gamunex connexions®

PATIENT ASSISTANCE PROGRAM APPLICATION

- **This form includes sections for the patient and the prescriber to complete and sign. The patient must also enroll in Gamunex Connexions.**
- Return the completed form by FAX to 1-877-375-0758 or EMAIL to grifolsconnexions@cardinalhealth.com.
- If you prefer, you may MAIL the completed form to: Gamunex Connexions, 2730 South Edmonds Ln, Suite 300, Lewisville, TX 75067
- If you have any questions, please call **1-888-MYGAMUNEX (1-888-694-2686)**, Monday to Friday, 8 AM to 8 PM ET.

The Patient Assistance Program enables eligible patients to receive medication at no cost. Patients must be diagnosed with primary immunodeficiency disease or chronic inflammatory demyelinating polyneuropathy (eligible diagnosis codes available upon request), be a US citizen or legal resident (excluding Puerto Rico and US territories), and meet financial eligibility requirements.

PATIENT INFORMATION

Name: _____ Date of Birth: / /

First *Last* *MM/DD/YYYY*

*Address: _____ *City: _____ *State: _____ *ZIP: _____

**Optional Information*

Please check one: ☐ I currently have prescription drug coverage OR ☐ I certify that I have no insurance

Are you currently receiving prescription reimbursement, in whole or in part, by any of the following:

☐ Medicaid ☐ Medicare ☐ Medigap ☐ VA ☐ DOD ☐ Tricare

☐ Other federal or state funded program (please specify:) _____

Patient must be a **US citizen** or **legal resident of the US**, excluding Puerto Rico and US territories.

A Connexions representative will review all information to confirm eligibility and contact you if additional information is necessary.

PATIENT CONSENT

I agree that 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 reaffirm 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 the 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 nontransferable.

Grifols or its authorized third-party agency may use my date of birth or Social Security number and/or additional demographic information as needed to access my credit information and information derived from public or other sources to estimate my income.

Grifols may obtain information from my credit profile from Experian Health for the purpose of verifying my income eligibility for the Gamunex Connexions Patient Assistance Program.

I understand that Grifols or its third-party vendor administering the program may ask me for a copy of my IRS 1040 form or other proof of income for the purpose of verifying my eligibility for the program at any time. I agree to provide any requested financial documentation in a timely manner.

Patient Name: _____ PATIENT SIGNATURE: _____ Date: _____

Patient Representative: _____ REPRESENTATIVE SIGNATURE: _____ Date: _____

Name and relationship

Financial documentation demonstrating household income is also required with your submission. Please review a detailed list of the acceptable documents on the following page.

Please see Important Safety Information on pages 4 and 5, and see accompanying full Prescribing Information for GAMUNEX-C.

GRIFOLS

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

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

PHYSICIAN/PRESCRIBER ATTESTATION

My signature certifies that I am licensed to practice medicine under state law. I certify that the information provided in this document is complete and accurate to the best of my knowledge. 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. 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.

I further certify that if any units of product are shipped to me under the Patient Assistance Program for this patient, they will be provided to the above-named patient only for his or her treatment and will not be sold or otherwise distributed. I further certify that no patient or third party will be charged for the product. Additionally, no units of product will be submitted for Medicare, Medicaid, or any public or private third-party reimbursement, or returned for credit.

I will supervise the patient's overall treatment plan, to include periodically verifying continued use of the provided product and resubmitting current prescriptions. I understand eligibility under this program is subject to Grifols approval and the patient's continuing compliance with all eligibility requirements, as set by Grifols from time to time.

I agree to allow Grifols or its authorized agent to review the medical, financial, and insurance records for this patient at any time for the purposes of verifying the patient's eligibility status for the Patient Assistance Program and the patient's receipt of any product provided to him or her through the Patient Assistance Program.

Physician Name: _____ PHYSICIAN SIGNATURE: _____ Date: _____

A physician's signature is required to assure that both parties are informed about the patient's enrollment in the Patient Assistance Program.

Please see Important Safety Information on pages 4 and 5, and see accompanying full Prescribing Information for GAMUNEX-C.

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,

Important Safety Information (cont.)

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.

GRIFOLS

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

gamunex connexions®

GAMUNEX CONNEXIONS ENROLLMENT FORM

Thank you for your interest in Gamunex Connexions, a patient support program from Grifols, the manufacturer of GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified). The program provides financial assistance for eligible patients and can help answer your questions throughout treatment.

To enroll, please complete the fields below and return this form by mail, fax, or email. **For patients: if you complete the Patient Information section below, you may submit this form without your insurance information, physician's information, or their signature. However, including any of this information that you have available can help Gamunex Connexions support you.**

1. COMPLETE THE FORM

PATIENT INFORMATION

If you are a patient, please complete the fields below.

Name: _____ Date of Birth: / / Gender: ☐ Male ☐ Female ☐ Unspecified

First *Last* *MM/DD/YYYY*

Address (Home): _____ City: _____ State: _____ ZIP: _____

Primary Phone: _____ Secondary Phone: _____ Email: _____

Preferred Contact: ☐ Primary Phone ☐ Secondary Phone ☐ Email ☐ Text ☐ OK to leave voicemail?

By providing a phone number, I authorize Grifols and its service providers to use automated or non-automated means to call me at the number I provided with information and updates on program services. Privacy Policy applies: https://www.grifols.com/en/grifols-products-privacy-policy

Alternate Contact Name: _____ Relationship: _____

Phone: _____ Email: _____

PATIENT AUTHORIZATION

HIPAA Consent:

☐ By checking this box, I authorize my healthcare providers, pharmacies, health plans, or payers ("my healthcare organizations") to share personal and health information about me related to my Grifols therapies ("my information") with Grifols, its affiliates, agents, and service providers. I understand that my prescribed product may be provided to me by a pharmacy contracted to provide service by Grifols, and that contracted pharmacy will receive compensation by Grifols. I authorize Grifols to: (1) confirm my health plan eligibility and benefits, identify other payers for my therapy, or determine my eligibility for assistance programs; (2) analyze data to improve services related to my disease; and (3) disclose my information for safety reasons or as required by law. This Authorization will expire 5 years from the date signed below unless a shorter period is required by the law of my state of residence. I may discuss the scope of my authorization or cancel anytime by calling the program at 1-844-699-3624 or 1-888-694-2686 and/or by sending a letter to Connexions to 2730 South Edmonds Ln, Suite 300, Lewisville, TX 75067.

Texting Opt-In:

☐ By checking this box, I authorize Grifols and its service providers to use automated or non-automated means to text me at the number I provided with information and updates on program services. Consent is not required. To learn how Grifols will use and protect your personal information, review our privacy policy at https://www.grifols.com/en/grifols-products-privacy-policy.

Patient Education Opt-In:

☐ By checking this box, I give Grifols permission to use my personal information to receive product, disease-state, or other helpful information from Grifols and service providers and third parties acting on its behalf. To learn how Grifols will use and protect your personal information, review our privacy policy at https://www.grifols.com/en/grifols-products-privacy-policy.

Patient Name (first and last): _____ **PATIENT SIGNATURE:** _____ Date: _____

Caregiver (name and relationship): _____ ***CAREGIVER SIGNATURE:** _____ Date: _____

**Parent or guardian must sign if patient is under 18 years of age.*

Please see Important Safety Information on page 3 and see accompanying full Prescribing Information for GAMUNEX-C.

GRIFOLS

Continued on page 2 ▶

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

PATIENT INSURANCE INFORMATION (OPTIONAL)

Please complete the fields below and provide a copy of the front and back of your insurance card.

Primary Insurance: _____ Insurance Type: ☐ Commercial ☐ Government ☐ Unknown/Other ☐ None

Insurance Phone: _____ Policy ID: _____ Group #: _____

BIN #: _____ PCN #: _____

Policyholder Name: _____ Policyholder DOB: _____ Relation to Patient: _____

MM/DD/YYYY

Secondary Insurance: _____ Insurance Type: ☐ Commercial ☐ Government ☐ Unknown/Other

Insurance Phone: _____ Policy ID: _____ Group #: _____

BIN #: _____ PCN #: _____

Policyholder Name: _____ Policyholder DOB: _____ Relation to Patient: _____

MM/DD/YYYY

PHYSICIAN INFORMATION

If you are a prescriber, please complete the fields below.

Name: _____ Prescriber NPI: _____ Tax ID #: _____

Physician Address: _____ City: _____ State: _____ ZIP: _____

Physician Phone Number: _____ Office Contact: _____ Contact Phone: _____

Physician Fax Number: _____ Contact Email Address: _____

By providing a phone number, I authorize Grifols and its service providers to use automated or non-automated means to call me at the number I provided with information and updates on program services. Privacy policy applies: https://www.grifols.com/en/grifols-products-privacy-policy

PHYSICIAN CERTIFICATION

☐ I verify that the patient and prescriber information contained in this enrollment form is complete and accurate to the best of my knowledge. I also attest that I have obtained the patient's affirmative authorization to release the above information and such other personal information as may be necessary to Gamunex Connexions and/or their agents. If patient is younger than 18 years of age, then I attest that I have obtained permission from the patient's legal guardian.

Physician Name (First and Last): _____ **PHYSICIAN SIGNATURE:** _____ Date: _____

2. RETURN COMPLETED FORM

Mail
Gamunex Connexions
2730 South Edmonds Ln
Suite 300
Lewisville, TX 75067

Fax
1-877-375-0758

Email
grifolsconnexions@cardinalhealth.com

NEED ASSISTANCE?

Call **1-888-MYGAMUNEX (1-888-694-2686)** if you have any questions or visit **www.gamunex-c.com** for more information and access to additional forms.

You may make changes to communication preferences or cancel your enrollment in this program at any time by calling **1-888-MYGAMUNEX (1-888-694-2686).**

Please see Important Safety Information on the next page and see accompanying full Prescribing Information for GAMUNEX-C.

GRIFOLS

Continued on page 3

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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.

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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.

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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.

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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

Please see Important Safety Information on the next page and see accompanying full Prescribing Information for GAMUNEX-C.

Important Safety Information (cont.)

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).

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