These ongoing issues can lead to chronic stress, social isolation and a reduced quality of life, all of which are significant risk factors for mental health problems.

However, psychosocial factors alone do not fully explain the high prevalence of mental health issues among PI patients. The biological disruptions caused by the immune deficiencies themselves also play a significant role. The immune system's involvement in brain function and development means that immune dysregulation can directly impact mental health. This dual impact — both the chronic stress of living with a PI and the biological effects of immune system dysfunction — contributes to the complex relationship between PI and mental health issues, which underscores the need for a comprehensive care approach that addresses both the physical and psychological aspects of living with PI.

Recent studies have shown that people with a PI are much more likely to have psychiatric disorders than the general population. For example, 20.5 percent of those with a PI have been diagnosed with at least one psychiatric disorder, compared to only 10.7 percent of people without a PI.[2] This increased risk includes a range of mental health issues such as depression, anxiety, schizophrenia, eating disorders and autism spectrum disorders (ASDs). The connection between PI and psychiatric conditions is especially strong for ASDs, with individuals having nearly three times the risk. Research suggests that immune system

problems during pregnancy or after birth might contribute to the development of ASDs and other psychiatric disorders.

The Role of Comorbidities and Gender

Having an autoimmune disease along with a PI further increases the risk of psychiatric disorders. About 27.6 percent of those with a PI also have an autoimmune disease, compared to only 6.8 percent of those without a PI, which shows a significant difference.[2] This combination of immune-related conditions can worsen mental health outcomes. Additionally, the link between PI and psychiatric disorders, including suicidal behavior, is stronger in women; they are more likely to experience psychiatric disorders and suicidal thoughts or actions, partly because women have higher rates of autoimmune conditions. Women attempt suicide four times more often than men, which might explain why the impact is more noticeable in female PI patients. These findings highlight the need for gender-sensitive care and support for people with PI, especially considering the added risks from autoimmune diseases and ongoing stress.

Maternal Health and Psychological Disorders in Children

Recent research has highlighted that when mothers have a PI, their children are at a higher risk of developing mental health issues such as anxiety, depression, autism and even suicidal behavior. A mother's immune system disruptions during pregnancy can have a profound impact on a child's brain development: Immune problems can create an environment in the womb that affects the baby's neurodevelopment, leading to these increased risks.[2]

Interestingly, the same heightened risk of mental health issues is not seen in children whose fathers have a PI. This difference suggests that the unique environment provided by the mother during pregnancy plays a crucial role in the child's development. While both parents share genetic material with their children, only the mother provides the in-utero environment that is essential for early brain development.[2]

This finding highlights the importance of monitoring and supporting the mental health of both mothers and their children, especially in families dealing with chronic illnesses like PI. By addressing both physical and mental health needs, we can help improve the overall well-being of families affected by these conditions.

Strategies for Patients and Families

While there is an increased risk for psychological issues with PI, having PI does not mean you will have an issue with your mental health! It is important to remember that steps can be taken to avoid or lessen the psychological burden associated with PI. Prioritizing both physical and mental health are necessary. Here are supportive strategies to consider:

• *Participate in support groups.* Connecting with others who face similar challenges can significantly reduce feelings of isolation. Sharing tips and experiences, such as recipes and schedule management strategies, can provide practical help and emotional support. Relating to others in similar situations also helps foster a sense of belonging and mutual encouragement, which is crucial for mental well-being.

• *Incorporate physical activity in your lifestyle.* Incorporating physical activity into your daily routine is another essential self-care strategy. Exercise releases chemicals in the brain that improve mood and boost confidence. Whether you choose yoga, walking or simply taking the stairs instead of an elevator, moving your body can help shift your focus away from negative thoughts associated with chronic illness. Physical fitness also helps alleviate both the physical and psychological effects of chronic illness. However, it is important to consult with your medical team before starting a new exercise routine to ensure it aligns with your health needs and capabilities.

• *Eat a nutritious diet*. Eating a nutritious diet is crucial for those living with chronic illness. A diet that supports your overall health often includes foods that also promote mental well-being. Introducing new healthy foods gradually and seeking guidance from a dietitian can make this transition smoother. Consistent minor changes in your diet can lead to significant improvements over time. Following a healthy diet not only benefits your physical health but also contributes to better mental health outcomes, creating a win-win situation for overall wellness.

• *Seek mental health support.* Do not hesitate to reach out to psychologists, counselors or support groups specializing in chronic illnesses. Talking to a professional can provide valuable insights, coping strategies and a safe space to express your emotions.

• *Address sources of stress*. Finding ways to manage your stress is essential for reducing the mental burden of chronic illness. Practicing mindfulness can help you stay present and calm, while seeking support from friends or family provides emotional relief and a sense of community. Effectively managing daily tasks by prioritizing, organizing and delegating responsibilities can also alleviate stress. Understanding your medications, recognizing symptoms

and knowing when to seek help are all critical components of a comprehensive health plan too, helping you feel more in control and less overwhelmed by your condition.

• *Get adequate sleep*. Sleep is vital for maintaining mental clarity and mood stability. Keeping a regular sleep schedule and creating a restful environment by avoiding screentime and heavy meals before bedtime can improve sleep quality. Discussing any sleep concerns with your healthcare provider can help you determine how many hours of sleep you need each night and address any issues that might be disrupting your rest.[6] Adequate sleep supports both physical recovery and mental resilience, making it a cornerstone of effective self-care.

Finding ways to manage your stress is essential for reducing the mental burden of chronic illness.

Relationship Management Is Important

Living with PI profoundly impacts not just the individual who has it but the entire family as well. Effective relationship management becomes crucial as family dynamics shift under the stress of chronic illness. Open communication, understanding and mutual support are essential to navigate these changes. Families should consider seeking professional support, such as family therapy, to develop strategies for coping with the emotional and practical challenges of PI. Learning to communicate more effectively, manage stress and support each other through tough times is key. Establishing regular family meetings and involving everyone in discussions about needs and achievements helps maintain a strong, supportive family unit.[7] This whole-family approach to dealing with PI, addressing both the physical and emotional aspects, can strengthen family resilience.

Promoting Resilience and Well-Being

Despite the challenges, it is possible to cultivate resilience and well-being in the face of a PI diagnosis. Building a solid foundation for managing a difficult condition involves a combination of education, realistic goal-setting and celebrating achievements. Here are some strategies that can help:

• *Educate and advocate*. Learn as much as possible about the condition and advocate for patient needs within the healthcare system. Knowledge empowers us to make informed decisions and actively participate in our care plans.

• *Set realistic expectations*. Understand that managing a PI is a journey, and progress takes time.

• *Celebrate achievements*. Recognize and celebrate achievements, no matter how small. Each step forward, whether it is attending a social event or managing symptoms effectively, is worth acknowledging and celebrating.

You Are Not Alone

It is essential to treat both the physical and mental aspects of a patient's well-being. Comprehensive care that includes mental health support is crucial for individuals with chronic illnesses such as PI. Integrating psychological care into the treatment plan can help mitigate feelings of frustration, fear and uncertainty. By addressing mental health alongside physical health, patients can achieve better overall outcomes, leading to improved quality of life and greater resilience.

Patients with chronic illness must manage stress effectively to reduce the mental burden of their condition. Practicing mindfulness can help patients stay present and calm, while seeking support from friends or family provides emotional relief and a sense of community. Additionally, effectively managing daily tasks by prioritizing, organizing and delegating responsibilities can significantly alleviate stress. Understanding medications, recognizing symptoms and knowing when to seek help are vital components of a comprehensive health plan. These strategies can help patients feel more in control and less overwhelmed by their condition.

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Thriving Alone: Strategies for Navigating Chronic Illness on Your Own

Facing a difficult disease can feel overwhelming and scary — especially when you're flying solo — but these strategies can help you find peace of mind.

By Surayyah Morris, PharmD

LIVING WITH a chronic illness can be an uphill battle, but facing it alone can make the journey even more daunting. While many people rely on friends, family or support groups for comfort and assistance, some individuals find themselves navigating the challenges of chronic illness entirely on their own. The idea of living well with a chronic illness may become significantly overwhelming for this population, as it is filled with physical, emotional and psychological challenges. (Overwhelming may seem like an understatement!) If you are one of these warriors, know that you are not alone. The following strategies can help you manage your condition and live your best life even without a traditional support network.

Acknowledge Your Feelings and Inner Strength

First and foremost, it's important to acknowledge and accept your feelings. Living with a chronic illness can evoke a range of emotions, including frustration, anger, sadness and fear. It's OK to experience these emotions and to give yourself permission to feel them fully. Denying or suppressing them can ultimately exacerbate your stress and anxiety. Instead, find healthy ways to express your emotions, whether through journaling, talking to a therapist or engaging in creative outlets like art or music.

Next, recognize the incredible strength within you. Managing a chronic illness on your own requires resilience, courage and determination. Acknowledge the challenges you face and the obstacles you've overcome. Celebrate your victories, no matter how small they may seem. Remember, every step forward, no matter how tiny, is a testament to your inner strength and perseverance.

Empower Yourself Through Education

The more you understand your illness, the better equipped you'll be to manage it effectively on your own. In fact, knowledge is your most powerful weapon in the fight against chronic illness. Take the time to educate yourself from A to Z on how to manage your condition safely and appropriately. Learn about symptoms, triggers and treatment options. Consult reputable sources such as medical websites, scholarly articles and

books written by experts in the field, which all provide valuable information and insights. For additional support, use keywords in social media search engines to find people and organizations that reflect your specific interests, needs and resources. Gathering knowledge from many sources will empower you to make informed decisions about your health and well-being.

Advocate for Yourself

Take an active role in your healthcare by communicating openly and honestly with your healthcare providers. Ask questions, seek second opinions and assert your needs and preferences. Keep detailed records of your symptoms, treatments and any changes in your condition. Remember, you are the expert on your own body, and your voice matters in your healthcare decisions. Below are some ways to ensure you are making good decisions if doing so independently:

- Know the name of your condition(s) and symptoms you experience.
- Know what medications/supplements you are taking and why.
- Know what causes and relieves your symptoms, and what exacerbates or worsens your overall condition.
- Keep all necessary contact information, including provider names, phone and fax numbers, addresses and personal identifiers, so it is accessible upon request.
- Cover yourself with written communications (versus relying on he-said/she-said) when interacting with healthcare providers.

Compile this information in your chronic illness toolkit, and keep it accessible.

Establish Routines and Structure

Living with a chronic illness often means dealing with unpredictable symptoms and fluctuations in health. Don't compare your experience to others' experiences: Every patient is different as far as how their condition manifests, so every patient's approach to illness management will also be different — including yours. Don't worry if your method doesn't look exactly like someone else's. However, establishing routines and structure that work for you can provide a sense of stability and control in the midst of uncertainty and help you better manage your energy and symptoms.

Create a daily schedule that includes time for rest, medication management, meal preparation and activities that fulfill you and bring you joy. Break tasks down into manageable chunks, and prioritize your most important activities.

With your symptoms, treatments and potential complications in mind, proactively plan the most effective ways to manage on your "worst" day. This could look like setting up your space where your chronic illness toolbox is accessible with ease and little effort. It could also look like prepping for the week ahead: Make your meals, pick out your clothes and decide on a low-maintenance style or routine for each day so you can adjust easily to any unforeseen or anticipated changes and remain stress-free.

Keep your chronic illness toolbox current to reflect both your most recent medical visits and significant doctor visits, medication refills, infusion sessions, procedures, labs, imaging, etc. Having copies and/or access to all your medical information can streamline a lot of the processes that are frustrating to have to go through, especially the spiel of your medical history to every provider you come in contact with. When there's something new to add, do it right away.

Utilize Smartphone Tools

In today's digital age, technology can be a powerful ally in managing chronic illness solo. Smartphones are particularly helpful.

Apps: Use apps and online tools to track your symptoms, medications and appointments. Don't forget to include apps that keep you distracted such as games, and to keep your wheels turning such as brain teasers, puzzles or word finds.

Automated reminders: Set alarms for medication doses, doctor's appointments and self-care activities (and aim to be early, instead of on time, which will allow for extra time if you experience an issue along the way).

Virtual community groups: Explore virtual support groups and online communities where you can connect with others who share similar experiences. Social media platforms such as Facebook, TikTok and Instagram also offer opportunities to find support and inspiration from fellow chronic illness warriors.

Health: Use the health app to document your important medical information (conditions, medications, allergies, blood type, primary language, etc.). This information can be used to help communicate pertinent information in the case of emergency.

Emergency contact: Document who to call if something were to happen to you.

SOS: In Case of Emergency

One of the biggest concerns when you're flying solo is what to do in case of an emergency. Seemingly contrary to the title of this article, it's still advisable to designate an

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.

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

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

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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US-HYQ-0299v5.0 02/24

emergency contact — someone you trust and who knows you well enough to be of assistance or support in the event you cannot help yourself. This person does not need to be a family member or even a close friend, but should be at least minimally informed about your situation or needs so they can be of quality assistance when necessary. It might be a neighbor, coworker or someone else you know. Include their name and contact information on necessary forms.

Also, take advantage of your smartphone's emergency feature so your important medical information is clearly communicated in case you are found alone or are in a situation where you need assistance. You don't have to disclose everything; it is OK to include only the most significant information pertaining to your health that will better allow someone you don't know to help you effectively. Here are the pieces of information that will be most useful to add to your smartphone's emergency feature:

• Medical conditions: Keep it concise but thorough. Prioritize conditions by severity.

• Medications: Include everything you take, including prescriptions, over-the-counter medicines and supplements. It's important for healthcare workers to have this information when making treatment decisions.

• Allergies: Include medications, foods, environmental factors, etc. This specifies treatment options and prevents the risk of adverse reactions.

• Emergency contact: Designate someone you trust (neighbor, coworker, friend) as the person emergency personnel should contact in case something happens to you.

Seek Professional Support When Needed

While you may be managing your chronic illness alone, you don't have to do it all by yourself. Consider consulting with a social worker or patient advocate who can help you access resources and services that will support you in your journey to live the life you desire. A life coach is beneficial to some as well. If you're struggling to cope, don't hesitate to seek professional support. A therapist or counselor can provide you with the tools and strategies to manage the emotional toll of living with a chronic illness.

Cultivate Self-Compassion

The emotional tax of living with a chronic illness is significant, and it's easy to be hard on yourself. Cultivate self-compassion by treating yourself with kindness and understanding. Acknowledge the challenges you face and the limitations imposed by your illness without judgment. Practice self-care activities that nourish your body, mind and spirit, whether it's indulging in a warm bath, meditating, spending time in nature or playing video games. Remember, you deserve compassion and care, especially from yourself.

Make your mental and physical health a priority. The top of your list should be to obtain the best quality of life, however that may look for you. Build a support network using the resources available to you. Outline your limitations and respect those boundaries. Adjust as you see fit to maintain a safe and healthy lifestyle. Validate your own experience, and be confident in your decisions. Be confident with how you address and respond to misfortunes, inconveniences and unexpected life events. Give yourself grace.

Navigating life is hard enough, but doing it while simultaneously battling your body complicates the process immensely. Be kind to yourself. Treat yourself how you want others to treat you (or better). Give yourself the compassion, patience, understanding and positivity you need to keep living well and progressing, rather than just maintaining.

One Last Thing ...

Living with a chronic illness without a support system presents unique challenges, but it is possible to thrive and live a fulfilling life with the right strategies in place. In fact, the best part of having a chronic illness is the strength and resilience you possess in great proportions. Your lifestyle will reflect it! You are more resourceful than most. You adapt in so many ways that you will even surprise yourself. You know practices and tools that manage your quality of life efficiently, and they help you conserve time, energy, (hopefully) money and definitely a bit of your sanity.

By acknowledging your feelings, educating yourself, advocating for yourself, building structure, using available resources, prioritizing self-care and seeking professional help when needed, you can manage your condition with resilience and grace. Remember, you are not alone. Use the many available resources and strategies to help you thrive! You are stronger than you know, and you have the power to overcome any obstacle that comes your way. IG

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

Coping with Chronic Illness at College

Managing college life is doable with the "I CAN" attitude.

By Rachel Maier, MS

CAN COLLEGE and chronic illness mix? Absolutely! Thousands of young adults live with chronic illnesses just like you do, and a great many of them successfully attend college.[1] Thankfully, colleges and universities are well-equipped with staff members and resources designed to help you navigate your transition and support you throughout your college career. In fact, your college experience can even be tailored to meet your unique needs.

But setting yourself up for success and maintaining that success throughout your college years is a detailed (and sometimes daunting) task. Adjusting to life away from home and the newfound freedom of post-high school life is hard enough for healthy students. Adding on the extra task of learning how to navigate your new surroundings with your chronic disease might seem like more trouble than it's worth. But while you must do your part to ensure your needs are met, the good news is you can do it by embracing an "I CAN" attitude.

"I" — Investigate and Inquire

First and foremost, do your research: Know your rights, responsibilities and resources. Start with the Americans with Disabilities Act (ADA), which provides protections for students with chronic illnesses. The law requires colleges and universities to provide reasonable accommodations for students with disabilities, that is "any person who (i) has a physical or mental impairment which substantially limits one or more major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment."[2] This covers hidden disabilities such as diabetes, allergies and immunologic disease, among other chronic conditions.[2] Unlike elementary and secondary school, postsecondary schools (colleges and universities) are not required to identify students with disabilities (which means they aren't allowed to ask for that information on your application), but they are required by law to provide information about the resources and services available to students with disabilities to those who ask for it.[2] Ultimately, though, it is up to you to notify your college about your disability status if you wish to take advantage of the many resources the campus offers. (See Figure for the general process for this.)

Before you commit to attending a particular college, ask lots of questions and gather as much information as you can about a variety of schools and their surrounding areas. Find out about living accommodations, academic adjustments and auxiliary aids, then choose the school that is the best fit for you. Here is a sampling of what campuses may offer:[2]

- Office of disability services (ODS), which coordinates support for students with chronic illnesses
- Student health center
- Modified class schedule that allows time for regular medical appointments, therapies or counseling services, or for conservation of energy or rest and recuperation following intensive therapies
- Modified testing arrangements such as oral testing or different testing formats
- An array of assistive technology such as audio recordings of lectures in case you need to miss class
- Adapted physical education requirements
- Adjusted rules for on/off campus living

Beyond the campus boundaries, explore the surrounding area with a list of things you need (a doctor, pharmacy, infusion clinic, etc.). Once you select a school, take time to find a doctor you like and establish care there. You might have a great doctor back home, but having access to a local doctor will give you peace of mind while you are away. Also, locate the nearest 24-hour pharmacy (if at all possible, but if not, at least locate the nearest regular pharmacy), urgent care center and hospital/emergency room. Know where they are before you need them, and hope that you never do. Find a grocery store that carries specialized foods you need (if applicable). In short, get familiar with the surroundings so you know where to go when you need something off-campus.

Armed with this information, you'll be equipped to pick the best school for you.

"C" — Communicate Your Needs

Next, you'll need to communicate with the school about your needs. Talking about your illness might be the last thing you want to do. College is a fresh start, and maybe you're looking forward to starting over and letting people get to know you for you, not your illness. That's totally understandable. However, you really do need to tell some people about your illness.

As previously mentioned, at the very least, you'll want to inform your school about your illness so you get access to accommodations. Before a new semester begins, register at the ODS and get to know the staff there. Submit documentation about your diagnosis and request accommodations best suited to you. The ODS is there to help you, so the more transparent you can be about your condition and needs, the better they will be able to assist you and/or point you toward resources you need. Review your requests every year (at minimum) to make sure they are still appropriate, and add new ones as they come up.

Further, if you have roommates, letting them know about your disease, as well as important information about your disease that might affect their interaction with you, is a good idea from the get go. Tell them about symptoms they may need to watch out for (symptoms of hypoglycemia or anaphylaxis, for example); where your important medications are kept; and what to do in the case of an emergency, including important numbers to call. You might want to inform your resident assistant about these action items, too. Also, talk to your roommates about boundaries and expectations right away as well (talk about sleep habits, hygiene/cleanliness needs, noise, etc.).

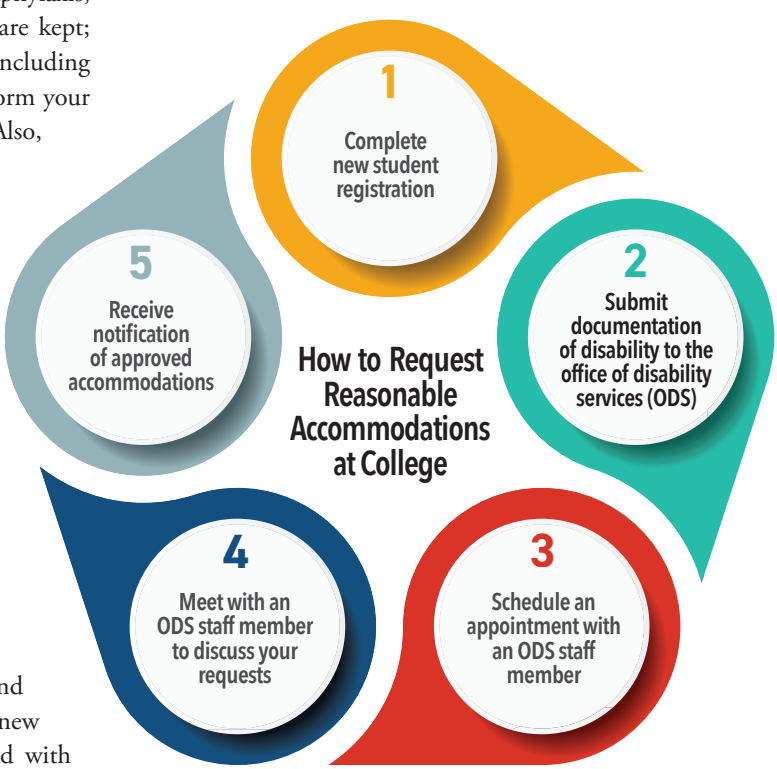
Depending on your condition, you might want to inform your professors about your illness, too. You'll definitely want to talk to them if you require special accommodations for their class. The ODS will help you coordinate accommodations for their classes, but you might still want to talk to them personally so they can match your face with your name. Tell them how excited you are to be in their class, and thank them for working with you to make it possible for you to succeed. If possible, get in touch with them before the semester begins.

Beyond that, you can choose who to inform and how much you're willing to tell. When meeting new people in social situations, you don't need to lead with your condition. For example, don't introduce yourself with your condition ("Hi, my name is Gabe and I have a primary immune deficiency."). Instead, mention it when it comes up organically if you want to. As you make friends and begin spending a lot of time with them, consider entrusting them with more information so they can help you if you need it. It might be helpful to join a support group on campus or online that gives you a place and the space to talk about your illness with people who understand.

Bottom line: Don't keep your illness to yourself completely. Of course, disclose only what you need to and/or what feels comfortable, knowing that the more open and honest you are about your condition, the better able your new community will be able to support you.

"A" — Ask for Accommodations

Again, ask your campus ODS for accommodations best suited to you. The ODS works with you to tailor them to your needs. For example, if you have a chronic lung disease, you can request a newer dorm room, as it will naturally have less dust and/or mold than older buildings (which is much healthier for your lungs). If you have a condition such as multiple sclerosis that makes note-taking a



challenge, you can request note-taking assistive technology. Remember that accommodations are made on a case-by-case basis, so the quicker you begin the conversation, the better chance you'll get your needs met.

You might not know what accommodations you need. That's OK — you can learn as you go. Issues will come up, but your campus ODS is there to help you and it has plenty of experience matching students with resources. However, it might help to have a list of a basic considerations as you prepare to talk to your campus ODS for the first time:[2]

- Housing: What would be the best situation for you? Does your college offer that as an option (for example, roommate with a shared bathroom vs. single room with a private bathroom; newer build vs. older build; on-campus vs. off-campus)?
- Food services: How does the dining hall work? Would a pre-paid cafeteria plan work well for you, or do you need to cook your own meals? Is it possible to arrange for special dietary accommodations (i.e., gluten-free, vegan, allergy friendly)?
- Transportation/parking: Are underclassmen allowed to have cars on campus? Is there accessible parking nearby? Do parking garages have elevators? Is there public transportation nearby? What does it cost? Are there stops near your preferred doctor, pharmacy or grocery store?
- Mobility challenges: Does your college have accessible architecture such as ramps, elevators, stair lifts and wide hallways? If so, can your classes be scheduled in those buildings?
- Assistive technology: What kinds of devices, software and apps does the college provide to help you succeed in the classroom?
- Physical education: Do you need modified requirements for physical education classes?
- Course load: Would you benefit from a reduced course load? Can you get the syllabus ahead of time to help you manage your time?

"N" — Nurture Healthy Habits

Set yourself up for success by establishing and maintaining healthy habits. There isn't one "right" way to do this, although some basic, familiar principles do apply: Set boundaries and stick to them. Eat healthy foods and get enough sleep. Drink plenty of water. Avoid binge-drinking and illicit drugs. Study hard and do your best. Save more money than you spend. Get fresh air and adequate exercise. Say hello to someone new. Smile. Spend time with friends. Take a walk in the sunshine. (You know the drill.) But beyond those basic principles, you'll also want to do the following:

- Remember to carry medically necessary emergency medicines with you.
- Do not seek out prescription pills over the Internet or social media. Talk to your doctor before taking any new medication, and purchase it from a verified pharmacy.
- Learn about the effect of mixing your medications with alcohol and the effect of alcohol on your disease.
- Schedule your most difficult classes during times of day you usually feel your best.
- Keep up with necessary medical appointments and therapies.
- Stick to your medically necessary diet (i.e., gluten-free, allergen-free, sugar-free, etc.).
- Seek out community. Spend time with other people and make friends. Find a disabled student support group, join a club, get a job, etc.
- Keep your dorm room clean. Do laundry, change your sheets and wipe down high-touch areas often.
- Maintain personal hygiene.
- Take time for yourself. Rest and recharge often.
- Ask for help when you need it.
- Listen to your body. If something seems "off," acknowledge it and seek help (go to the student health center, seek student counseling services, etc.).

You Can Do It!

Leaving home and managing your illness without the safety net of your parents and support system is a big step! It's normal and natural to feel intimidated and nervous or excited and enthusiastic! (You might even feel all of them at once!) Setting out on your own and embracing independence is part of growing up. Sometimes it's scary; sometimes it's not. Regardless, remind yourself that you can do it, and there are lots of resources out there to help you. And don't forget to give yourself grace as you learn how to juggle it all. Everyone, regardless of their health, goes through a transitional period in which they learn to manage life on their own. IG

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

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Moving Toward Better Health

By Kerri Sowers, PT, DPT, PhD

Are you a PI patient who's reluctant to exercise? You aren't alone. But research shows it's not only safe for PI patients, it's also an important part of disease management and health maintenance.

PHYSICAL ACTIVITY is a critically important part of physical and mental health and well-being. The World Health Organization (WHO) has found that one in four adults do not meet the global recommended levels of physical activity.[1] A 2018 study about exercise perceptions and behaviors found approximately 40 percent of individuals with primary immune deficiency disease (PI) were not engaging in any exercise.[2] Exercise provides significant benefits that improve overall health and well-being, reduces symptoms of anxiety and depression and contributes to chronic disease management.[1]

Exercise and the Immune System

One concern that has been repeatedly expressed by the PI community is that exercise will make them sicker or will weaken their immune system. Research has shown that exercise and physical activity can cause changes in both innate and adaptive immune function; it may also impact the numbers and functions of immune cells. However, longitudinal studies involving sedentary individuals who exercised did not show any significant change in immune markers 24 hours after exercise.[3] Additional studies have demonstrated there was no significant change in serum

immunoglobulin levels in response to both brief or prolonged exercise.[4,5] One study compared aerobic exercise to stretching over 12 months and found there was no significant effect on IgG, IgM or IgA levels. Based on current research, there is no conclusive evidence that upper respiratory tract infections are correlated with exercise intensity, duration or frequency.[6] And, there is research that suggests moderate-intensity exercise and physical activity may provide a protective effect to the immune system.

In the aforementioned 2018 study specific to exercise in the PI community, researchers sought to learn more about exercise behaviors in those with a diagnosis of PI. This was an online survey administered to individuals with a diagnosis of PI to learn more about their exercise perceptions and behaviors. Of the 264 responses, it was found there was a low engagement in exercise (40.89 percent were not exercising). For those who did exercise, low intensity walking (75.74 percent) and stretching (57.02 percent) were the most common physical activities. The greatest barrier to exercise was fatigue, which was reported by 86.97 percent of respondents. The respondents did see exercise as beneficial to their overall well-being and felt it could decrease stress levels, but they also feared exercise would worsen their health.[2]

The Importance of Exercise

You might ask: Why is it so important to be physically active? Regular physical activity is often used as primary prevention for many chronic medical conditions. Just a small amount of physical activity is linked to a significant reduction in risk for chronic disease, with an overall estimated risk reduction of 20 to 30 percent.[7] WHO recommends adults obtain at least 150 to 300 minutes of moderate-intensity aerobic physical activity or at least 75 to 150 minutes of vigorous-intensity aerobic physical activity throughout the week. For adults 65 years and older, individuals with chronic medical conditions and individuals with a disability, WHO recommends they should also include a variety of activities focused on balance (to address fall prevention) three or more days a week.[1]

The research is irrefutable that people who are physically active have a better quality of life.[8] In some cases, exercise may be as effective as pharmacological medications[9]; despite this, exercise is underprescribed in most chronic medical conditions. Research has shown it is appropriate to recommend appropriate exercise interventions, even to immunocompromised individuals, without concern for negative effects on immune function.[5] There are very few absolute contraindications to prescribing exercise for people with chronic conditions or immunodeficiency diseases, though it is always recommended that you consult with your physician and/or other healthcare professionals before starting a formalized exercise program.

When to Avoid Exercise

The American College of Sports Medicine has provided a list of absolute contraindications for those who should avoid exercise.[10] This includes a variety of unstable or uncontrolled cardiac conditions, acute pulmonary embolism or severe acute infection. There are also relative contraindications for exercise; those with these conditions should discuss with their physician the frequency, duration and intensity of physical activity.[10] Relative contraindications include some cardiac conditions; electrolyte abnormalities; severe arterial hypertension at rest; neuromotor, musculoskeletal or rheumatoid disorders exacerbated by exercise; uncontrolled metabolic disease; and chronic infectious disease.

You should proceed carefully or modify your physical activity if you have a risk of falls, severe osteoporosis or bone metastasis that may lead to fracture; uncontrolled blood glucose; critically low platelet levels; acute systemic infections; severe exacerbations of inflammatory joint disease; or musculoskeletal injury (such as a soft tissue injury or fracture). Again, consulting with your physician or a

gamunex®-C
immune globulin injection (human), 10%
caprylate/chromatography purified

Step out of the symptoms of CIDP and back into your life with GAMUNEX-C

GAMUNEX-C blocks the autoimmune and inflammatory processes of CIDP, which may improve symptoms and protect your nerves from damage.[1-3]*

*The way in which GAMUNEX-C works in treatment of people with CIDP is not completely understood.

GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is approved to treat primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older. If you have PIDD, you may take GAMUNEX-C under the skin (subcutaneously) or in a vein (intravenously). GAMUNEX-C is also approved to treat idiopathic thrombocytopenic purpura (ITP) in adults and children and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. If you have ITP or CIDP, you may only take GAMUNEX-C intravenously.

Do not take GAMUNEX-C if you have an allergy to immune globulin. Tell your doctor if you have had a serious reaction to other medicines that contain human immune globulin. Also tell your doctor if you have immunoglobulin A (IgA) deficiency. If you have a serious reaction while taking GAMUNEX-C, stop taking it immediately and tell your doctor.

CIDP, chronic inflammatory demyelinating polyneuropathy.

Please see Important Safety Information for GAMUNEX-C on the following page.

Learn more at GAMUNEX-C.com or call 1-888-MYGAMUNEX (1-888-694-2686)

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IMPORTANT SAFETY INFORMATION

GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) is approved to treat primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older. If you have PIDD, you may take GAMUNEX-C under the skin (subcutaneously) or in a vein (intravenously). GAMUNEX-C is also approved to treat idiopathic thrombocytopenic purpura (ITP) in adults and children and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults. If you have ITP or CIDP, you may only take GAMUNEX-C intravenously.

If you take GAMUNEX-C or a similar immune globulin product, you could experience a serious and life-threatening blood clot (thromboembolism), which 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. You are more likely to develop a blood clot if you have a history of hardening of the arteries (atherosclerosis), stroke, heart attack, or heart failure (low volume of blood pumped by the heart). You may also be more likely to get a blood clot if you are elderly, if you have a blood clotting disorder, if you are inactive for long periods of time (such as long bed rest), if you use estrogens, or if you have thickening of your blood. For patients at risk, GAMUNEX-C should be administered at the lowest dose and slowest infusion rate that is practical. However, blood clots may occur in the absence of any of the known risk factors. Patients should be well hydrated by drinking enough water before GAMUNEX-C is administered. Tell your doctor immediately if your medical history is similar to what is described here, and especially if you start having any of these symptoms while taking GAMUNEX-C.

If you take GAMUNEX-C or a similar immune globulin product intravenously, you could experience serious kidney disease and death. You may have symptoms of decreased urination, sudden weight gain, swelling in your legs (edema), or shortness of breath. You are more likely to develop serious kidney disease if you already have a kidney problem, have Type II diabetes mellitus, or are older than 65. You are more likely to develop serious kidney disease if you are dehydrated, have a blood infection (sepsis), have high protein content in your blood, or if you are receiving other medicines that are harmful to your kidneys. Tell your doctor immediately if your medical history is similar to what is described here, and especially if you start having any of these symptoms while taking GAMUNEX-C.

You are more likely to develop serious kidney disease if you take an intravenous immune globulin product that contains sugar (sucrose). GAMUNEX-C does not contain sugar. If your situation makes you more likely to experience serious kidney disease, you should take GAMUNEX-C at the lowest concentration available and the slowest infusion rate that is practical.

Do not take GAMUNEX-C if you have an allergy to immune globulin. Tell your doctor if you have had a serious reaction to other medicines that contain human immune globulin. Also tell your doctor if you have immunoglobulin A (IgA) deficiency. If you have a serious reaction while taking GAMUNEX-C, stop taking it immediately and tell your doctor.

Periodic monitoring of kidney function and urine output is particularly important in patients more likely to experience severe kidney disease.

You could experience other serious and life-threatening problems due to immune globulin. You could get aseptic meningitis (a type of brain inflammation with symptoms of severe headache, stiff neck, fatigue, fever, sensitivity to light, painful eye movements, nausea, and vomiting), a blood problem called hemolytic anemia (common symptoms include increased heart rate, fatigue, yellow skin or eyes, and dark-colored urine), and/or a lung problem called transfusion-related acute lung injury (commonly referred to as TRALI). TRALI is a condition where you build up fluid in the lungs (called pulmonary edema) that is not the result of heart failure.

If you have higher than normal body fluid volumes or if you have a condition where increasing body fluid volume may be a concern, a higher dose, such as 1g/kg for 1-2 days, is not recommended.

Because GAMUNEX-C 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.

You may not take GAMUNEX-C subcutaneously if you have ITP. **If you have ITP and take GAMUNEX-C subcutaneously, you could experience a very serious and life-threatening black and blue wound (hematoma, which is a pocket of blood within a tissue).**

After you take GAMUNEX-C, your blood antibody levels may rise, which could cause some blood antibody tests to give false results.

The most common side effects in a clinical study with PIDD patients who got subcutaneous injections of GAMUNEX-C were infusion-site reactions such as redness, swelling, and itching; extreme tiredness; pain in the region of the head or neck; a runny nose, nasal congestion, sneezing, cough, and sputum production; joint pain; loose stools; a sensation of unease and discomfort in the upper stomach; swelling of the tissue lining the sinuses; inflammation of the airways that carry air to your lungs; a feeling of unhappiness, sadness, melancholy, gloom, hopelessness, or low spirits; red rash or bumps, itchy, swollen, and tender skin with or without blisters or a burning feeling; a severe throbbing pain or a pulsing sensation, usually on just one side of the head; muscle pain; familiar infectious diseases such as the common cold or flu; and raised body temperature or fever. In clinical studies with PIDD patients who got GAMUNEX-C intravenously, the most common side effects were cough; irritation and inflammation of the mucous membrane inside the nose; sore throat caused by inflammation of the back of the throat; pain in the region of the head or neck; a condition in which your airways narrow and swell and produce extra mucus; a sensation of unease and discomfort in the upper stomach; raised body temperature or fever; loose stools; and swelling of the tissue lining the sinuses. In a clinical study with CIDP patients who got GAMUNEX-C intravenously, the most common side effects were pain in the region of the head or neck; raised body temperature or fever; abnormally high blood pressure; feelings of coldness accompanied by shivering; a noticeable change in the texture or color of your skin such as your skin becoming scaly, bumpy, itchy, or otherwise irritated; a sensation of unease and discomfort in the upper stomach; joint pain; and abnormal physical weakness or lack of energy. In clinical trials with ITP patients who got GAMUNEX-C intravenously, the most common side effects were pain in the region of the head or neck; a discoloration of the skin resulting from bleeding underneath, typically caused by bruising; vomiting, fever, nausea, rash, abdominal pain, back pain, and a pain or an uncomfortable feeling in the upper middle part of your stomach.

The most serious side effects in clinical studies were a blood clot to the lung (pulmonary embolism) in 1 patient with a history of this condition (in CIDP), a flare-up of an existing type of anemia (autoimmune pure red cell aplasia) in 1 patient (in PIDD), and heart inflammation (myocarditis) in 1 patient (in ITP).

Please see brief summary of the full Prescribing Information 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.

References: 1. Merkies IS, Bril V, Dalakas MC, et al. Health-related quality-of-life improvements in CIDP with immune globulin IV 10%: the ICE Study. *Neurology.* 2009;72(15):1337-1344. **2.** Hughes RAC, Donofrio P, Bril V, et al; on behalf of the ICE Study Group. Intravenous immune globulin (10% caprylate-chromatography purified) for the treatment of chronic inflammatory demyelinating polyradiculoneuropathy (ICE study): a randomised placebo-controlled trial. *Lancet Neurol.* 2008;7(2):136-144. **3.** Dalakas MC, Latov N, Kuitwaard K. Intravenous immunoglobulin in chronic inflammatory demyelinating polyradiculoneuropathy (CIDP): mechanisms of action and clinical and genetic considerations. *Expert Rev Neurother.* 2022;22(11-12):953-962.

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GAMUNEX®-C

Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use GAMUNEX®-C safely and effectively. See full prescribing information for GAMUNEX-C.

GAMUNEX®-C, [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified]

Initial U.S. Approval: 2003

WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE

See full prescribing information for complete boxed warning.

- **Thrombosis may occur with immune globulin products, including GAMUNEX-C. 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 GAMUNEX-C 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.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients.**
- **Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. GAMUNEX-C does not contain sucrose.**
- **For patients at risk of renal dysfunction or failure, administer GAMUNEX-C at the minimum concentration available and the minimum infusion rate practicable.**

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

GAMUNEX-C is an immune globulin injection (human), 10% liquid indicated for treatment of:

- Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older
- Idiopathic Thrombocytopenic Purpura (ITP) in adults and children
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in adults

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

Intravenous Administration Only: ITP and CIDP

Indication	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
ITP	2 g/kg	1 mg/kg/min	8 mg/kg/min
CIDP	loading dose 2 g/kg maintenance dose 1 g/kg	2 mg/kg/min	8 mg/kg/min Every 3 weeks

- Ensure that patients with pre-existing renal insufficiency are not volume depleted; discontinue GAMUNEX-C if renal function deteriorates.
- For patients at risk of renal dysfunction or thrombosis, administer GAMUNEX-C at the minimum infusion rate practicable.

Intravenous or Subcutaneous Administration: PI
DO NOT ADMINISTER SUBCUTANEOUSLY FOR ITP PATIENTS

Route of Administration	Dose	Initial Infusion Rate	Maintenance Infusion Rate (if tolerated)
Intravenous (IV)	300-600 mg/kg	1 mg/kg/min	8 mg/kg/min Every 3 to 4 weeks
Subcutaneous (SC)	1.37 x current IV dose in grams/ IV dose interval in weeks	Adult:† 20 mL/hr/site Pediatric:† 10 mL/hr/site (< 25 kg) 15 mL/hr/site (≥ 25 kg)	Adult:† 20 mL/hr/site Pediatric:† 10 mL/hr/site (< 25 kg) 20 mL/hr/site (≥ 25 kg) Weekly

† Adults: use up to 8 infusion sites simultaneously; pediatric: use up to 6 infusion sites simultaneously; for all ages, ensure infusion sites are at least 2 inches (5 cm) apart.

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

GAMUNEX-C is a sterile solution for injection supplied in 1 g (10 mL), 2.5 g (25 mL), 5 g (50 mL), 10 g (100 mL), 20 g (200 mL), or 40 g (400 mL) single use vials.

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

- Anaphylactic or severe systemic reactions to human immunoglobulin
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity

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

- IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available immediately to treat any acute severe hypersensitivity reactions.
- Hyperproteinemia, with resultant changes in serum viscosity and electrolyte imbalances may occur in patients receiving IGIV therapy.
- Aseptic Meningitis Syndrome (AMS) may occur, especially with high doses or rapid infusion.
- Hemolysis, either intravascular or due to enhanced RBC sequestration, can develop subsequent to GAMUNEX-C treatments. Risk factors include high doses and non-O blood group. Closely monitor patients for hemolysis and hemolytic anemia, especially in patients with pre-existing anemia and/or cardiovascular or pulmonary compromise.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- Volume overload.
- GAMUNEX-C is made from human plasma and may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
- GAMUNEX-C is not approved for subcutaneous use in ITP patients. Due to a potential risk of hematoma formation, do not administer GAMUNEX-C subcutaneously in patients with ITP.
- Passive transfer of antibodies may confound serologic testing.

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

The most common adverse reactions observed in ≥ 5% patients were:

PI: Intravenous: Cough increased, rhinitis, pharyngitis, headache, asthma, nausea, fever, diarrhea, and sinusitis.
Subcutaneous: Local infusion site reactions, fatigue, headache, upper respiratory tract infection, arthralgia, diarrhea, nausea, sinusitis, bronchitis, depression, allergic dermatitis, erythema, migraine, myalgia, viral infection, and pyrexia.

ITP: Headache, ecchymosis, vomiting, fever, nausea, rash, abdominal pain, back pain, and dyspepsia.

CIDP: Headache, pyrexia, hypertension, chills, rash, nausea, arthralgia, and asthenia.

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

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

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

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

- Geriatric: In patients over 65 years of age do not exceed the recommended dose, and infuse GAMUNEX-C at the minimum infusion rate practicable.

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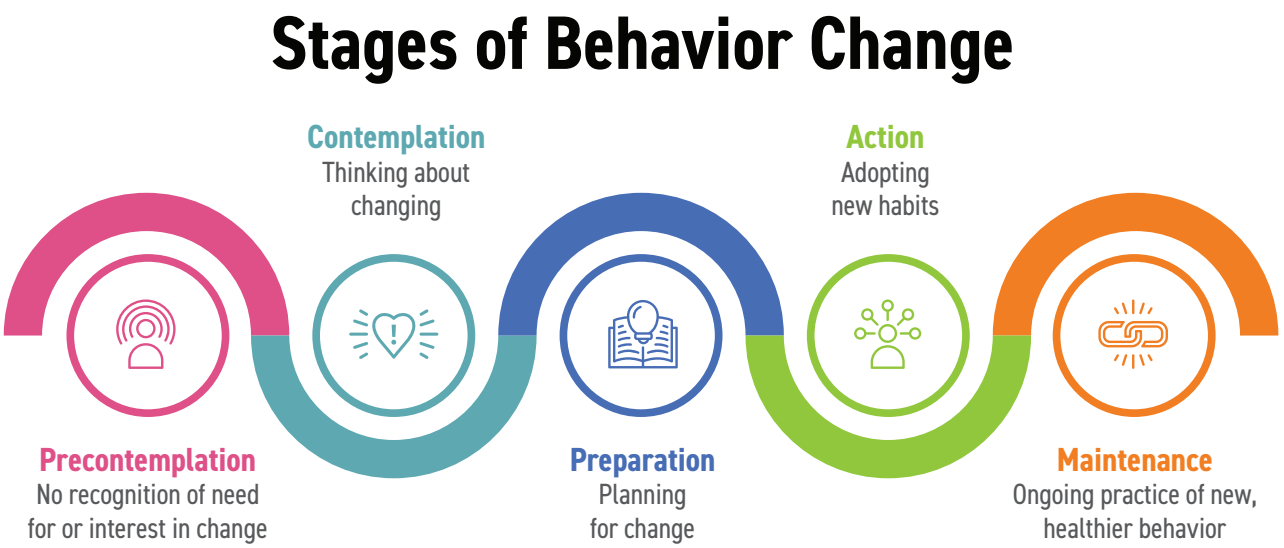
Revised: 1/2020



healthcare professional trained in prescribing exercise can help you formulate a safe and effective exercise plan.

Motivation and Maintenance

Now that we've addressed the concerns about exercise causing people to become sicker or to weaken their immune system (which it doesn't), we are going to turn our focus onto how to get the PI community more engaged in exercise and physical activity.

The two most challenging aspects of beginning an exercise program and increasing your physical activity are getting started with a new activity and maintaining your engagement in the activity. The Transtheoretical Model of Behavior Change, also referred to as the "Stages of Change" model, can help you better understand how behavior change happens. This model takes you through the five stages: 1) precontemplation (no recognition or interest in making a change), 2) contemplation (thinking about change), 3) preparation (planning to make a change), 4) action (adopting new habits) and 5) maintenance (continuation of the new behavior).[11] You will probably move back and forth between different stages at any point in your exercise journey.

The first step is recognizing that you need to be more physically active. Hopefully, since you're reading this article, you are thinking about your own level of physical activity and whether you need to increase your daily movement. Recognizing that you need to be more physically active is the critically important first step. This is an acknowledgement that you need to make a change in your current behavior. Once you have made the decision to start moving more, you should make a list of physical activities you enjoy.

Many people dread going to a gym or performing high-impact exercise. If you are one of those people, it's OK to admit you hate the traditional gym model, as it helps you identify alternate activities that you will enjoy. The key to staying engaged in a new exercise routine is to find activities you look forward to and won't feel like a chore. Another easy way to increase your physical activity is to start incorporating more movement and physical activity into your daily routine. This might mean parking farther away, taking the stairs instead of the elevator or standing instead of sitting when working on a task.

Now that you've decided you need to make a change, it is important to set realistic goals and hold yourself accountable. Setting goals will help you stay on track with your new exercise plan. These goals should be realistic, measurable and attainable; you should set both short-term goals and long-term goals that can be modified as you evaluate your progression with your new activities. Starting with small changes in your behavior or lifestyle is important. Setting a goal that is unrealistic or unobtainable will leave you feeling frustrated, and this may cause you to abandon your plan to increase your physical activity. Small goals will help you build your confidence and give you a sense of satisfaction as you reach each target.

Staying motivated, especially when you are not feeling well or are fatigued, can be another major challenge. Finding ways to help motivate yourself can be very important in

Barriers to Exercise Participation (PI)

Response	Percentage (%)		Number	
	Overall	CVID Only	Overall	CVID Only
Fatigue	86.97	83.73	207	175
Exercise is painful	39.50	36.36	94	76
Fear of health condition worsening	30.25	25.84	72	54
Lack of motivation	27.31	25.32	65	55
Lack of time	18.07	14.83	43	31
Fear of being injured	17.65	15.79	42	33
Other	14.71	14.35	35	30
Exercise is not enjoyable	9.66	9.57	23	20
Lack of success in the past	8.40	9.09	20	19
Lack of place or equipment	7.14	6.70	17	14
Lack of support or encouragement	6.30	5.26	15	11
Difficulty setting goals	6.30	5.74	15	12
Lack of confidence	4.62	4.30	11	9
Exercise is boring	3.78	3.83	9	8

Sowers, K, Litwin, BA, Lee, ACW, and Galantino MLA. Exercise Perception and Behaviors in Individuals with Primary Immunodeficiency Disease. *Journal of Clinical Immunology*, 2018 Feb;38(2):174-184.

your ability to stay on track with your new exercise plan. If you are struggling to get started that day, one trick is to "get dressed and show up." What this means is that you prepare and attempt to engage in your chosen exercise program even if you don't really feel like doing it. Sometimes just getting the routine started is enough to motivate you to continue the activity.

There may be days when you start the activity but still find you can only tolerate half of what you usually achieve. That's OK because you still accomplished some level of activity (certainly more than not doing anything that day). If you begin the activity and find that you still can't engage, that's when you know it's time to acknowledge you need a rest day. You might also find that you need to reduce the intensity or duration of your activity that day, especially if there was a physical or mental reason for you to have less energy.

Ultimately, you should listen to your body, and modify your exercise program or activities as needed. Don't feel guilty about needing to perform less activity or rest on some days. Even elite athletes take time off to rest their bodies, so you can too! If you find you are having to modify your exercise plan too frequently, then you should reevaluate your exercise goals and take smaller steps.

Simple Ways to Move More

One of the most effective ways to exercise more is to simply increase your level of activity in a normal day. People often think that they need to set aside a significant amount of time to exercise or they need to engage in a formalized exercise program, but that is simply not true. You can assess your day-to-day activities and look for small ways to increase your physical activity or movement during a normal day. This may only require 5 to 10 minutes spaced throughout the day, which can make the activity less stressful and fatiguing for you. Examples include:

- A simple walk outside (or wheel, if you are a wheelchair user), beginning with a trip down the driveway and back, can be a great first start. If the weather is not optimal, you can find a local mall which often provides an accessible and climate-controlled environment.
- If you have stairs at home or at work and you are physically able to climb them, stairs are a great activity to challenge your fitness. Start with adding in one flight (or even a few steps up and down, if a full flight is too taxing), then progress to adding multiple flights per day.
- When you bring home groceries, instead of taking everything in at one time, make multiple trips between the

car and house, as this will add more walking.

• Parking your car father away and increasing your walking distance can be a great way to add physical activity to your day.

• If you are a wheelchair user, adding to the distance that you wheel is an easy way to add to your activity level. Performing wheelchair pushups and more frequent transfers to and from your wheelchair is another way to increase your physical activity.

• Other common activities that provide great physical activity, which people don't often count as exercise, are things like gardening, yard work, housecleaning, dog walking and even playing with your pets or children.

Barriers to Exercise

Typical barriers people with PI often worry about are being exposed to germs at the gym and the cost of an expensive gym membership. However, increasing physical activity doesn't require a gym membership. Instead of free weights, you can use full water bottles, canned goods or bags of rice or potatoes. Exercise bands can be purchased inexpensively and can be attached to a chair or bed to provide resistance. You can perform wall squats and push-ups using a wall or sturdy countertop. If you are spending time watching television or preparing meals, you can perform standing or sitting activities. Try stretching while watching your favorite show. There are many free fitness apps and online videos if you need some help to learn about the activities you can perform; these apps can help you perform the activity correctly, which will also help prevent injury while exercising. The bottom line is you do not need any fancy equipment — you just need to start moving!

Ideas for Accountability

For some people, it can be hard to stay motivated when exercising alone at home. If you are that person, consider joining an outside activity or taking classes. A few suggestions are sports, dancing, yoga, tai chi, Pilates, Zumba, gym membership, fitness classes, CrossFit, guided nature walks, swimming or community gardening/clean-ups. Paid fitness apps can provide you with on-demand classes with a guide to take you through the fitness activity you choose. Another place to look for classes or group fitness activities is your local senior center, YMCA, community center or local college/university. You might also find that your health insurance or workplace will provide reimbursement or incentives to participate in fitness programs. For many people, having an accountability partner might be all you need. This could be a friend you participate with in the activity, someone you can call or FaceTime with while you exercise together, or just someone you do regular check-ins with to ensure you are holding each other accountable.

Start Small, But Get Going!

The bottom line is you need to commit to making a change in your level of physical activity and move more. Start small and give yourself time to build up; you don't need to do an Ironman tomorrow, or ever! Also, don't compare your progress to others; your exercise program needs to meet your individual goals and needs. Make your physical activity fun (or at least make it something you don't hate to do)! Set flexible and realistic goals, and understand it is OK to modify those goals when needed. Understand what motivates you, and build your exercise and physical activity goals around that motivation. Use technology to help track your activity so you can see the progress you are making. This also lets you see if you have plateaued or regressed, so that you can reevaluate your goals. The most important thing of all is to be kind to yourself as you make this change. Change takes time and effort. Now go get moving! IG

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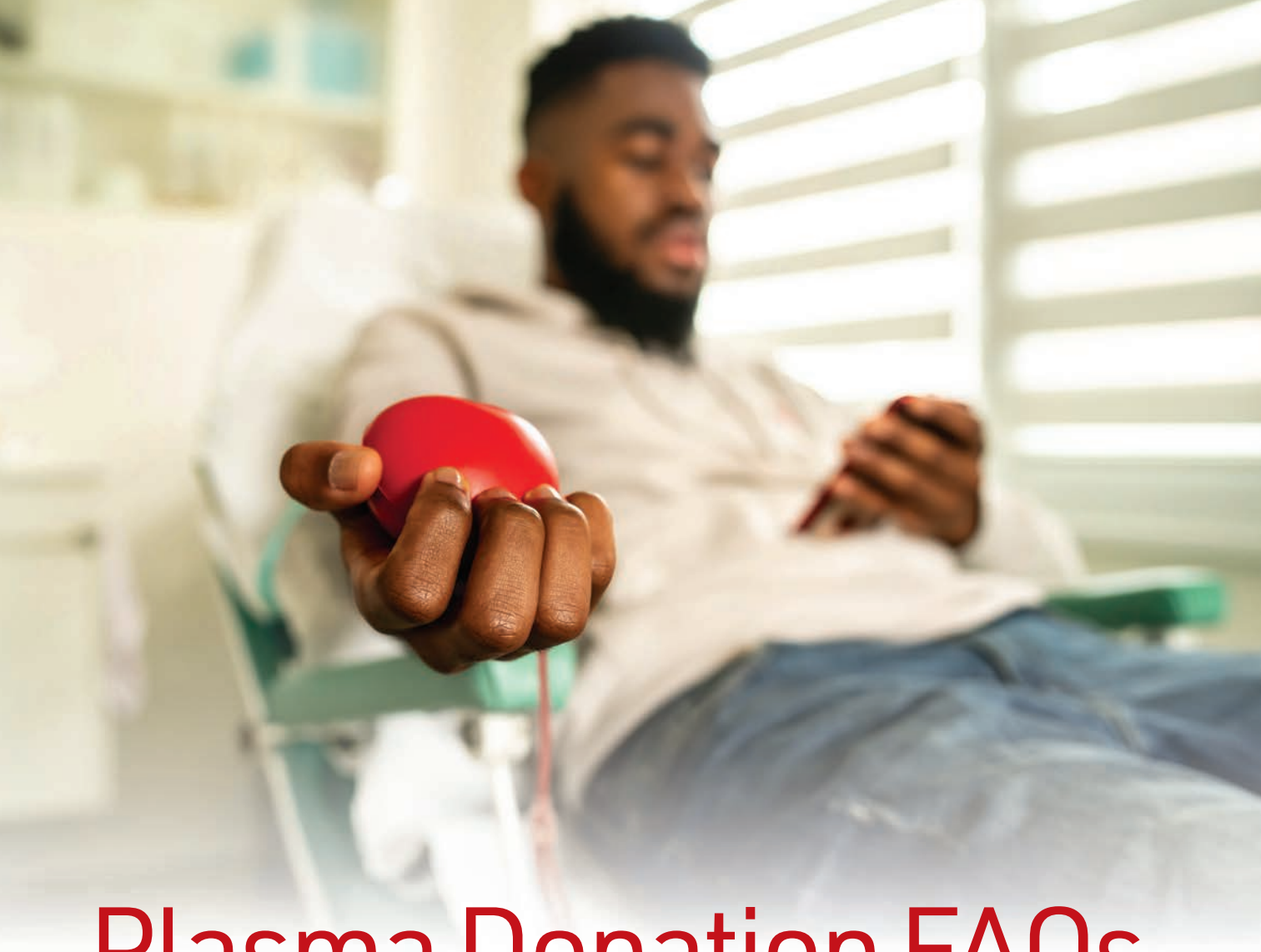

Plasma Donation FAQs

Patients treated with immune globulin will benefit by understanding the plasma donation process that is used to manufacture their lifesaving therapy.

By Ronale Tucker Rhodes, MS

PLASMA DONATIONS save countless lives each year. Donated plasma is used to produce a variety of plasma-derived medicines that are often the only therapies for many rare and chronic diseases.[1] One of those plasma-derived medicines is immune globulin (IG), which is approved by the U.S. Food and Drug Administration (FDA) to treat immunodeficiency diseases, immune thrombocytopenic purpura, chronic lymphocytic leukemia, chronic inflammatory demyelinating polyneuropathy, Kawasaki disease, multifocal motor neuropathy and dermatomyositis. IG therapy is also prescribed off label (meaning it is not approved by FDA) to treat other autoimmune and inflammatory disorders.

In addition to IG, plasma is used to make therapies such as clotting factors, alpha-1 antitrypsin, albumin, hyperimmune globulins and others to treat hemophilia, septic shock, trauma, burn victims, cancer patients and other disorders. And, just as there is no substitute for blood, there is no substitute for the therapeutic proteins that come from plasma.[2] To make one batch of IG, it takes the pooled plasma of 3,000 to 10,000 healthy blood donors.

What Is Plasma?

Plasma is the often-forgotten component of blood. White blood cells, red blood cells and platelets are all important

components of blood to ensure bodily function.[3] But, plasma is the single largest component of human blood that makes up more than half (about 55 percent) of its overall content. When separated from the rest of the blood, plasma is a light yellow liquid,[4] comprised of approximately 92 percent water, with the remaining eight percent a mix of vital substances such as glucose, hormones, proteins, mineral salts, fats and vitamins.

The main role of plasma is to take nutrients, hormones and proteins to the parts of the body that need it. The proteins in plasma include antibodies that alert the immune system to the presence of potentially harmful foreign substances.[4] Indeed, the pooled plasma for IG therapy is purified to contain more than 90 percent antibodies (the natural proteins that the body normally makes to help fight infections and to serve other functions for the immune system). Plasma also helps remove waste products (put there by cells) from the body. In addition, plasma carries all parts of the blood through the circulatory system.[5]

How Are Plasma Donations Made?

There are more than 1,000 International Quality Plasma Program (IQPP)-certified plasma donation centers in the United States.[6] The Protein Plasma Therapeutics Association's (PPTA) IQPP provides an independent evaluation of adherence to global industry standards for source plasma, specifically focusing on donor management and health. In 2010, approximately 19.8 million plasma donations were made. Nine years later, the annual number of donations was 53.5 million.[7]

While individuals are allowed to donate blood only every 56 days (or approximately every two months) for a total of six donations per year,[5] individuals can donate plasma up to two times per week since plasma is 92 percent water and regenerates much faster than blood. In fact, countries that collect source plasma rather than extracting it from blood (known as recovered plasma) are about 800 percent more efficient.[8]

Not everyone is eligible to donate plasma, but most are. According to Olgam Life, a plasma donation service, eligibility criteria ensure both the safety of the donor and the quality of the collected plasma. Generally, donors must be at least 18 years old and weigh at least 110 pounds (50 kilograms). They must be in good health and must pass a medical examination. Additionally, potential donors must complete a health history questionnaire to rule out risky behaviors and exposure to certain diseases. (These criteria may vary slightly among different plasma donation centers.)[5]

In addition, individuals can donate plasma regardless of their blood type. The plasma used in therapeutic treatments is known as AB plasma, which is universal, meaning it can be given to anyone. As such, the plasma of people with an AB blood type is especially helpful. But, again, it doesn't matter what the blood type is; plasma from any blood type can be used in manufacturing therapeutic treatments.[5]

Donating plasma is similar to donating blood. During the donation process, a small needle is inserted into a vein in the arm, which can result in a little discomfort.[9] After the needle is inserted, staff at the donation center do all they can to make donors comfortable throughout the process. The one difference between plasma and blood donation is that individuals are also required prior to plasma donation to submit to a finger stick test each time so the collection center medical staff can evaluate their protein and hemoglobin levels. The first plasma donation appointment typically takes approximately two hours, while subsequent appointments take about 90 minutes.[10]

Is Plasma Donation Safe?

Plasma donation is safe for both donors and for patients treated with plasma-derived therapies.

Plasma is a type of apheresis donation, which means the donor gives blood with the help of a machine that draws out whole blood, centrifuges it (spins to separate it), retains the plasma and then returns the other blood products back to the donor, all through the same needle. This allows the

Plasma Donation FAQs

- Individuals between the age of 18 and 69 years are eligible to donate plasma.
- A plasma donation can range from 690 mL to 880 mL depending on the donor's weight.
- Approximately 70 percent of the globally collected plasma is used to treat primary immune deficiencies.
- The U.S. is the largest exporter of plasma, contributing around 70 percent of the global supply.
- Approximately 55 percent of blood is plasma.
- Plasma is used in the treatment of a variety of autoimmune diseases such as Guillain-Barré syndrome and chronic inflammatory demyelinating polyneuropathy.
- The process of collecting plasma is called plasmapheresis. It separates the plasma from the blood cells, which are then returned to the donor.
- Plasma donors are often compensated for their time and can typically receive, on average, $500 per month, depending on what state they live in.

Source: Olgam Life. Plasma Facts and Info. Accessed at olgam.com/usa-plasma-donation-statistics.

collection of a greater quantity of plasma without risking the health of the donor. A single donor can safely donate up to four units (pints) of plasma every four weeks due to its abundance in the body and ability to quickly replenish.[11]

Plasma donation in collection centers is performed in a highly controlled, sterile environment by professionally trained medical staff. All plasma collection equipment is sterilized, and any equipment that comes into contact with the donor is used only once to eliminate the possibility of transmitting viral infections.[8] In addition, all supplies used in the donation process are single use.[8]

All new plasma donors go through medical screening during which their vital signs, hematocrit and total protein levels are checked, a physical exam is performed, and medications and health conditions are reviewed. Only when donors are determined to be healthy to donate are they allowed to. Indeed, many potential donors do not pass this rigorous health screening. But if they are allowed to donate, each time they return, they go through another medical screening and are allowed to donate only if their vital signs, hematocrit or total protein levels are in range. Protein levels are also checked periodically, and if they are not within range, the donors are temporarily deferred until the protein levels return to normal.[8]

There is of course, as with any other procedure, a small risk of side effects for donors. Bruising and nerve irritation are among the most common side effects, typically around the injection site, which can be treated with cold packs. Nerve irritation causes immediate, intense pain at the injection site and can cause shooting pain down the arm and into the hand. If this happens, a technician will immediately remove the needle.

More serious risks of donating plasma may be a drop in blood pressure, which can result in lightheadedness or fainting. Other possible side effects include sweating and paleness, weakness, sudden warmness and nausea or vomiting. Dizziness and blurred or tunnel vision may also occur. A citrate reaction could occur if individuals are sensitive to the chemical citrate, which is added to the separated blood to prevent clotting. If a severe citrate reaction occurs, the donation process is halted. When the remnants of the donation are returned, individuals may experience tingling around their mouth, face, hands or feet. More severe reactions include cramping of the hands or feet, sudden weakness, muscle spasms, chills and shaking, nausea or vomiting, and numbness around the mouth.[12]

Some individuals question whether donated plasma is safe since donors are paid. But, payment is necessary to meet the global demand for plasma, which continues to rise by six to eight percent each year. What's more, the United States supplies two-thirds of the world's blood plasma, the majority of which is used to develop lifesaving drugs and to treat life-threatening conditions. There is no synthetic substitute for plasma, so drug manufacturers rely on a steady stream of human donors to make up their supply. Unfortunately, global demand for plasma far outpaces supply. "The bottom line is if the U.S. didn't compensate donors, there would not be enough plasma and lives would be lost globally," then-president of the Immune Deficiency Foundation wrote in a February 2019 statement.[13]

Others question whether donated plasma is safe because many donors are believed to live unhealthy lifestyles. While it's true that compensation is beneficial, especially for those who need it, individuals are intensely screened to ensure that any effects of unhealthy lifestyles don't affect the quality of the plasma. Again, strict health screenings are conducted at the beginning of each donation to help ensure the donor is healthy. Every single donation is also tested for transmissible diseases such as HIV, hepatitis A, B, C and syphilis.[8] Throughout the entire process, a donor interacts with a minimum of four staff members who are trained to identify signs and symptoms that suggest an unhealthy lifestyle. If a donor does not pass the strict health screening criteria, he or she cannot donate plasma.[14] Those donors are then entered into a national database that plasma centers must check prior to registering a new donor.[8] And, if an approved donor's medical tests come back positive for certain viruses/diseases, his or her plasma is immediately destroyed.[15]

In addition to screening, plasmapheresis and fractionation are intensive processes that create clean, safe plasma for those treated with plasma-derived therapies. As mentioned earlier, plasmapheresis is a sanitary, self-contained, automated process during which plasma is separated from red blood cells and other cellular components of blood that are then returned to the donor. According to PPTA, the manufacturing process is known as fractionation. During fractionation, "proteins are separated to create a number of plasma protein therapies using well-established purification methods such as precipitation, centrifugation, separation and filtration. Fractionation employs time, temperature, pH and alcohol concentrations to extract specific therapeutic proteins. These are then subjected to various purification methods and viral inactivation and removal processes to further ensure their safety and efficacy. Preparing a therapy often takes between

seven and 12 months between donation and final product release. This sets the production of plasma protein therapies apart from chemical pharmaceuticals and other biologics whose manufacturing processes are much more condensed and whose direct manufacturing costs are a significantly smaller portion of the overall cost. In addition, fractionators invest substantially in research and technologies to increase the quality of proteins extracted from plasma, known as the 'yield,' and create new and more effective therapies."[16]

Plasma Donors Save Lives

Donating plasma is a selfless act. It saves lives, and it is the only way to provide those who require plasma protein therapies with the treatments they need to survive. What's more, donating plasma is safe, and adverse events are infrequent.

The future of treatments with plasma-derived therapies depends on the supply of plasma. To help prevent shortages, patients and their caregivers should encourage plasma donation and recognize those who give their time to help save lives. IG

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

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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).

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.

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

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.

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PP-CQG-USA-0561

March 2023

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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).

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Profile: Mindy Bedrossian

By Trudie Mitschang

AT AGE 70, Mindy Bedrossian lives with multiple chronic illnesses, including chronic inflammatory demyelinating polyneuropathy (CIDP). But that didn't stop the Ohio resident from catching eleven flights, enduring hours sitting in multiple airports and essentially circumventing the globe for a once-in-a-lifetime trip to India and Thailand this past December. Here, she shares highlights from her fearless journey and tips for others who want to push past boundaries and see the world on their own terms.

Trudie: When were you diagnosed with a chronic immune disease, and what is your diagnosis?

Mindy: I had my first symptoms when I was 30 years old and pregnant with twins. I was on complete bed rest, and since I loved quilting, I kept myself busy by creating two baby quilts for myself. But I kept dropping the needle and my hands kept getting numb and tingly. The doctor said it was carpal tunnel. "In both hands?" I asked. I knew immediately that was the wrong diagnosis. That was the start of a 20-plus year journey to the real diagnosis, finally in my 50s, of CIDP. It took that long to get it right.

Trudie: Tell us about your immune globulin (IG) treatment plan.

Mindy: I started on monthly intravenous IG (IVIG) once I was correctly diagnosed and after a whole lot of tests. I was not one of those people who have a quick response and there's an astonishing improvement overnight, but over the next four months I did see improvement. I also got aseptic meningitis from the IVIG being administered too quickly. Once it was slowed down dramatically, the migraines I initially suffered were not as debilitating. I was a high school teacher at the time, and it was not unusual to see me walking the halls of the high school wearing sunglasses the days of my infusions.

Trudie: When and why did you switch to subcutaneous IG (SCIG)?

Mindy: I was on my third port over 15 years when COVID came along. I always had my infusions at home, but at age 65, Medicare insisted I go to an infusion center. I know that in some areas Medicare approves home infusions, but not where I live. I immediately switched to SCIG and have never looked back. My last port was surgically removed about a year after I switched to SCIG. And no more migraines!

Trudie: What was the inspiration for your three-week globe-trotting trip?

Mindy: My younger son was getting married to a young lady from India this past December, and of course, I wasn't going to miss an Indian wedding! My older son is married to a Thai woman (we're a very international family!) and I would be traveling straight from Mumbai to Chiang Mai in Thailand where they live. I literally would have to circumnavigate the world to get back home to Ohio where I live.

Trudie: How did you prepare given your medical condition and physical limitations?

Mindy: I honestly spent months working out all the details of this trip. I would be traveling alone the entire time, and this would not be easy. Like many autoimmune disease patients, I have had a virtual cascade of common and strange autoimmune diseases descend on me. From diabetes to arthritis to rare things such as inflammation on the inside of my eyes, to sores covering my tongue, to an outbreak of plaque psoriasis appearing for the first time at age 70. All these things required a lot of medicine for me to carry, in addition to carrying three weeks of SCIG doses plus supplies. Also, because of the CIDP, I walk with a cane. I am slow, easily fatigued and have very poor balance. There was a lot to consider!

Trudie: Tell us about the planning process.

Mindy: I created all sorts of lists, trying to anticipate every possible scenario. First, I registered with all the airlines, including foreign ones, to make sure I would get wheelchairs to and from every plane. My daughter-in-law in Thailand assisted in getting some of the foreign airlines to agree to provide a wheelchair. Just registering with U.S. airlines does not get you help overseas. Each one of those airlines requires a separate contact, either by phone or email. This was incredibly important because I didn't want to have to wait on long lines

in which I would have to stand, which I just can't do. Second, I looked at my medications, especially the SCIG. If you look online, you will see these little suitcases for medical items, but have you tried to carry these with your other bags? They are heavy, awkward and ridiculous to carry if you've got a large bag with all your other items, plus a big suitcase to haul. My hands are weak, so there was no way I could manage that. Yet I knew I needed the IG medication on my person at all times.

Trudie: What airline restrictions did you navigate?

Mindy: Many flights now forcibly take your carry-on suitcase and insist it goes in the luggage compartment of the plane anyway. That cannot be permitted with IG medication. I bought a special backpack that's theft-proof (lined with cut-proof mesh inside), and I put the IG medication and all the supplies necessary inside (including the vials, pump, syringes, tubing, gloves, etc.). Inside, I had a letter from my physician verifying it was a medical necessity. Carrying everything in a backpack made it easier to walk with a cane.

Trudie: How did you find space in hotel rooms to do your infusions?

Mindy: This was actually a bit tricky. I would spread a sterile drape on the bed, lay out my materials, and basically do it that way. If the room had a chair and desk, I did it there instead. I kept a clean towel and a soapy washcloth with me as well so I could clean my hands as needed. There were a lot of different rooms I stayed in, so I had to adjust to each one. I did not have a single problem doing it this way. I just needed to make sure I was in a comfortable position to get it done.

Trudie: What other unique challenges did you face, and how did you overcome them?

To carry all of her medications, including her SCIG supplies, as she navigated eleven different flights to India for her son's wedding, Mindy purchased a theft-proof backpack she could wear on her back while also managing her other luggage.

Mindy: Most people are unaware of the fact that the IG medication is stable at room temperature for up to a month. I didn't have to worry about keeping it refrigerated for this three-week trip. However, something to be aware of is that some hotels in Asia are set up so the electricity in the room only turns on when a card key is inserted into a slot. That means that even if there is a fridge in the room, it will go off once you leave. Since it can easily hit 100° F or more outside, these rooms can get very hot. Always request a second card key so you can keep the power on when you're not there. Make sure you explain to the staff that the AC/fridge must remain on at all times so the medication doesn't get too hot.

Trudie: Were there any issues with airport security?

Mindy: I only needed to show my letter when there were questions about the supplies. I think that it was quite obvious it was some sort of medication, and I was in a wheelchair with a cane as well.

Trudie: What did you learn about yourself during this adventure?

Mindy: My family tried to convince me not to do this trip. Nobody thought I could manage it! Eleven flights, hours sitting in airports waiting for the next plane, wondering if I could make it to the next ticket counter. It was quite the adventure, and I did it!

Trudie: What advice do you have for others who want to travel, despite their physical limitations and diagnosis?

Mindy: Plan for every single possible eventuality — from cancelled flights, to lost luggage, to getting sick on the journey. Keep your medications with you at all times. Go slow, leave long layovers so you don't have to rush or worry about delays interfering with the next flight. Since I was traveling around the world in December during COVID and flu season, I bought expensive medical travelers' insurance that guaranteed a flight home for medical care. Thanks to my mask, the worst I caught was a mere cold.

Trudie: Were there any specific setbacks you had to navigate?

Mindy: Since I had to carry my IG supplies along with insulin and other medications, I only carried some high protein snacks and a Kindle with me. Some of my flights left me overnight in airports where all the food kiosks were closed. One airport was so crowded that people were sitting on the floor with piles of luggage around them. I couldn't go to the bathroom the entire night because I would lose my seat if I did. But looking back, I wouldn't have missed this trip for the world! IG

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

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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 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

"Summer Lovin' Had Me a Blast"

By Michelle Searle

I GREW UP in Florida where it's warm year-round, but now that I no longer live there, I yearn for the summer season: beaches and swimming, sundresses and sandals, picnics and ice cream — and warmth! Since I'm a teacher, I love summers even more than I did when I was growing up. Summer feels exceptionally freeing now: Free from layers of sweaters, scarves and coats. Free from harsh, cold wind hitting my face. Free from keeping hand lotion and lip balm nearby. Free to gather outside with other people.

Although I fantasize about spending my summer days outside reading, swimming and taking long walks, that's not how my summers usually go. I still work, study, get sick and deal with regular adult day-to-day responsibilities. Even when I'm free from work or school, I don't always take full advantage of the season like I could. So, I'm writing this month's column as a reminder to us all to get out and enjoy the season before it's gone.

Get Out of Your Town

Take a break from where you live and explore somewhere new. I know summer can be an expensive, crowded time to travel, but I'm not saying go to Europe like everyone on Instagram. Take a road trip or a train ride to a nearby city and explore it. Do you have friends in other parts of your state or country you'd like to visit? Go see them. Not only would it be fun to catch up with friends, but you could also save money by staying with them, too. When I was in college, I loved visiting friends throughout Florida and seeing what their college and campus life was like.

Socialize Like a Butterfly

Between the fear of getting sick and my hatred for cold weather, I didn't get out much during the winter months. In the spring, I started to attend group classes at my gym again, went to events and hit the dance floor without a mask. Now that it's summer, there are a lot of opportunities to do the things I like outside such as yoga, going out to eat with friends and walking around open-air markets. Whatever you like to do, reach out to some friends or family and head outside, especially if you're healthy enough to do it. When the weather is bad or we're too sick to do anything, we have no choice but to stay inside, isolate, watch TV or read a book. When the sun's out and we're feeling good, we've got to take advantage of that.

Go Near Water

If you don't live near a body of water, head to a beach, lake or even a water park this summer. It's great for your mental health! Relax on an inner tube while floating down a lazy river, have fun swimming in the waves at the beach or in a wave pool, or grab some cold drinks and yummy food and have a picnic in the sand. Go with friends, family or a furry friend. You can even go alone! Lounging by the water is great to do independently. You can listen to your favorite podcast, read a book, walk along the water, work out or talk on the phone. My favorite thing to do is lie by the water with a book and some food: I could spend hours getting lost in a book and the sound of waves! Not only does it provide an escape from my reality for a bit, but looking out at the ocean reminds me that my problems are not as significant as they feel. The waves will continue to roll, the sun will continue to rise and set, and the clouds will continue to move through the sky.

Enjoy It While It Lasts

Whatever you do this summer, remember two essential things: Enjoy yourself outside, and wear sunscreen! I know we're young and hot now, but we've got to protect our skin. Our future selves will thank us! I hope you all stay warm, healthy and hydrated this summer and soak up a lot of vitamin D. Even if you grow tired of the heat and sweat, it'll be gone before you know it, and you'll miss it once again. IG

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

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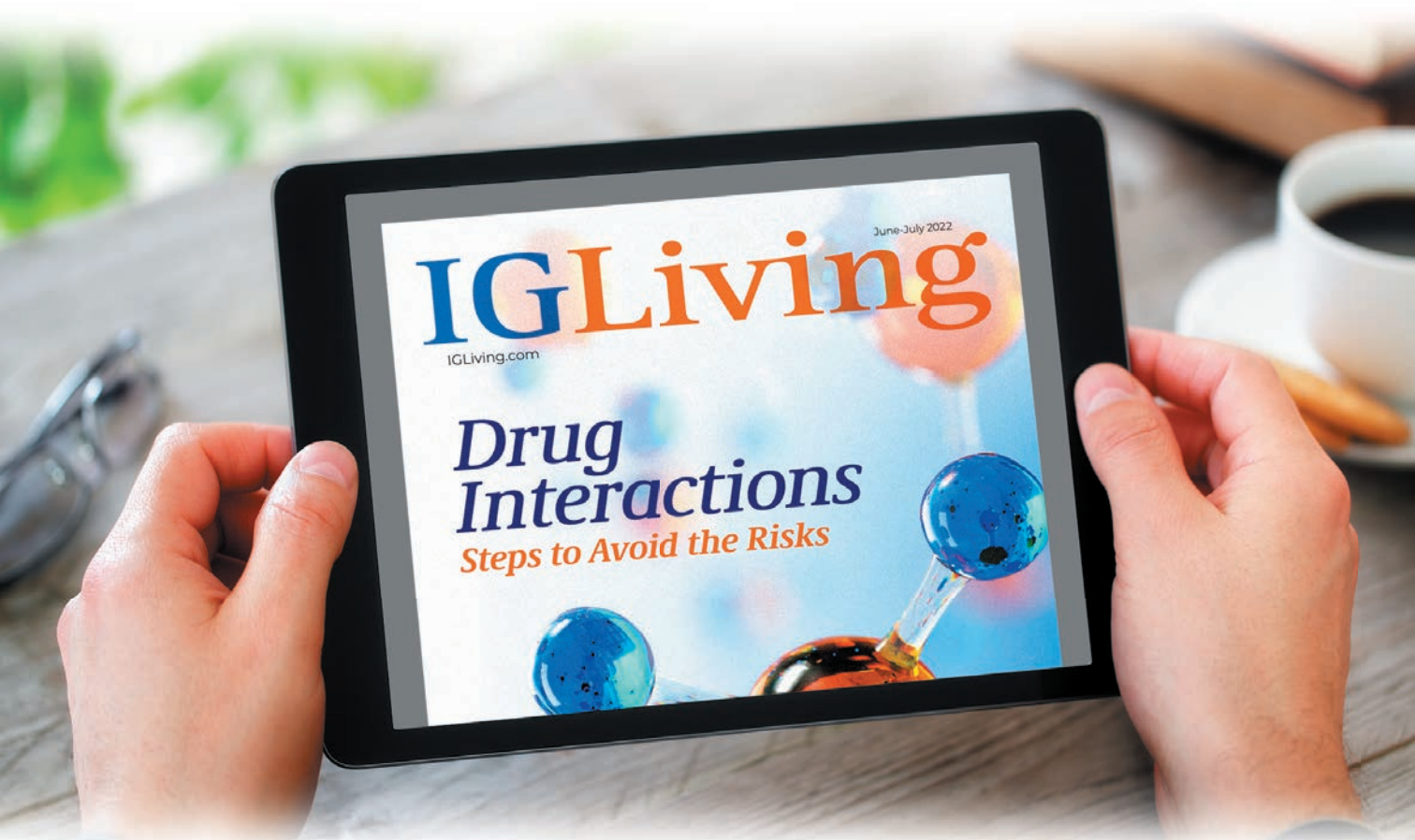

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Reconnect with friends over dinner

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.

Want to learn more about the effectiveness and safety of CUVITRU?

Scan the code to see the data and browse around the website.

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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US-CUV-0408v1.0 07/21

10 Things That 20-Plus Years of Chronic Illness Taught Me

By Megan Ryan

FOR CHRONIC ILLNESS patients, there's the journey of diagnosis, and then there's the journey called the rest of your life. With more than 22 years of living with a complex and evolving chronic disease, I have learned a few things worth sharing with others.

Sleep is powerful. Both quantity and quality of sleep is key. Yes, how many hours of continuous sleep you get is important, but the quality of those hours is also important. I've found that the quality of my sleep is influenced by evening eating and screen time habits, as well as bedtime routines.

Manage your energy like you manage your time. Managing time is important, but I've learned that managing all elements of energy, including my physical and emotional energy, impacts my overall health.

Pacing is key. The boom-and-bust cycles of managing fatigue and pain make life increasingly challenging. I've slowly learned I cannot exert all of my energy when I'm feeling great and must pace myself.

Find activities that refuel you. Just like the battery on your phone needs to be charged to keep working, so does your mind and body. Sleep and a healthy diet are important kinds of fuel, but so are a variety of activities that help you get your mind off your illness or condition.

Positive thoughts or prayer do not solve everything. Yes, there is incredible power in prayer, meditation and positive thinking, and research shows these are powerful tools in healing and physical medicine, but psychosocial support and mental health therapy, and in some cases, medication are pillars for the journey.

I am Megan — a wife, daughter and friend to many, who also happens to live with some unique medical challenges.

Kale salads and CrossFit are not going to cure your disease, but a healthy diet and regular exercise are essential. My diet is not perfect, but focusing on healthy eating habits and proper hydration have served me well. I don't engage in extreme sports, but brisk walking and hiking are my go-to activities.

Routine screening exams do not go away just because you are perpetually poked and prodded. While I wish visits with my core team of "ologists" could cover all my health needs, I still have to get regular preventive care, including cancer screening exams and eye and dental exams.

Medicine is both science and art. And good medicine includes honest and candid conversations from me with my doctors so they can offer the best treatment options available.

Maintaining personal medical records is essential. Don't count on electronic medical records from your providers to be your personal medical history. Keep a list of all current medications easily accessible. Document your diagnoses (including diagnosis date), and keep a copy of the diagnostic tests that confirmed that diagnosis. Maintain a list of all doctors and their contact information, including phone and fax numbers.

A disease cannot and should not define any person. I am not Megan with common variable immune deficiency and a host of other diagnoses. I am Megan who gives my time to projects that matter to me and my community. I am Megan — a wife, daughter and friend to many, who happens to live with some unique medical challenges. 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.

Establishing a Cooperative Relationship with the School Nurse

By Jessica Leigh Johnson

WHEN MY OLDEST son was first diagnosed with a primary immune deficiency disease (PI), he wasn't yet 3 years old. We were in the pediatric intensive care unit of a large hospital where he had been for almost a month, suffering from a serious bout of viral pneumonia and a secondary blood disorder called HLH. We nearly lost him. The relief my husband and I felt when his health made a turn for the better was dampened by his diagnosis with a lifelong chronic illness. We worried that he wouldn't have the same chances as other kids or that he wouldn't get to experience the same things. All we wanted for him was a shot at a normal life.

He is now 21, and he has had about as normal a life as anyone else, save for weekly subcutaneous infusions, daily chest physiotherapy sessions and a chronic cough. He has participated in sports, gone to summer camp and taken camping trips and snowmobile trips with friends. But the first big milestone he reached, when he left the safety and comfort of home and the protection of mom and dad, was his first day of public school at 6 years old.

Sending my chronically ill child off into the world, away from my watchful eye, for seven hours a day, was a tough transition, but it was made easier by the fact that his school had a nurse on staff who would be there every day with him. She knew about his condition and what to watch out for, what could harm him and what to do about it, and when to call me so I could pick him up and remove him from situations that could potentially threaten his health. My mind was mostly at ease sending him (and his two brothers after that) to public school each day knowing there was someone looking out for him.

Of course, I may not have felt quite so comfortable if I hadn't first established a good relationship with the school nurse prior to my son's first day, and explained to her the details of his chronic health condition. For parents of children with chronic illness, getting the school nurse involved in that child's care is imperative, both for the child's well-being and for the parents' peace of mind.

Step One: Arrange a Meeting with the School Nurse

School nurses handle everything from scraped knees and bloody noses to chronic conditions such as type 1 diabetes, epilepsy and food allergies. However, considering how rare some conditions are, such as many forms of PI, there is a good chance the school nurse has never heard of a child's particular condition. For parents of students with a chronic illness, especially a rare one, it's important to set up a meeting with the school nurse and possibly other staff members at the school who will be working closely with the student. Parents should bring along any educational material they may have that explains the condition, as well as a list of things to look out for and when parents should be notified such as during disease/viral outbreaks within the student body, etc.

According to M. Elizabeth M. Younger, CRNP, PhD, a pediatric nurse practitioner and long-time member of the Immune Deficiency Foundation's (IDF) Nurse Advisory Committee, school nurses also play an important role in "raising the index of suspicion"[1] when it comes to students with undiagnosed conditions, so the more they can learn about these rare conditions, the better off future students will be.

Step Two: Develop a Plan

Once the nurse is fully aware of the student's health issues, he or she can work with the parents to develop a plan* to communicate new medical information between home and school.[1] Some of the items to include in the plan might be:

- Include family members in all decisions regarding the child's care while at school.
- Provide short-term care for acute injuries (such as scraped knees) or illnesses.
- Administer pre-approved medication to the child.
- Perform healthcare procedures required by a child with special health needs.[1]

Step Three: Implement the Plan

The plan for the child's healthcare while at school should be tailored to the child's specific needs. Once the school year starts, that plan gets put into action.

For example, part of my son's school healthcare plan required that we be notified when the number of absences in the school, as well as in his individual classroom, hit a certain number. Due to his condition, we were concerned with him being surrounded by so many other children (especially for the first time in his life when he started kindergarten), and we worried about viral outbreaks and other illnesses such as strep. According to the plan, we would keep him home from school when the number of absences got too high.

My son started kindergarten in August 2009, right about the time the H1N1 swine flu pandemic was spreading across the globe. Right off the bat, we got a chance to see how well our school healthcare plan worked. To say I was nervous sending him to school each day would be an understatement. Our school nurse kept close tabs on the number of children calling out sick with flu-like symptoms, and when my son's class hit that predetermined "magic" number of absences, we kept him home for a week. Because we had already put this plan in place, we had the teacher's and the nurse's blessing. And unlike my usual mode of operation, I wasn't frantic or panicked — the nurse simply called me and said, "There are 13 kids out today in your son's class. You probably shouldn't send him tomorrow." Thankfully, he managed to escape the swine flu that year.

Recommendations for School Nurses Regarding PI

For parents of children with PI who are nervous about sending their child to school for the first time, IDF has several resources available on its website (www.primaryimmune.org) to educate people about PI. Although each specific disease under the umbrella of PI has unique challenges, Dr. Younger has suggested some general guidelines for school nurses who have a child with PI in their school:

- Do not administer a vaccine or treatment without a parent or guardian's permission.
- Understand what types of precautions the child should take and what concerns need immediate reporting to parents.
- Determine the best route of communication (email, phone, text, etc.) with parents about issues such as illnesses at school, and have a list of contacts in order of priority.
- Discuss with parents whether they want other students or parents to know about their child's condition, and if so, what details to share.
- Monitor any environmental accommodations that have been put into place and amend if needed.[1]

Ensuring a Successful School Experience

Sending a child with a chronic condition to in-person school, especially when they're little, can be very stressful for parents, but the school experience isn't something children need to avoid to stay healthy. Allowing the school nurse to play a role in their care will ensure that they're being looked out for while away from home. An open and trusting relationship with the nurse allows parents to feel more at ease and confident that their child's condition will not prevent them from having a successful educational experience. IG

**Editor's note: Section 504 of the Rehabilitation Act of 1973 provides protections for students with disabilities, including those with chronic illnesses such as immunologic disease. Talk to your child's school about creating a 504 plan, which is a legal document parents and schools prepare together to record appropriate accommodations for your child.*

Reference

1. School Nurses Aid in Care of Children with Primary Immunodeficiency. Immune Deficiency Foundation. April 16, 2024. Accessed at primaryimmune.org/resources/news-articles/school-nurses-aid-care-children-primary-immunodeficiency.

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

Practical Ways to Support Chronically Ill Friends, Family and Neighbors

By Rachel Maier, MS

WHEN PEOPLE we care about are sick or suffering, it's natural to want to help them. We almost can't help it! But wanting to help and knowing how to help are two very different things.

Last year, a friend's son was diagnosed with terminal cancer. I wanted to help, but I felt stuck: What could I say or do to help ease the burden even a little bit? Providing comfort and encouragement is one thing; providing practical help is another. An encouraging note doesn't make dinner for someone who is too tired or emotionally wrung out to cook.

Sometimes the gap between recognizing someone needs help and knowing how to help them is wide and intimidating. We want to respect privacy and boundaries, and we don't want to intrude or be a bother. But if you've ever been through a hard time, you know how meaningful simple gestures are; all of them encourage us and help us remember we aren't facing hardship alone. We also know the sheer joy of a hot meal we don't have to cook; a bill we don't have to pay; a load of laundry we don't have to fold. No, you can't do everything — but you can do *something*!

Five Easy Ideas

Here are practical ways you can help serve the people in your family and community who could use a helping hand. This is a short list to get you started, but once you start brainstorming, I bet you'll come up with all sorts of other great ideas!

1) *Provide meals.* Cooking is one of those daily tasks that can feel overwhelming. Set up a meal train, and invite friends and neighbors to sign up for a slot. Call your friend and tell them you'd like to provide them with one meal per week for the next three months, and ask what day of the week works best. Find out their family's favorite local restaurant, and send a digital gift card so they can get takeout on a night that works for them.

2) *Do household chores.* The last thing folks feel like doing during a really tough season is clean their house. (Can I get an amen?) Pitching in to get the house cleaned up would mean the world to someone who doesn't have the time or energy to do it themselves. Pick up their towels and return them clean, dry and folded. Set up a weekly appointment to come scrub their toilets. Send your teenager over to cut their grass or pick up after the dog on Saturdays. Go in with some friends or neighbors and hire a house cleaning service.

3) *Run errands.* Call or text and offer to pick up or return library books, run outgoing mail to the post office, pick up dog food or even do the weekly grocery shopping. You can even offer to drive them to and from medical appointments if they need that.

4) *Give gas cards.* From attending physical therapy to picking up prescriptions, folks with chronic conditions are often on the go. With all the extra driving, a gift card for gas would be a welcome blessing. Grab a gas card in the checkout line at the grocery store, and send it in a "thinking of you" card through the mail, drop it by their house or include it in a care package.

5) *Offer to babysit.* As willing as they are to devote their time and energy to their chronically ill kids, parents rarely get a break. Offer to watch the child(ren) while the parents enjoy a massage, catch a movie or grab dinner. Or, if the parent is the one who is chronically ill, offer to have the kids over for ice cream while they attend to their own needs.

Better Than Nothing

Maybe you're tempted to feel like what you have to give is too small to make a difference, so why even bother? You're right: You can't change or fix their situation. Here's what I've learned: What you *can* do is ease their burden, even if it's just for one day. Talk to the person in need. Listen to their needs. Give them something unexpected to make them smile. Offer what you have, then give it with a cheerful heart — and you'll be blessed in the process, too!

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

Spoonful of Comfort Care Package

Send a handcrafted care package with hearty, homemade soup, rolls and cookies, or choose a combination of comfort food and gift items such as snuggly blankets, cozy socks or candles. The soup is flash frozen and sent fresh directly to your loved one's door in eco-friendly gift packaging inside an insulated bag with ice packs. With traditional, gluten-free and vegan options, there's something to feed just about everyone. *Soup gifts start at $99.99; www.spoonfulofcomfort.com*

Shell Gas Gift Cards

A prepaid gas gift card is a great way to help take some of the stress off of your loved one's wallet. There are over 14,000 Shell stations around the country serving millions of Americans each day. Both physical and digital gift cards are available. (Check to make sure there's a Shell station near your loved one; if not, consider purchasing a gift card for their local gas station.) *Choose an amount up to $200 per card; www.shell.us/motorist/ways-to-pay/shell-gift-card.html*

Shopping Guide for Practical Support

Once Upon a Book Club

Once Upon a Book Club is a unique, interactive, subscription-based online community where readers receive a monthly box containing a newly released book to read for the month, along with three to five wrapped gifts with book page numbers attached to them to be opened when they reach that particular page. The monthly read-a-longs and discussion questions included with every box allow readers to interact with other subscribers and discuss the book/gifts. It's all the wonder of a book club without leaving the living room! *Starts at $49.99; www.onceuponabookclub.com*

Wag! Pet Services

Whether your loved one needs help with daily walks, is preparing for a hospital stay or just wants their best friend to have some company — Wag! Pet Services offers any day, anytime pet care. Sign up for what is needed, and pay for the service you choose. You might consider gifting your friend a Wag! Premium Membership to give them a discount on all services (walks, drop-in visits, petsitting and more), waived booking fees, access to a free vet chat and VIP support. *$14.99 for one month, or 119.99 for a one-year membership; wagwalking.com/wag-premium*

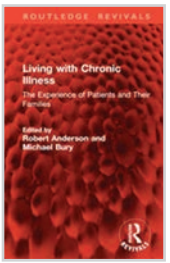
Lotsa Helping Hands

Easily organize help for someone in need using Lotsa Hands' centralized tool for coordinating meals and practical help for friends and family in need. This free app allows you to create a community around a person in need and includes a care calendar to schedule and sign up for tasks such as meal delivery and rides to appointments; a place to post encouraging messages; announcements to keep the support team updated on progress and other ways to help; and a photo gallery for sharing milestones and memories. *Free; lotsahelpinghands.com*

Molly Maid Cleaning Services

The Molly Maid team understands that maintaining a well-cleaned home can be a challenge, so they offer custom cleaning services designed to meet unique needs and preferences. Service frequency can be adjusted to meet your needs. In addition to a sparkling clean home, Molly Maid services also minimize germs and other contaminants in the home so families can breathe easier. Less dirt and germs can also mean fewer incidents of the flu, common cold and respiratory illnesses. *Minimum $100 purchase; www.mollymaid.com/gift-certificates*

Living with Chronic Illness: The Experience of Patients and Their Families (Routledge Revivals), 1st Edition



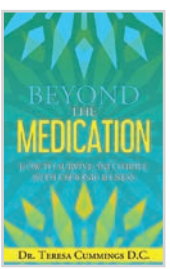
Editors: Robert Anderson and Michael Bury
Publisher: Routledge

First published in 1988, *Living with Chronic Illness* presents a vivid account of the reality of life with chronic illness — from the perspective of patients and their families. The authors look at the expectations, priorities and problems of those most affected by chronic illness, and examine the strategies they have developed to cope with their considerable disadvantages. The experience of carers and the ways in which their problems change over time are also major themes in the book. This volume will be of importance to all those concerned with providing support and planning care for the chronically ill — in the health and social services and in voluntary organizations.

Beyond The Medication: How To Survive and Thrive With Chronic Illness

Author: Teresa Cummings, DC
Publisher: Independently Published

The author of *Beyond the Medication* understands that beyond pills, patients need practical knowledge and emotional support to truly move forward. This guide is written for those who are stuck in the uncertainties that follow a diagnosis, offering a lifeline of practical solutions and heartfelt reassurance. It is intended as a roadmap to embracing possibilities, offering a supportive hand as patients move from uncertainty to empowerment.



New and Useful Reading

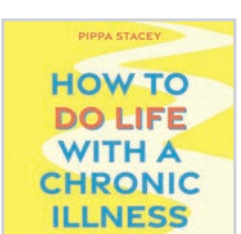
A Spoonies Best Friend: Journal for People with Chronic Illness

Author: Elisa J. Flynt
Publisher: Independently Published

This journal is designed to help and guide patients through tracking symptoms, pain levels, helpful aids, menstrual cycle, gratefulness, emotional well-being, sleep, food tracking and three custom trackers to help individualize this journal for them. It includes reverse coloring pages (which have all been hand painted by the author). Patients can use these as a little art therapy, or while they're sitting in the endless waiting rooms or hospital beds.

How to Do Life with a Chronic Illness: Reclaim Your Identity, Create Independence, and Find Your Way Forward

Author: Pippa Stacy
Publisher: Jessica Kingsley Publishers



Instead of focusing on the medical side of long-term conditions, this book dives into the important parts of everyday living that often go unspoken about — from practical advice on friendships, dating and independent living, to more reflective guidance on rediscovering one's identity and learning to self-advocate. Readers will find bespoke information and resources curated through 10-plus years of lived experience, alongside words of wisdom from diverse contributors and subject experts. This book also contains journal prompts, resource lists and words of comfort and validation that people with life-altering conditions simply do not hear enough.

Want to Learn About Topics Important to Chronic Illness Patients Living with Autoimmune and Immunodeficiency Disorders?

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Abbie Cornett, MBA
IG Living Patient Advocate

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- Changes in Medicare That Affect Patients Treated with Immune Globulin
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- The Road to Diagnosis

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

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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