Guide to Coverage and Reimbursement

Please see Important Safety Information on pages 18 to 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.

Please contact Gamunex Connexions at 1-888-MYGAMUNEX (1-888-694-2686) for more information about financial support for patients with CIDP.
Disclaimer

The information contained in this guide is provided for informational purposes only. Providers are encouraged to contact their payers for specific information. Coding rules and guidelines are subject to payer discretion and should always be verified by the paying entity. Healthcare providers make the ultimate determination as to when to use a specific product, based on clinical appropriateness for a particular patient. This guide is not intended to provide specific guidance on how to utilize, code, bill, or charge for any product or service. Third-party payment for medical products and services is affected by numerous factors and Grifols cannot guarantee success in obtaining insurance payments.

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*CPT® 5-digit codes, nomenclature, and other data are ©2017 American Medical Association (AMA). All rights reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein.

Please see Important Safety Information on pages 18 to 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.
Introduction

Grifols has developed the Guide to Coverage and Reimbursement for GAMUNEX-C to assist its customers in understanding third-party payment for GAMUNEX-C, a biological product approved by the US Food and Drug Administration (FDA) for the following indications:

• Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
• Primary immunodeficiency disease (PIDD) in patients 2 years of age and older
• Idiopathic thrombocytopenic purpura (ITP) in adults and children

GAMUNEX-C is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Health insurance reimbursement policies can seem exceedingly complex and confusing, but mastering the basics of reimbursement for GAMUNEX-C is quite simple. Grifols has designed this guide to provide easy-to-understand general information on coding and claims submission. This guide represents just part of the commitment of Grifols to providing its customers with reimbursement assistance. Codes are subject to change. Additional support, updated information, and one-on-one assistance are available from Gamunex Connexions at 1-888-MYGAMUNEX (1-888-694-2686).

• Copay Assistance Program to help your patients save up to $2500 over 12 months on deductibles, copayment, and coinsurance
• Patient Assistance Program to help your patients in the event of loss of insurance
• Committed case managers provide a dedicated, single point of contact for you, your office staff, and your patients

Speak to your regional contact Monday through Friday from 8 am to 8 pm ET by calling 1-888-MYGAMUNEX (1-888-694-2686)
Coding for GAMUNEX-C

This section describes the types of codes that are likely to be most relevant to provider claims for GAMUNEX-C. GAMUNEX-C may be administered intravenously (IV) by a healthcare professional in an office/facility for all indications. Additionally, it may be administered in the home subcutaneously (SC) for patients 2 years of age and older with PIDD using an SC infusion pump. There are coding similarities and differences between these 2 methods of infusion for patients in terms of sites of care, procedure codes, use of modifiers, etc. the details of which follow.

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODE

Public and private payers require physicians and hospitals to use the HCPCS to bill for infused drug and biological products. HCPCS codes are 5-character, alpha-numeric codes used to identify drugs, biologicals, medical supply products, and certain medical services. The Centers for Medicare and Medicaid Services (CMS) has assigned the following HCPCS code for GAMUNEX-C:

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1561</td>
<td>Injection, immune globulin, (GAMUNEX-C), nonlyophilized (eg, liquid), 500 mg</td>
</tr>
</tbody>
</table>

Because the HCPCS description specifies 500 mg, each gram represents 2 units. For example, if 30 g of GAMUNEX-C are administered, 60 units should be billed on the claim.

NATIONAL DRUG CODES (NDCs)

NDCs are usually used for billing drugs and biologicals provided by pharmacies and by some home infusion providers. On some claims, certain payers may require NDCs in addition to HCPCS codes. GAMUNEX-C has been issued the following NDCs:

<table>
<thead>
<tr>
<th>OUTER PACKAGE NDC 11</th>
<th>INNER PACKAGE NDC 11</th>
</tr>
</thead>
<tbody>
<tr>
<td>13533-0800-12 (1.0 g)</td>
<td>13533-0800-13 (1.0 g)</td>
</tr>
<tr>
<td>13533-0800-15 (2.5 g)</td>
<td>13533-0800-16 (2.5 g)</td>
</tr>
<tr>
<td>13533-0800-20 (5.0 g)</td>
<td>13533-0800-21 (5.0 g)</td>
</tr>
<tr>
<td>13533-0800-71 (10.0 g)</td>
<td>13533-0800-72 (10.0 g)</td>
</tr>
<tr>
<td>13533-0800-24 (20.0 g)</td>
<td>13533-0800-25 (20.0 g)</td>
</tr>
<tr>
<td>13533-0800-40 (40.0 g)</td>
<td>13533-0800-41 (40.0 g)</td>
</tr>
</tbody>
</table>

*Use the Outer Package 11-digit NDC number for billing purposes.

INTERNATIONAL CLASSIFICATION OF DISEASE, 10TH REVISION, CLINICAL MODIFICATION (ICD-10-CM) CODES

ICD-10-CM diagnosis codes are used to describe the patient’s condition requiring treatment. A menu of appropriate ICD-10-CM codes is below. Select codes that accurately identify the patient’s diagnosis.

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>D80.1</td>
<td>Nonfamilial hypogammaglobulinemia</td>
</tr>
<tr>
<td>D80.2</td>
<td>Selective deficiency of immunoglobulin A (IgA)</td>
</tr>
<tr>
<td>D80.4</td>
<td>Selective deficiency of immunoglobulin M (IgM)</td>
</tr>
<tr>
<td>D80.3</td>
<td>Selective deficiency of immunoglobulin G (IgG) subclasses</td>
</tr>
<tr>
<td>D80.0</td>
<td>Hereditary hypogammaglobulinemia</td>
</tr>
<tr>
<td>D80.5</td>
<td>Immunodeficiency with increased immunoglobulin M (IgM)</td>
</tr>
<tr>
<td>D83.0</td>
<td>Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function</td>
</tr>
<tr>
<td>D83.2</td>
<td>Common variable immunodeficiency with autoantibodies to B or T cells</td>
</tr>
<tr>
<td>D83.8</td>
<td>Other common variable immunodeficiencies</td>
</tr>
<tr>
<td>D83.9</td>
<td>Common variable immunodeficiency, unspecified</td>
</tr>
<tr>
<td>D80.7</td>
<td>Transient hypogammaglobulinemia of infancy</td>
</tr>
<tr>
<td>D82.0</td>
<td>Wiskott-Aldrich syndrome</td>
</tr>
<tr>
<td>D81.0</td>
<td>Severe combined immunodeficiency (SCID) with reticular dysgenesis</td>
</tr>
<tr>
<td>D81.1</td>
<td>Severe combined immunodeficiency (SCID) with low T- and B-cell numbers</td>
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<tr>
<td>D81.2</td>
<td>Severe combined immunodeficiency (SCID) with low or normal B-cell numbers</td>
</tr>
<tr>
<td>D81.6</td>
<td>Major histocompatibility complex I deficiency</td>
</tr>
<tr>
<td>D81.7</td>
<td>Major histocompatibility complex II deficiency</td>
</tr>
<tr>
<td>D81.89</td>
<td>Other combined immunodeficiencies</td>
</tr>
<tr>
<td>D81.9</td>
<td>Combined immunodeficiency, unspecified</td>
</tr>
<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
</tr>
<tr>
<td>G61.81</td>
<td>Chronic inflammatory demyelinating polyneuropathy</td>
</tr>
</tbody>
</table>

Optum, for Hospitals and Payers, Volumes 1, 2, and 3 (with ICD-10-CM), publisher of the official code set issued by the Department of Health and Human Services.

Please see Important Safety Information on pages 18 to 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.
CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODES

Healthcare professionals’ outpatient services are most commonly billed using CPT codes. The most common route of administration for GAMUNEX-C in the healthcare professional’s office or facility setting is IV; however, there may be instances where SC administration is appropriate. The following CPT codes apply:

<table>
<thead>
<tr>
<th>INTRAVENOUS ADMINISTRATION</th>
<th>SUBCUTANEOUS ADMINISTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT CODE</strong></td>
<td><strong>DESCRIPTION</strong></td>
</tr>
<tr>
<td>96365</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial up to 1 hour</td>
</tr>
<tr>
<td>96366</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>96371</td>
<td>Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); additional pump set-up with establishment of new subcutaneous infusion site(s) (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

DURABLE MEDICAL EQUIPMENT (DME) CODES

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0779a</td>
<td>Ambulatory infusion pump, mechanical, reusable for infusion 8 hours or greater</td>
</tr>
<tr>
<td>E0780</td>
<td>Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours</td>
</tr>
<tr>
<td>E0781</td>
<td>Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient</td>
</tr>
<tr>
<td>E0791</td>
<td>Parenteral infusion pump, stationary, single, or multichannel</td>
</tr>
</tbody>
</table>

EXTERNAL INFUSION PUMP SUPPLIES

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4221</td>
<td>Supplies for maintenance of drug infusion catheter, per week (list drugs separately)</td>
</tr>
<tr>
<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe type cartridge, sterile, each</td>
</tr>
</tbody>
</table>

HOME INFUSION THERAPY CODE

Payers, other than Medicare, may accept the following code to represent the clinical services provided in the patient’s home when GAMUNEX-C is administered:

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9338b</td>
<td>Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>

HOSPITAL REVENUE CODE

For hospital claims, most public and private payers require providers to use revenue codes. Revenue codes are 4-digit codes that identify the general types of services or products under broad revenue centers. The following revenue code most commonly applies to drug and biological products such as GAMUNEX-C:

<table>
<thead>
<tr>
<th>REVENUE CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>0636</td>
<td>Pharmacy, drugs requiring detailed coding</td>
</tr>
</tbody>
</table>

Codes are subject to change. Please contact Gamunex Connexions at 1-888-MYGAMUNEX (1-888-694-2686) to receive personalized assistance.

Please see Important Safety Information on pages 18 to 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.
Sample Physician Office Claim Form (CMS-1500)

IV ADMINISTRATION

The vast majority of claims filed by healthcare providers are paid in a timely manner. We have prepared this section of sample claim forms to offer providers guidance in submitting accurate claims for IV administration of GAMUNEX-C.

Sample Hospital Outpatient Claim Form (UB-04/CMS 1450)

IV ADMINISTRATION

Please see Important Safety Information on pages 18 to 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.
This sample claim form offers providers guidance in submitting accurate claims for SC administration of GAMUNEX-C in patients 2 years of age and older with PIDD. Enter the appropriate diagnosis code(s) and link each to the procedure performed.

**ICD-10-CM**

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>D80.1</td>
<td>Nonfamilial hypogammaglobulinemia</td>
</tr>
<tr>
<td>D80.4</td>
<td>Selective deficiency of immunoglobulin G (IgG)</td>
</tr>
<tr>
<td>D80.5</td>
<td>Immunodeficiency with increased immunoglobulin M (IgM)</td>
</tr>
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<td>D83.0</td>
<td>Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function</td>
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<td>D83.2</td>
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<tr>
<td>D83.8</td>
<td>Other common variable immunodeficiencies</td>
</tr>
<tr>
<td>D83.9</td>
<td>Common variable immunodeficiency, unspecified</td>
</tr>
<tr>
<td>D84.1</td>
<td>Transient hypogammaglobulinemia of infancy</td>
</tr>
<tr>
<td>D82.0</td>
<td>Wiskott-Aldrich syndrome</td>
</tr>
<tr>
<td>D81.0</td>
<td>Severe combined immunodeficiency (SCID) with reticular dysgenesis</td>
</tr>
<tr>
<td>D81.1</td>
<td>Severe combined immunodeficiency (SCID) with low T- and B-cell numbers</td>
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</tr>
<tr>
<td>D81.6</td>
<td>Major histocompatibility complex class I deficiency</td>
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<tr>
<td>D81.7</td>
<td>Major histocompatibility complex class II deficiency</td>
</tr>
<tr>
<td>D81.9</td>
<td>Other combined immunodeficiencies</td>
</tr>
</tbody>
</table>

**CPT and HCPCS Codes**

Enter the CPT and HCPCS codes that correctly describe the procedure(s) performed and the product(s) administered.

**J1561-JB**

Injection globulin, (GAMUNEX-C), nonlyophilized (eg, liquid), 500 mg: subcutaneous administration. Home infusion providers, enter the appropriate pump, supply, and service codes (see code list).

**J1561**

Injection, immune globulin, (GAMUNEX-C), nonlyophilized (eg, liquid), 500 mg: subcutaneous administration. Home infusion providers, enter the appropriate pump, supply, and service codes (see code list).

**I1561**

Injection, immune globulin, (GAMUNEX-C), nonlyophilized (eg, liquid), 500 mg: subcutaneous administration. Home infusion providers, enter the appropriate pump, supply, and service codes (see code list).
A partnership with dedicated support

SUPPORTING PATIENTS THROUGHOUT THEIR TREATMENT

FOR YOUR PATIENTS
- Educational information and resources about their condition
- Answers to questions about their treatment
- Support throughout their patient journey when they need it most

FOR YOU AND YOUR OFFICE STAFF
- Information about GAMUNEX-C
- Insurance coverage
- Benefits investigation

• Copay Assistance Program to help your patients save up to $2500 over 12 months on deductibles, copayment, and coinsurance
• Patient Assistance Program to help your patients in the event of loss of insurance
• Committed case managers provide a dedicated, single point of contact for you, your office staff, and your patients

A SINGLE POINT OF CONTACT

15

Please see Important Safety Information on pages 18 to 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.
Quick Reference Coding Summary

**GAMUNEX-C HCPCS CODES**
- **J1561**—Injection, immune globulin, (GAMUNEX-C), intravenous nonlyophilized (eg, liquid), 500 mg

Attach modifier -JB to indicate subcutaneous (SC) administration for billing to the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs):
- **J1561-JB**

Non-Medicare payers may accept the following code for billing home-based services:
- **S9338**—Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

**GAMUNEX-C NDC CODES**

<table>
<thead>
<tr>
<th>OUTER NDC 11</th>
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<tbody>
<tr>
<td>13533-0800-12 (1.0 g)</td>
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<td>13533-0800-24 (20.0 g)</td>
<td>13533-0800-25 (20.0 g)</td>
</tr>
<tr>
<td>13533-0800-40 (40.0 g)</td>
<td>13533-0800-41 (40.0 g)</td>
</tr>
</tbody>
</table>

**CPT® CODES**

<table>
<thead>
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**ICD-10-CM CODES**

<table>
<thead>
<tr>
<th>ICD-10-CM</th>
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<tr>
<td>D80.4</td>
<td>Selective deficiency of immunoglobulin M (IgM)</td>
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<tr>
<td>D80.3</td>
<td>Selective deficiency of immunoglobulin G (IgG) subclasses</td>
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<tr>
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<td>Hereditary hypogammaglobulinemia</td>
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<td>Common variable immunodeficiency, unspecified</td>
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<td>Transient hypogammaglobulinemia of infancy</td>
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<td>Other combined immunodeficiencies</td>
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<tr>
<td>D81.9</td>
<td>Combined immunodeficiency, unspecified</td>
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<tr>
<td>D69.3</td>
<td>Immune thrombocytopenic purpura</td>
</tr>
<tr>
<td>G61.81</td>
<td>Chronic inflammatory demyelinating polyneuropathy</td>
</tr>
</tbody>
</table>

**HOSPITAL REVENUE CODES**
- **0636**—Pharmacy, drugs requiring detailed coding

*Use the Outer Package 11-digit NDC number for billing purposes.
*Optum Current Procedural Coding Expert, publisher of CPT, a registered trademark of the AMA.

Please see Important Safety Information on pages 18 to 19 and refer to accompanying full Prescribing Information for GAMUNEX-C.®
Important Safety Information

GAMUNEX-C (immune globulin injection [human], 10% caprylate/chromatography purified) is indicated for the treatment of primary humoral immunodeficiency disease (PIIDD) in patients 2 years of age and older, idiopathic thrombocytopenic purpura (ITP) in adults and children, and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

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 central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known 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 (IVIG) products in predisposed patients. Patients predisposed to renal dysfunction include those with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IVIG 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.

GAMUNEX-C is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

Severe hypersensitivity reactions may occur with IVIG products, including GAMUNEX-C. In case of hypersensitivity, discontinue GAMUNEX-C infusion immediately and institute appropriate treatment.

Monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output in patients at risk of developing acute renal failure.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IVIG treatment, including GAMUNEX-C.

There have been reports of asesitic meningitis, hemolytic anemia, and noncardiogenic pulmonary edema (transfusion-related acute lung injury [TRALI]) in patients administered with IVIG, including GAMUNEX-C.

The high-dose regimen (1g/kg x 1-2 days) is not recommended for individuals with expanded fluid volumes or where fluid volume may be a concern.

Because GAMUNEX-C is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Do not administer GAMUNEX-C subcutaneously in patients with ITP because of the risk of hematoma formation.

Periodic monitoring of renal function and urine output is particularly important in patients judged to be at increased risk of developing acute renal failure. Assess renal function, including measurement of BUN and serum creatinine, before the initial infusion of GAMUNEX-C and at appropriate intervals thereafter.

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, because of the potentially increased risk of thrombosis.

If signs and/or symptoms of hemolysis are present after an infusion of GAMUNEX-C, perform appropriate laboratory testing for confirmation.

If TRALI is suspected, perform appropriate tests for the presence of antineutrophil antibodies and anti-HLA antibodies in both the product and patient’s serum.

After infusion of IgG, 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.

In clinical studies, the most common adverse reactions with GAMUNEX-C were headache, pyrexia, hypertension, chills, rash, nausea, arthralgia, and asthenia (in CIDP), cough, rhinitis, pharyngitis, headache, asthma, nausea, fever, diarrhea, and sinusitis with intravenous use (in PIDD) and local infusion-site reactions; fatigue, headache, upper respiratory tract infection, arthralgia, diarrhea, nausea, sinusitis, bronchitis, depression, allergic dermatitis, migraine, myalgia, viral infection, and pyrexia with subcutaneous use (in PIDD); and headache, ecchymosis, vomiting, fever, nausea, rash, abdominal pain, back pain, and dyspepsia (in ITP).

The most serious adverse reactions in clinical studies were pulmonary embolism (PE) in 1 subject with a history of PE (in CIDP), an exacerbation of autoimmune pure red cell aplasia in 1 subject (in PIDD), and myocarditis in 1 subject that occurred 50 days post-study drug infusion and was not considered drug related (in ITP).
Please see accompanying full Prescribing Information for GAMUNEX-C.

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Go to www.gamunex-c.com for additional resources and updates.

Please contact Gamunex Connexions at 1-888-MYGAMUNEX (1-888-694-2686) for more information about financial support for patients with CIDP.