



# Guide to Coverage and Reimbursement

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**GRIFOLS**

Please see Important Safety Information on pages 11 to 12 and refer to accompanying full Prescribing Information for GAMUNEX-C.

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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.

## 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.

GAMUNEX-C is an immune globulin injection (human), 10% liquid indicated for treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older, idiopathic thrombocytopenic purpura (ITP) in adults and children, and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults.

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.

### PLEASE NOTE:

**These codes are not all-inclusive; appropriate codes can vary by patient, setting of care, and payer. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and special billing requirements. Grifols does not make any representation or guarantee concerning reimbursement or coverage for any service or item.**

## DOSING AND ADMINISTRATION FOR GAMUNEX-C

The recommended intravenous dose for GAMUNEX-C in patients with ITP is 2 g/kg at an initial infusion rate of 1 mg/kg/min and may be increased to a maximum infusion of 8 mg/kg/min if tolerated. In patients with CIDP the recommended loading dose is 2 g/kg at an initial infusion rate of 2 mg/kg/min followed by a maintenance dose of 1 g/kg at a maintenance infusion rate of 8 mg/kg/min, if tolerated, every 3 weeks. GAMUNEX-C is not approved for subcutaneous administration in patients with ITP or CIDP.

The recommended intravenous dose for GAMUNEX-C in patients with PIDD is 300 mg/kg to 600 mg/kg at an initial infusion rate of 1 mg/kg/min followed by a maintenance infusion of 8 mg/kg/min, if tolerated. The recommended subcutaneous dose for GAMUNEX-C in patients with PIDD is 1.37 times the current IV dose in grams divided by the IV dose interval in weeks. For adult patients, the recommended initial infusion rate is 20 mL/hr/site followed by a maintenance infusion of 20 mL/hr/site. For pediatric patients who weigh less than 25 kg, the recommended initial infusion rate is 10 mL/hr/site followed by a maintenance infusion of 10 mL/hr/site weekly. For pediatric patients who weigh 25 kg or more, the recommended initial infusion rate is 15 mL/hr/site followed by a maintenance infusion of 20 mL/hr/site weekly, if tolerated.



Please see Important Safety Information on pages 11 to 12 and refer to accompanying full Prescribing Information for GAMUNEX-C.

# Coding for GAMUNEX-C

This section describes codes 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 subcutaneously (SC) at home 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\*

HCPCS CODE	DESCRIPTION
<b>J1561</b>	Injection, immune globulin, (GAMUNEX-C), nonlyophilized (eg, liquid), 500 mg

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.

The HCPCS J1561 code for GAMUNEX-C is listed by CMS and Medicare Part B Administration Contractors in their National Drug Code (NDC) to HCPCS crosswalk files.

To specify drug administration, Medicare requires that modifiers JA and JB accompany the GAMUNEX-C code. Use J1561-JA for intravenous administration and J1561-JB for subcutaneous administration claims billed to the DME Medicare Administrative Contractors (MACs).

To specify discarded drugs and biologicals, suppliers and providers are required to report the JW and JZ modifiers for claims payable under Medicare Part B. The JW modifier is used to record wasted drug, while the JZ modifier is used when there is no wasted drug.

For drug amounts discarded and not administered to any patient, suppliers and providers are to use modifier JW. Effective July 1, 2023, you must report the JZ modifier on all claims that bill for drugs separately payable under Part B when there's no discarded amount from single-dose containers or single-use packages. For the amount you administer, the claim line should include the billing and payment code, such as a HCPCS code describing the given drug, the JZ modifier showing there were no discarded amounts, and the number of units administered in the units' field.

## 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 the following NDCs:

OUTER PACKAGE NDC 11†	INNER PACKAGE NDC 11
<b>13533-0800-12 (1 g)</b>	<b>13533-0800-13 (1 g)</b>
<b>13533-0800-15 (2.5 g)</b>	<b>13533-0800-16 (2.5 g)</b>
<b>13533-0800-20 (5 g)</b>	<b>13533-0800-21 (5 g)</b>
<b>13533-0800-71 (10 g)</b>	<b>13533-0800-72 (10 g)</b>
<b>13533-0800-24 (20 g)</b>	<b>13533-0800-25 (20 g)</b>
<b>13533-0800-40 (40 g)</b>	<b>13533-0800-41 (40 g)</b>

\*Centers for Medicare and Medicaid Services (CMS). HCPCS file located at: <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57187>.

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

Please see Important Safety Information on pages 11 to 12 and refer to accompanying full Prescribing Information for GAMUNEX-C.

## INTERNATIONAL CLASSIFICATION OF DISEASES, 10TH REVISION, CLINICAL MODIFICATION (ICD-10-CM) CODES\*

ICD-10-CM diagnosis codes are used to describe the patient's condition requiring treatment. Please select the code(s) that accurately identify the patient's diagnosis.

ICD-10-CM CODE	DESCRIPTION
<b>G61.81</b>	Chronic inflammatory demyelinating polyneuritis
<b>D69.3</b>	Immune thrombocytopenic purpura

D80	IMMUNODEFICIENCY WITH PREDOMINANTLY ANTIBODY DEFECTS
<b>D80.0<sup>†</sup></b>	Hereditary hypogammaglobulinemia Autosomal recessive agammaglobulinemia (Swiss type) X-linked agammaglobulinemia [Bruton] (with growth hormone deficiency)
<b>D80.1</b>	Nonfamilial hypogammaglobulinemia Agammaglobulinemia with immunoglobulin-bearing B-lymphocytes Common variable agammaglobulinemia [CVAgamma] Hypogammaglobulinemia NOS
<b>D80.2<sup>†</sup></b>	Selective deficiency of immunoglobulin A (IgA)
<b>D80.3<sup>†</sup></b>	Selective deficiency of immunoglobulin G (IgG) subclasses
<b>D80.4<sup>†</sup></b>	Selective deficiency of immunoglobulin M (IgM)
<b>D80.5<sup>†</sup></b>	Immunodeficiency with increased immunoglobulin M (IgM)
<b>D80.6<sup>†</sup></b>	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
<b>D80.7<sup>†</sup></b>	Transient hypogammaglobulinemia of infancy
<b>D80.8</b>	Other immunodeficiencies with predominantly antibody defects Kappa light chain deficiency
<b>D80.9</b>	Immunodeficiency with predominantly antibody defects, unspecified

D81	COMBINED IMMUNODEFICIENCIES
<b>D81.0<sup>†</sup></b>	Severe combined immunodeficiency (SCID) with reticular dysgenesis
<b>D81.1<sup>†</sup></b>	Severe combined immunodeficiency (SCID) with low T- and B-cell numbers
<b>D81.2<sup>†</sup></b>	Severe combined immunodeficiency (SCID) with low or normal B-cell numbers
<b>D81.31</b>	Severe combined immunodeficiency due to adenosine deaminase deficiency
<b>D81.4</b>	Nezelof's syndrome
<b>D81.5<sup>†</sup></b>	Purine nucleoside phosphorylase (PNP) deficiency
<b>D81.6<sup>†</sup></b>	Major histocompatibility complex class I deficiency
<b>D81.7<sup>†</sup></b>	Major histocompatibility complex class II deficiency
<b>D81.82<sup>†</sup></b>	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
<b>D81.89<sup>†</sup></b>	Other combined immunodeficiencies
<b>D81.9<sup>†</sup></b>	Combined immunodeficiency, unspecified Severe combined immunodeficiency disorder [SCID] NOS

\*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.

<sup>†</sup>Indicates ICD-10 codes covered by Medicare Part B/DME for GAMUNEX-C

Please see Important Safety Information on pages 11 to 12 and refer to accompanying full Prescribing Information for GAMUNEX-C.

<b>G11 HEREDITARY ATAXIA</b>	
<b>G11.3*</b>	Cerebellar ataxia with defective DNA repair Ataxia-telegiectasia

<b>D82 IMMUNODEFICIENCY ASSOCIATED WITH OTHER MAJOR DEFECTS</b>	
<b>D82.0*</b>	Wiskott-Aldrich syndrome Immunodeficiency with thrombocytopenia and eczema
<b>D82.1*</b>	Di George's syndrome Pharyngeal pouch syndrome Thymic aplasia Thymic aplasia or hypoplasia with immunodeficiency
<b>D82.4*</b>	Hyperimmunoglobulin E [IgE] syndrome
<b>D82.9</b>	Immunodeficiency associated with major defect, unspecified

<b>D83 COMMON VARIABLE IMMUNODEFICIENCY</b>	
<b>D83.0*</b>	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
<b>D83.1*</b>	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
<b>D83.2*</b>	Common variable immunodeficiency with autoantibodies to B- or T-cells
<b>D83.8*</b>	Other common variable immunodeficiencies
<b>D83.9*</b>	Common variable immunodeficiency, unspecified

\*Indicates ICD-10 codes covered by Medicare Part B/DME for GAMUNEX-C

## CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODES\*

<b>INTRAVENOUS ADMINISTRATION</b>		<b>SUBCUTANEOUS ADMINISTRATION</b>	
<b>CPT CODE</b>	<b>DESCRIPTION</b>	<b>CPT CODE</b>	<b>DESCRIPTION</b>
<b>96365</b>	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial up to 1 hour	<b>96369</b>	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); initial, up to 1 hour, including pump set-up and establishment of subcutaneous infusion site(s)
<b>96366</b>	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	<b>96370</b>	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)
		<b>96371</b>	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)

\*Optum Current Procedural Coding Expert, publisher of CPT, a registered trademark of the AMA.

Please see Important Safety Information on pages 11 to 12 and refer to accompanying full Prescribing Information for GAMUNEX-C.

## HOME INFUSION SERVICES

HCPCS/CPT*	DESCRIPTION
<b>S9338</b> <sup>†</sup>	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
<b>G0089</b> <sup>‡</sup>	Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes
<b>G0069</b> <sup>‡</sup>	Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes
<b>99601</b> <sup>†</sup>	Home infusion/specialty drug administration, per visit (up to 2 hours)
<b>99602</b> <sup>†</sup>	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour

\*Centers for Medicare and Medicaid Services (CMS). HCPCS file located at: <http://www.cms.gov/Medicare/Coding/CPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>.

<sup>†</sup>This code is not for use on Medicare claims, but may be covered by payers other than Medicare.

<sup>‡</sup>May be accepted by Medicare.

## DURABLE MEDICAL EQUIPMENT (DME) CODES

HCPCS CODE*	DESCRIPTION
<b>EXTERNAL INFUSION PUMP CODES</b>	
<b>E0779</b> <sup>†</sup>	Ambulatory infusion pump, mechanical, reusable for infusion 8 hours or greater
<b>E0780</b>	Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours
<b>E0781</b>	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
<b>E0791</b>	Parenteral infusion pump, stationary, single, or multichannel
<b>EXTERNAL INFUSION PUMP SUPPLIES</b>	
<b>A4221</b> <sup>†</sup>	Supplies for maintenance of drug infusion catheter, per week (list drugs separately)
<b>A4222</b> <sup>†</sup>	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)
<b>K0552</b> <sup>†</sup>	Supplies for external drug infusion pump, syringe type cartridge, sterile, each

\*Centers for Medicare and Medicaid Services (CMS). HCPCS file located at: <http://www.cms.gov/Medicare/Coding/CPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>.

<sup>†</sup>External Infusion Pump types and supplies covered for GAMUNEX-C by Medicare Part B/DME Local Coverage Determination (L33794) and Article (A52507)

## 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:

REVENUE CODE*	DESCRIPTION
<b>0636</b>	Pharmacy, drugs requiring detailed coding

\*National Uniform Billing Committee (NUBC) guidance located at: <http://www.nubc.org/>.

Please see Important Safety Information on pages 11 to 12 and refer to accompanying full Prescribing Information for GAMUNEX-C.

# Sample CMS-1500 For GAMUNEX-C

## IV ADMINISTRATION

**HEALTH INSURANCE CLAIM FORM**  
 APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BLK LUNG OTHER  
 (Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#) (ID#) (ID#)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)  
 3. PATIENT'S BIRTH DATE MM DD YY SEX M F  
 4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)  
 6. PATIENT RELATIONSHIP TO INSURED  
 Self Spouse Child Other  
 7. INSURED'S ADDRESS (No., Street)

CITY STATE CITY STATE  
 ZIP CODE TELEPHONE (Include Area Code) ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)  
 10. IS PATIENT'S CONDITION RELATED TO:  
 a. OTHER INSURED'S POLICY OR GROUP NUMBER  
 b. RESERVED FOR NUCC USE  
 c. RESERVED FOR NUCC USE  
 d. INSURANCE PLAN NAME OR PROGRAM NAME  
 10a. EMPLOYMENT? (Current or Previous)  
 YES NO  
 10b. AUTO ACCIDENT?  
 YES NO PLACE (State)  
 10c. OTHER ACCIDENT?  
 YES NO  
 10d. CLAIM CODES (Designated by NUCC)

11. INSURED'S POLICY GROUP OR FECA NUMBER  
 a. INSURED'S DATE OF BIRTH MM DD YY SEX M F  
 b. OTHER CLAIM ID (Designated by NUCC)  
 c. INSURANCE PLAN NAME OR PROGRAM NAME  
 d. IS THERE ANOTHER HEALTH BENEFIT PLAN?  
 YES NO If yes, complete items 9, 9a, and 9d.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.  
 SIGNED DATE  
 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.  
 SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (M/P)  
 MM DD YY QUAL  
 15. OTHER DATE QUAL MM DD YY  
 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION  
 FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE  
 17a. ICD-9-CM  
 17b. NPI  
 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES  
 FROM MM DD YY TO MM DD YY  
 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)  
 20. OUTSIDE LAB? \$ CHARGES  
 YES NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. #  
 A. L. B. L. C. L. D. L.  
 E. L. F. L. G. L. H. L.  
 I. L. J. L. K. L. L. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.  
 23. PRIOR AUTHORIZATION NUMBER

24. A.	DATE(S) OF SERVICE	B.	PLACE OF SERVICE	C.	EMG	D.	PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)	E.	DIAGNOSIS POINTER	F.	\$ CHARGES	G.	DAYS OR UNITS	H.	SPRINT Family Plan	I.	ID. QUAL.	J.	RENDERING PROVIDER ID.#
1	MM DD YYYY	MM DD YYYY																	
	MM DD YYYY	MM DD YYYY																	
	MM DD YYYY	MM DD YYYY																	
	MM DD YYYY	MM DD YYYY																	

25. FEDERAL TAX I.D. NUMBER SSN EIN  
 26. PATIENT'S ACCOUNT NO.  
 27. ACCEPT ASSIGNMENT? (or govt. claims, see back) YES NO  
 28. TOTAL CHARGE \$  
 29. AMOUNT PAID \$  
 30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)  
 SIGNED DATE  
 32. SERVICE FACILITY LOCATION INFORMATION  
 a. NPI b. NPI  
 33. BILLING PROVIDER INFO & PH # ( )  
 a. NPI b. NPI

NUCC Instruction Manual available at: [www.nucc.org](http://www.nucc.org) PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

**BOX 21**  
 Enter the appropriate diagnosis code(s) from page 5 or 6, and link each to the procedure performed.

**BOX 24D**  
 Enter the CPT and HCPCS codes that correctly describe the procedure(s) performed and the product(s) administered. Insert HCPCS code J1561. For intravenous administration use the JA modifier J1561-JA. Subcutaneous administration use the JB modifier J1561-JB. 1 HCPCS unit equals 500mg, therefore, 1 g equals 2 units.



# Sample CMS-1450/UB-04 Uniform Bill For GAMUNEX-C

Injection, immune globulin, (GAMUNEX-C), nonlyophilized (eg, liquid), 500 mg

## IV ADMINISTRATION

1 PATIENT NAME		2 PATIENT ADDRESS		3a PAT. CNTL. # b. MED. REC. #		5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM		7 THROUGH																																			
8 PATIENT NAME		9 PATIENT ADDRESS		10 BIRTH DATE		11 SEX		12 DATE		13 ADMISSION HR		14 TYPE		15 SRC		16 DHR		17 STAT		18		19		20		21		22		23		24		25		26		27		28		29 ACDT STATE		30	
31 OCCURRENCE DATE		32		33 OCCURRENCE DATE		34		35 OCCURRENCE DATE		36		37		38		39 VALUE CODES AMOUNT		40		41 VALUE CODES AMOUNT		42		43		44		45		46		47		48		49									
42 RE. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE		46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49																															
50 PAYER NAME		51 HEALTH PLAN ID		52 REL. INFO		53 ASST. BEN.		54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRIV ID		58 INSURED'S NAME		59 P.PREL.		60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.		63 TREATMENT AUTHORIZATION CODES		64 DOCUMENT CONTROL NUMBER		65 EMPLOYER NAME		66 DX		67		68									
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE		72 ECI		73		74 PRINCIPAL PROCEDURE DATE		75		76		77 OPERATING		78 OTHER		79 OTHER		80 REMARKS		81CC a		81CC b		81CC c		81CC d		82		83		84									

**BOX 42**  
 Enter the revenue codes that correspond to the items and services provided.

**Examples include**  
**0636**—Pharmacy, drugs requiring detailed coding

**BOX 44**  
 Enter the CPT and HCPCS codes that correctly describe the procedure(s) performed and the product(s) administered.

**Examples include**  
**J1561**—Injection, immune globulin, (GAMUNEX-C), nonlyophilized (eg, liquid), 500 mg

**96365**—Intravenous infusion for therapy/diagnosis, up to 1 hour

**96366**—Intravenous infusion, each additional hour up to 8 hours

**BOX 67**  
 Enter the appropriate diagnosis code(s) from page 5 or 6, and link each to the procedure performed.

# A partnership with dedicated support

## SUPPORTING PATIENTS THROUGHOUT THEIR TREATMENT



- **Eligible patients can save up to \$10,000** over calendar year on their prescription for GAMUNEX-C\*
- **Copay Assistance Program** covers deductibles, copayment, and coinsurance medication costs
  - Patients with CIDP (IV only) and PIDD (IV and SC)
- **Eligibility**—patients must be enrolled in Gamunex Connexions and have commercial insurance that:
  - Covers medication costs for GAMUNEX-C
  - Allows for copay assistance

### A SINGLE POINT OF CONTACT

#### FOR YOUR PATIENTS

Educational information and resources to address their healthcare needs

A certified nurse to answer treatment questions about GAMUNEX-C

Support throughout their treatment when they need it most

#### FOR YOU AND YOUR OFFICE STAFF

Information about GAMUNEX-C and insurance coverage

Educational resources for infusion nurses

**UP TO \$10,000** in Copay Assistance\*

1-888-MYGAMUNEX  
1-888-694-2686

GAMUNEX-C.com

\*Subject to terms and conditions.

Please see Important Safety Information on pages 11 to 12 and refer to accompanying full Prescribing Information for GAMUNEX-C.

## Important Safety Information

GAMUNEX<sup>®</sup>-C (immune globulin injection [human], 10% caprylate/chromatography purified) is indicated for the treatment of primary humoral immunodeficiency disease (PIDD) 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 aseptic 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).



Go to [www.gamunex-c.com](http://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 and PIDD.

Please see Important Safety Information on pages 11 to 12 and refer  
to accompanying full Prescribing Information for GAMUNEX-C.

**GRIFOLS**