gamunex®-c

immune globulin injection (human), 10%
caprylate/chromatography purified

Guide to Coverage and Reimbursement

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
J1561	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
13533-0800-12 (1 g)	**13533-0800-13 (1 g)**
13533-0800-15 (2.5 g)	**13533-0800-16 (2.5 g)**
13533-0800-20 (5 g)	**13533-0800-21 (5 g)**
13533-0800-71 (10 g)	**13533-0800-72 (10 g)**
13533-0800-24 (20 g)	**13533-0800-25 (20 g)**
13533-0800-40 (40 g)	**13533-0800-41 (40 g)**

*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
G61.81	Chronic inflammatory demyelinating polyneuritis
D69.3	Immune thrombocytopenic purpura

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

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

†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.

G11	HEREDITARY ATAXIA
G11.3*	Cerebellar ataxia with defective DNA repair Ataxia-telegiectasia

D82	IMMUNODEFICIENCY ASSOCIATED WITH OTHER MAJOR DEFECTS
D82.0*	Wiskott-Aldrich syndrome Immunodeficiency with thrombocytopenia and eczema
D82.1*	Di George's syndrome Pharyngeal pouch syndrome Thymic alymphoplasia Thymic aplasia or hypoplasia with immunodeficiency
D82.2	Immunodeficiency with short-limbed stature
D82.4*	Hyperimmunoglobulin E [IgE] syndrome
D82.9	Immunodeficiency associated with major defect, unspecified

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

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

CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODES*

INTRAVENOUS ADMINISTRATION		SUBCUTANEOUS ADMINISTRATION	
CPT CODE	DESCRIPTION	CPT CODE	DESCRIPTION
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial up to 1 hour	96369	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)
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)	96370	Subcutaneous infusion for therapy or prophylaxis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)
		96371	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
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
G0089‡	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
G0069‡	Professional services for the administration of subcutaneous immunotherapy for each infusion drug administration calendar day in the individual's home, each 15 minutes
99601†	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602†	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.
†This code is not for use on Medicare claims, but may be covered by payers other than Medicare.
‡May be accepted by Medicare.

DURABLE MEDICAL EQUIPMENT (DME) CODES

HCPCS CODE*	DESCRIPTION
	EXTERNAL INFUSION PUMP CODES
E0779†	Ambulatory infusion pump, mechanical, reusable for infusion 8 hours or greater
E0780	Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours
E0781	Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient
E0791	Parenteral infusion pump, stationary, single, or multichannel
	EXTERNAL INFUSION PUMP SUPPLIES
A4221†	Supplies for maintenance of drug infusion catheter, per week (list drugs separately)
A4222†	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)
K0552†	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.
†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
0636	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.

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

Sample CMS-1500 For GAMUNEX-C

IV ADMINISTRATION

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)
1a. INSURED'S I.D. NUMBER (For Program in Item 1)
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
8. RESERVED FOR NUCC USE
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:
11. INSURED'S POLICY GROUP OR FECA NUMBER
a. OTHER INSURED'S POLICY OR GROUP NUMBER
a. EMPLOYMENT? (Current or Previous) YES NO
a. INSURED'S DATE OF BIRTH MM DD YY SEX M F
b. RESERVED FOR NUCC USE
b. AUTO ACCIDENT? PLACE (State) YES NO
b. OTHER CLAIM ID (Designated by NUCC)
c. RESERVED FOR NUCC USE
c. OTHER ACCIDENT? YES NO
c. INSURANCE PLAN NAME OR PROGRAM NAME
d. INSURANCE PLAN NAME OR PROGRAM NAME
10d. CLAIM CODES (Designated by NUCC)
d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.
READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.
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 (LMP) 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.
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? YES NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. B. C. D. E. F. G. H. I. J. K. L.
22. RESUBMISSION CODE ORIGINAL REF. NO.
23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 MM DD YYYY	MM DD YYYY									NPI	
2 MM DD YYYY	MM DD YYYY									NPI	
3 MM DD YYYY	MM DD YYYY									NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN
26. PATIENT'S ACCOUNT NO.
27. ACCEPT ASSIGNMENT? (For 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.
33. BILLING PROVIDER INFO & PH # ( )
a. NPI b.

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: 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, therfore, 1 g equals 2 units.

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

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

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

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

IV ADMINISTRATION

1 | 2 | 3a PAT. CNTL # | b. MED. REC. # | 5 FED. TAX NO. | 6 STATEMENT COVERS PERIOD FROM THROUGH | 7

8 PATIENT NAME a b | 9 PATIENT ADDRESS a b c d e

10 BIRTHDATE | 11 SEX | 12 DATE | ADMISSION 13 HR 14 TYPE 15 SRC | 16 DHR | 17 STAT | CONDITION CODES 18 19 20 21 22 23 24 25 26 27 28 | 29 ACDT STATE | 30

31 OCCURRENCE CODE DATE | 33 OCCURRENCE CODE DATE | 35 OCCURRENCE SPAN CODE FROM THROUGH | 36 OCCURRENCE SPAN CODE FROM THROUGH | 37

38 | 39 VALUE CODES CODE AMOUNT a b c d | 41 VALUE CODES CODE AMOUNT

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1							
2							
3							
4							
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23	PAGE ____ OF ____	CREATION DATE					

50 PAYER NAME A B C | 51 HEALTH PLAN ID | 52 REL. INFO | 53 ASG. BEN. | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | 57 OTHER PRV ID

58 INSURED'S NAME A B C | 59 P. REL | 60 INSURED'S UNIQUE ID | 61 GROUP NAME | 62 INSURANCE GROUP NO.

63 TREATMENT AUTHORIZATION CODES A B C | 64 DOCUMENT CONTROL NUMBER | 65 EMPLOYER NAME

66 DX 67 A B C D E F G H I J K L M N O P Q 68

69 ADMIT DX | 70 PATIENT REASON DX a b c | 71 PPS CODE | 72 ECI | 73

74 PRINCIPAL PROCEDURE CODE DATE | b. OTHER PROCEDURE CODE DATE | 75

d. OTHER PROCEDURE CODE DATE

76 ATTENDING NPI QUAL LAST FIRST

77 OPERATING NPI QUAL LAST FIRST

78 OTHER NPI QUAL LAST FIRST

79 OTHER NPI QUAL LAST FIRST

80 REMARKS | 81CC a b c d

UB-04 CMS-1450 APPROVED OMB NO. THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

NUBC National Uniform Billing Committee LIC9213257

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.

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

A partnership with dedicated support

SUPPORTING PATIENTS THROUGHOUT THEIR TREATMENT

gamunex® connexions

- **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®-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.

Please refer to accompanying full Prescribing Information for GAMUNEX-C.

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).

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

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 and PIDD.

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

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