Reset Form

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Patient Assistance Program Application

Fax to: 1-855-710-7035 Phone: 1-888-694-2686

Please complete all sections of this form and fax to 1-855-710-7035. If you prefer, you may mail this form to: Gamunex Connexions, PO Box 5428, Williamsburg, VA 23188. Should you have any questions about the application or process, please call **1-888-MYGAMUNEX** (694-2686).

Patient Assistance Program is for on-label use for patients with chronic inflammatory demyelinating polyneuropathy (CIDP) or primary immunodeficiency disease (PIDD). Please contact Connexions for a full list of approved diagnosis codes.

Patient Information

First Name: _____ Last Name: _____

Does the patient have prescription drug coverage? ☐ YES ☐ NO

Is the patient currently receiving prescription reimbursement, in whole or in part, by any of the following:
(select all that apply) ☐ Medicaid ☐ Medicare ☐ Medigap ☐ VA ☐ DOD
☐ Tricare ☐ Other federal or state funded program
(please specify) _____

Please include the Gamunex Connexions prescription enrollment form along with patient's proof of income (household adjusted gross income of 400% of the federal poverty level or less).
A Connexions representative will review all information to confirm eligibility and contact the patient if additional information is necessary. See Financial Documentation section for acceptable forms of financial documentation.

Patient Consent

I agree I have no insurance coverage for GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) at this time and insufficient financial resources to pay for the prescribed medication. I hereby permit my healthcare providers, physicians, or third-party service providers to disclose, share and use the information on these forms and other information pertaining to me, to the minimum extent necessary, for adjudication of the application, as requested by the Gamunex Connexions Patient Assistance Program. I verify that the information provided in this application is complete and accurate to the best of my knowledge. I understand that if my health insurance coverage or employment status changes, I will notify the Gamunex Connexions Patient Assistance Program promptly of such change. I understand that this may affect my eligibility to participate in the program before my eligibility period ends. I also understand that any and all information that I provide may be shared with my treating physician. I understand that this authorization will remain in effect throughout my participation in the program. I understand that I am approved for the calendar year and must re-affirm my status as requested and/or reapply at the end of the calendar year to continue my participation in the program. I understand that my access to GAMUNEX-C within this program may be delayed depending on the number of participants and the availability of drug product for the program. The Gamunex Connexions Patient Assistance Program may be discontinued or modified at any time, without notice. I understand that I am under no obligation to use or purchase any product or service as a condition of receipt of free product from Grifols, the manufacturer of GAMUNEX-C. I shall not seek reimbursement from any sources for the free product that I receive, and acknowledge that neither I nor any provider is entitled to reimbursement for free product. Free product is non-transferable.

Patient Name (print): _____ Date: _____

Patient Signature: _____ Date: _____
(If patient is <18 years of age, patient's representative must sign below)

Patient Representative (name & relationship) _____

Representative Signature: _____ Date: _____

Please see Important Safety Information on pages 3 and 4, and refer to accompanying full Prescribing Information for GAMUNEX-C.

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Physician/Prescriber Attestation

I represent that the information contained in this application is complete and accurate. I verify that, to the best of my knowledge, this patient has no prescription insurance coverage for the product prescribed, including all public programs, and the patient has insufficient financial resources to pay for the prescribed medication. I confirm that the patient prescription is for on-label use for CIDP or PIDD. I understand Grifols reserves the right to modify or terminate this program at any time. Furthermore, my signature certifies that these goods will not be sold or offered for sale, trade, or barter and will not be returned for credit. I understand that Grifols reserves the right to recall the product, if necessary.

Physician Name: _____ Date: _____

Physician Signature: _____

Financial Documentation:

Financial documentation demonstrating household income is required. Acceptable forms of income documentation include:

- Copy of W-2 or most recently filed US Income Tax Return (IRS Form 1040, 1040A, 1040EZ, 1040NR or 1040PR)
- Copy of most recent pay stub plus most recently filed US Income Tax Return
- Copy of transcript received through submission of IRS 4506-T (request for transcript form is not accepted)
- Copy of most recent Social Security/Disability monthly check, award letter, benefit statement, or 1099
- Copy of Unemployment Determination Letter

Please see Important Safety Information on the following pages, and refer to accompanying full Prescribing Information for GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified).

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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 aredehydrated, 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.

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Important Safety Information (continued)

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 bruise 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 (immune globulin injection [human], 10% caprylate/chromatography purified).

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.

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