



IgNS Immunoglobulin
National Society

Advancing Ig Therapy Practice

4TH ANNUAL PATIENT 360 CONFERENCE

Immersive Virtual Conference | October 22-26, 2020

Sponsored by:





Dear IgNS Patient 360 Attendees:

It is my pleasure to extend a warm welcome, and thank you for joining us at the IgNS 2020 4th Annual Patient 360 Conference!

The IgNS Patient 360 is the only conference that brings together patients with a large variety of conditions, all receiving Immunoglobulin (Ig) Therapy. Our faculty represents leading physicians, nurses, pharmacists, and advocates who are here to make this the most educational and valuable experience. In this program, we will focus on Ig therapy: how it is made, the differences between brands, how it works, different modes of administration, and side effects. We will also discuss insurance issues, financial planning, advocacy for patients and caregivers, and set aside time for all of your questions.

IgNS Patient 360 is an interactive meeting. While this year's format is virtual, we look forward to hearing your questions, addressing your concerns, and sharing insight about your treatment, quality of care, and any barriers you face.

We thank you for participating in the pre-meeting survey, which is an important research project IgNS and Purdue University are leading. The information collected will help shed light on major areas of concern for patients receiving Ig therapy. In turn, this information will help IgNS and our industry better educate physicians, nurses, and pharmacists, and improve the quality and standards of care.


Most of all, we hope you find a new community within IgNS. We are committed to sharing our expertise and educational programs, and to supporting you, learning from you, and improving the care you receive!

Sincerely,

Luba Sobolevsky, PharmD
Founding Executive Director, IgNS

AGENDA

SATURDAY, OCTOBER 24TH

11:00am–11:45am ET	Welcome and Introductions	<i>Luba Sobolevsky, PharmD, IgCP® Neil Ross</i>
11:45am–12:00pm ET	Break	
12:00pm–1:00pm ET	Ig Therapy 101: From Vein to Vein #Its My Turn Plasma Donation Campaign	<i>Tom Schleis, RPh, IgCP® Rachel Colletta, BSN, CRNI®, IgCN®</i>
1:00pm–2:00pm ET	EXPO HALL OPEN	<i>ALL</i>
2:00pm–3:00pm ET	Financial Planning in Chronic Illness	<i>Abbie Cornett</i>
3:00pm–3:15pm ET	Break	
3:15pm–4:15pm ET	Satellite Symposium	<i>Presented By</i> 
4:15pm–4:30pm ET	Break	
4:30pm–5:30pm ET	Round Tables – Pick 3 tables to attend. Each table will last for 20 mins <ol style="list-style-type: none">1. SCIG administration: pitfalls and practice pearls2. IVIg: side effects and formulation differences (rate, temp, etc)3. Smooth sailing: transitioning between brands4. Starting new medications while on Ig therapy5. Insurance issues – Q & A6. What happens when my Ig is denied by my payor?7. Patient 360 Survey Discussion	

AGENDA

SUNDAY, OCTOBER 25TH

11:00am ET	Welcome to the Day	<i>Iris Hall</i>
11:00am–12:00pm ET	CLINICAL APPLICATIONS Immunodeficiency Disorders Autoimmune Disorders	<i>Kenneth Paris, MD</i> <i>Jeffrey Rosenfeld, MD</i>
12:00pm–1:00pm ET	Patients and Clinicians: A Two-way Street	<i>All faculty and patients</i>
1:00pm–2:00pm ET	EXPO HALL OPEN	<i>ALL</i>
2:00pm–3:00pm ET	Nutrition in Chronic Disease	<i>Renee Lantner, MD</i>
3:15pm–3:30pm ET	Break	
3:30pm–4:30pm ET	Overcoming Pain and Needle Phobia	<i>Amy Baxter, MD</i>
4:30pm ET	Closing Remarks	<i>Luba Sobolevsky, PharmD, IgCP®</i> <i>Neil Ross</i>

SPEAKERS



Abbie Cornett

Abbie Cornett is the Patient Advocate for IG Living. A former Omaha police officer, Abbie was elected as a representative in the Nebraska state legislature in 2004. Abbie served as the Chair of the Revenue Committee, and is former Chair of the Business and Labor Committee. During her tenure as a legislator, she also served as President and Executive Director for the Alliance for BioTherapeutics, whose mission was to increase access to lifesaving therapies for patients and their families who rely on biotherapeutics, by serving as an educational resource and advocacy group.

To contact Abbie, please send your email to acornett@igliving.com or you can call (800) 843-7477, ext 1366.



Amy Baxter | MD, FAAP, FACEP

Amy Baxter founded Pain Care Labs in 2006 to eliminate unnecessary pain. She invented VibraCool® Vibrational Cryotherapy for tendinitis and to decrease opioid use. Her Buzzy® device has blocked needle pain for over 35 million procedures. After Yale and Emory Medical School, she trained in pediatrics, child abuse, and emergency pediatrics. She then founded PEMA Emergency Research, Scottish Rite, and Children's Healthcare of Atlanta (CHOA). Federally funded for needle pain & fear, opioid use, and neuromodulation research, she publishes and lectures on needle fear, procedural sedation, and pain. Scientific contributions include hepatic enzyme algorithm to time child abuse, creating and validating the BARF nausea scale for kids with cancer, identifying the cause of the needle phobia increase and its impact on vaccination, and Buzzy and VibraCool. Speaking venues include Exponential Medicine, Bloomberg, Converge, TEDx Peachtree, and TEDMED. Awards include 2017 Healthcare Transformer, *Wall Street Journal*, "Idea Person," Innovative GA Bio CEO of the Year, and a Top 10 Disrupter in Medical Tech.



Rachel Colletta | BSN, CRNI®, IgCN®

Rachel Colletta is a registered nurse with 32 years of experience in a variety of specialties, including trauma/ICU, medical devices, and home infusion therapy. The majority of her career has been in the infusion industry, both as a home infusion nurse and a nurse educator for a manufacturer of plasma products. Most recently, Rachel has become the Director of Educational Resources for the Ig National Society. Rachel carries certifications in Ig therapy and infusion therapy. She is actively involved in planning and education committees for the IgNS. Rachel's passion for education and knowledge led her to several international speaking engagements educating healthcare professionals from around the world about primary immunodeficiencies. Rachel is a graduate of LaRoche College and most recently Walden University, where she completed her BSN.



Iris Hall | RN, IgCN®

Iris Hall, RN, IgCN, is the Director of Clinical Education at OptionOne Pharmacy. Iris is the Co-Chair on the IgNS Educational Development Committee 2020 and has over 20 years of home infusion experience. She is a member of IgNS, INS, NHIA, has participated in manufacturers advisory boards and was a co-speaker at IgNS. Her responsibilities as the Director of Clinical Education include developing education materials and training programs for clinical staff, new patients, and home health agencies. She maintains her skills by providing infusion therapy to pediatric patients and patients with difficult vascular access. Iris collaborates with the clinical team to ensure appropriate and personalized care for patients.

Iris has created a "hands on" clinical lab, developed educational training materials, and utilizes INS Clinical Competencies to help prepare clinicians in providing quality patient care and safe delivery of various infusion therapies and injections. Iris has over 35 years of nursing experience and previous positions include Director of Nursing at OptionOne, Infusion Nurse with a national home infusion company, Physician's Assistant with a national Plasma center assessing and evaluating potential plasma donors, hospital-based practice in newborn and OB/GYN, hospital-based pediatric care at Oklahoma Children's Hospital, Quality Improvement Manager with a national Hospice Company, Clinical Product Specialist for Electronic Medical Record (EMR) software company, and Clinical IT Director with a local Home Health/Hospice Agency. Iris was featured on the front page of the Oklahoma's Nursing Times last year recognizing her achievements as an outstanding nurse in the medical field and recently voted Nurse of the Day on Oklahoma's local KOCO Channel 5 News.

SPEAKERS



Renee Lantner | MD

Renee Lantner is both a prescriber and recipient of immunoglobulin therapy. She is a board-certified physician in allergy, asthma, and immunology and has been practicing for over thirty years in the Chicago area. Because of her knowledge in abnormal food reactions related to her specialty and her interest in cooking, she went a step further to learn more in her journey to get healthier with her own autoimmune condition. She attended nutritional conferences, has done a lot of reading on the topic and for several years presented the nutritional lecture at The Myositis Association's annual conference.



Ken Paris | MD, MPH

Kenneth Paris, MD, is an associate professor at LSU Health Sciences Center New Orleans and division head of the department of Allergy/Immunology at Children's Hospital New Orleans. He is also the codirector of the Jeffrey Modell Diagnostic Center for Primary Immunodeficiency at LSUHSC. He participates in immunoglobulin research and has been a speaker at regional, national, and international conferences. As the director of the Allergy/Immunology fellowship at LSU and Children's Hospital New Orleans, Dr. Paris has been responsible for the education of the next generation of allergy/immunology physicians who will care for patients with primary immunodeficiency and other immunologic diseases.



Jeffrey Rosenfeld | MD, PhD, FAAN, FANA

Dr Rosenfeld is a Professor of Neurology at Loma Linda University School of Medicine. He is also the Associate Chairman of that Department and Director of the Neuromuscular ALS/MND Program at Loma Linda since June 2015. He has established the Center for Restorative Neurology at Loma Linda University where he serves as the medical director. Formerly Dr. Rosenfeld was Chief of Neurology at University of California, San Francisco (UCSF Fresno Program) from August 2008 to June 2015 and Director of the Neuromuscular and Amyotrophic Lateral Sclerosis (ALS) Programs at UCSF Fresno. He has over 25 years of experience treating neuromuscular patients with specialty focus in amyotrophic lateral sclerosis. He has previously established one of the most extensive and largest multidisciplinary clinical and research programs in North Carolina and continues to maintain a large subspecialty, multidisciplinary practice serving patients throughout California as well as those patients travelling from multiple other states. Dr Rosenfeld serves as clinical advisor and consultant to several pharmaceutical companies, foundations and pharmaceutical venture capital companies.



Neil Ross

Mr. Ross has over twenty years' experience in the Specialty Pharmacy market where he has gained experience in all aspects of the Specialty Pharmacy business. He is a patient with Primary Immune Deficiency and multiple autoimmune issues and is utilizing his experience and passion to help patients living with chronic diseases achieve an enhanced quality of life.

He spends his free time serving on numerous boards and is national speaker.



Tom Schleis | MS, RPh

Mr. Schleis holds a BS degree in chemistry, a MS degree in organic chemistry, and a BS degree in pharmacy. His background includes 7 years of hospital-based pharmacy experience followed by 16 years as the Director of Pharmacy at Northwest Medical Specialties in Tacoma, Washington. While at Northwest Medical Specialties, he established and managed an immune globulin therapy clinic where he provided direct patient care. Mr. Schleis then served for 7 years as the Director of Medical Affairs and Local Drug Safety Officer at Octapharma, an immune globulin manufacturer. He is currently the President of Schleis Professional Services, a company providing consultative and educational services in his areas of expertise. During the last 5 years, Mr. Schleis has worked closely with the Immunoglobulin National Society (IgNS) and has authored both editions of the IgNS Immunoglobulin Therapy Standards of Practice and developed a training guide for nurses seeking Immunoglobulin Certified Nurse (IgCN) Accreditation.

SPEAKERS



Luba Sobolevsky | PharmD, IgCP®

Luba Sobolevsky is the founding executive director of Immunoglobulin National Society, the central healthcare organization in the field of Ig therapy. Luba oversees all areas of IgNS, including education; standards of practice; certification; professional resources; development, advocacy, and alliances. Luba holds a Doctor of Pharmacy degree from University of Southern California, and has expertise across various fields in healthcare, including clinical, educational development, and pharmaceutical industry.

ROUNDTABLE SPEAKERS



Lou Anne Epperson | MSN, RN, IgCN®

Lou Anne Epperson received her MSN with Administration focus. She has been involved with nursing education, management and leadership, and home infusion for over 30 years. She has published several articles and has presented to national audiences in the field of nursing education, home infusion, and Ig therapy. She is an IgNS Advisory Board member.



Sharon McBride | RN, IgCN®

I have been an RN for over 30 years. My career started in Pediatric ICU and Pediatric Burns ICU before moving on to the Home infusion field.

I have worked for various companies in Home/Office infusions since 2001 as an Infusion nurse, Manager, and Educator. I am currently working for Kabafusion as their Regional Nurse Educator.

Not only do I have extensive experience in Ig infusions as an RN, I was diagnosed as a PI patient myself in 2014 and have been on SCIG since then.



Jan E. Jones | MSN, RN, IgCN®

Jan has been involved with Ig therapy since 2004. After working in Home Health in Los Angeles and finding a significant deficit in the knowledge of infusion nurses administering Ig Therapy in home care, she formed her own nurse infusion company specializing in Ig Therapy. She immediately began to train her nurses to administer Ig in a safe, effective manner. In 2005 she partnered with Biofusion Specialty Pharmacy, beginning a relationship that was to last for 15 years. In 2011 Biofusion brought her on board as Director of Nursing where Jan oversaw the growth and development of Ig trained nurses nationwide, using standards and guidance from IgNS. Jan joined IgNS in 2012 serving as president of the organization from 2013 until 2016. Biofusion transitioned to Kroger Specialty Infusion in 2016, where Jan remained as Director of Nursing while concurrently working with the Standards and Educational Development committees and assisting to implement an Ig certification for Nurses and Pharmacists. Jan currently serves on the IgNS Executive Board and as Co-Chair of the Educational Development Committee for conference planning, and is currently positioned as VP Business Development of Mobile Medical LA in Los Angeles, CA.

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GAMUNEX-C is the #1 prescribed immune globulin therapy for CIDP*†

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XEMBIFY provides steady protection and maximum purity for patients living with PI^{1-3‡}

Discover [XEMBIFY](#)

*LexisNexis Risk Solutions FL Inc. June 2016 – June 2020

†CIDP, chronic inflammatory demyelinating polyneuropathy

‡PI, primary humoral immunodeficiency disease

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

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

References:

1. Sleasman JW, Lumry WR, Hussain I, et al. Immune globulin subcutaneous, human - klhw 20% for primary humoral immunodeficiency: an open-label, Phase III study. *Immunotherapy*. 2019;11(16):1371-1386.
2. Alonso W, Vandeberg P, Lang J, et al. Immune globulin subcutaneous, human 20% solution (Xembify[®]), a new high concentration immunoglobulin product for subcutaneous administration. *Biologicals*. 2020;64:34-40.
3. Data on file, Grifols.

Please see Important Safety Information on the following pages and refer to accompanying full [Prescribing Information](#) for GAMUNEX-C.

Please see Important Safety Information on the following pages and refer to accompanying full [Prescribing Information](#) for XEMBIFY.

GRIFOLS

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 accompanying full [Prescribing Information](#) for GAMUNEX-C.

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.

IMPORTANT SAFETY INFORMATION

What is XEMBIFY®?

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

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

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

Who should not use XEMBIFY?

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

What are possible serious side effects of XEMBIFY?

- **Hypersensitivity.** Severe allergic reactions may occur with immune globulin products, including XEMBIFY. If you have a severe allergic reaction, stop the infusion immediately and get medical attention. XEMBIFY contains IgA. If you have known antibodies to IgA, you may have a greater risk of developing potentially severe allergic reactions
- **Aseptic meningitis syndrome (AMS).** Aseptic meningitis is a non-infectious inflammation of the membranes that cover the brain. It causes a severe headache syndrome, which may occur with human immune globulin treatment, including XEMBIFY. If you are showing signs and symptoms of AMS, your doctor may conduct a thorough neurological evaluation including spinal tap (sampling fluid which surrounds the spinal cord) to rule out other

causes of meningitis. Stopping human immune globulin treatment has resulted in the end of signs and symptoms within several days. Treatment may include analgesics (pain medicines) and/or a special procedure known as a "blood patch" to stop headache

- **Kidney problems or failure.** Kidney problems or failure may occur with use of human immune globulin products, especially those containing sucrose (sugar). XEMBIFY does not contain sucrose. If you have kidney disease or diabetes with kidney involvement, your doctor should perform a blood test to assess your hydration level and kidney function before beginning immune globulin treatment and at appropriate intervals thereafter. If your doctor determines that kidney function is worsening, they may discontinue treatment
- **Hemolysis.** Your doctor should monitor you for symptoms of hemolysis (destruction of red blood cells causing anemia, or low red blood cell count). If your doctor suspects hemolysis, they should perform additional tests to confirm
- **Transfusion-related acute lung injury (TRALI).** TRALI is a rare but serious syndrome characterized by sudden acute respiratory distress following transfusion. If your doctor suspects TRALI, they will monitor you for any other lung issues. TRALI may be managed with oxygen therapy
- **Transmissible infectious agents.** Because XEMBIFY is made from human blood, it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases or CJD have been associated with the use of XEMBIFY
- **Interference with lab tests.** Because XEMBIFY contains a variety of antibodies, blood tests to determine antibody levels may be falsely elevated. Be sure to tell your doctor or lab technician that you are using XEMBIFY

What are other possible side effects of XEMBIFY?

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

Please see accompanying full [Prescribing Information](#) for XEMBIFY.

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.

Thriving in the new normal

Program Reference Guide



To keep moving forward, we need to adjust to the new world we find ourselves in. That will look different for each of us—and that’s okay! But remember, we’re in this together. You are not alone! MylgSource and the primary immunodeficiency (PI) community is here to help. Together, we can thrive by being empowered to advocate for ourselves and our families, and by learning new ways to live better with PI. Keep reading to understand how you can find your new normal, even in challenging times.

Self-advocating in the time of COVID-19

Information about COVID-19 is being released in real time, so what is “known” is constantly evolving.

- Based on information available, people who are immunocompromised may be at higher risk for COVID-19
- It is not yet known if people living with PI are at greater risk for COVID-19
- Your doctor, the CDC, and the IDF* are the best sources of guidance for information on the impact of COVID-19 on PI

Tip!

Out-of-the-norm infection responses may make it challenging for people living with PI to get tested for COVID-19. Consider having a letter from your doctor explaining your PI.

When contacting your doctor during COVID-19:

- Ask for the best method of contact
- Be specific and provide all relevant and necessary information
- Be flexible, understanding, empathetic, and kind

Tip!

Telehealth is a great option during this time.

Advocating for the health of your family—some things to consider:

- Up-to-date communication plans and family health cheat sheets, easy to find—fast
- Food (2 weeks), emergency supplies, and medications (1-3 months) on hand
- Work, childcare, and self-isolation—plan ahead, assess, balance, adjust

*Immune Deficiency Foundation (IDF), a third party foundation that has a robust online and offline community, as well as an annual conference that connects the PI community.

Living and thriving with PI

Even in a pandemic, we can thrive:



T Try to be kind to yourself, physically and emotionally



H Help is out there; consider asking friends and family, neighbors, community groups, and the PI community for help when you need it

- Stay in and stay safe with contactless grocery and restaurant delivery and drive-thru pharmacy options
- Help others help you:
 - Be proactive, honest about what you need, specific, and appreciative
 - Don't be afraid to ask, be apologetic, or feel pressured to "return the favor"



R Relationships matter

- Limit social media
- Connect with others when you're ready
- Get creative with connecting
- Maintain social health
- Utilize peer-to-peer support

Tip!

Connect with peer-to-peer support and find other ideas for social health at [MylgSource.com](https://mylgsource.com).



I Informed, not overloaded

- Identify your anxieties
- Weed out negativity
- Turn off the news
- Seek out the positive



V Validated, but not stuck

- Feel what you feel—there's no right or wrong way
 - Write it down, talk it out
 - Reach out for help
- Breathe deeply
- Seek out positive people



E Everyone can do something

- Help someone if you feel helpless
- Send thank you cards to healthcare or delivery people
- Encourage others to donate plasma
- Teach others a favorite hobby or skill of yours
- Learn something new
- Volunteer virtually
- Finish or start small projects around the house
- Raise awareness about living with PI

Interested in joining us for our next virtual program?
Visit [MylgSource.com](https://mylgsource.com) for future dates!



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