



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.

Please see Important Safety Information on pages 11 to 12 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.

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.



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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) CODE¹

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 SC administration, Medicare requires that modifier -JB accompany the GAMUNEX-C HCPCS code. Use J1561-JB on claims billed to the DME Medicare Administrative Contractors (MACs).

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)

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

¹Centers for Medicare and Medicaid Services (CMS). HCPCS file located at: <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=57187>.

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INTERNATIONAL CLASSIFICATION OF DISEASES, 10TH REVISION, CLINICAL MODIFICATION (ICD-10-CM) CODES²

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
D81.4	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

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

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

²Optum, 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.

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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 aplasia Thymic aplasia or hypoplasia with immunodeficiency
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®) CODES³

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)

³Optum Current Procedural Coding Expert, publisher of CPT, a registered trademark of the AMA.

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HOME INFUSION SERVICES

HCPCS/CPT ⁴	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

*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 ⁴	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

*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 ⁵	DESCRIPTION
0636	Pharmacy, drugs requiring detailed coding

⁴Centers for Medicare and Medicaid Services (CMS). HCPCS file located at: <http://www.cms.gov/Medicare/Coding/CPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>.

⁵National Uniform Billing Committee (NUBC) guidance located at: <http://www.nubc.org/>.

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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. NAME
 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.#	
MM	DD	MM	DD	MM	DD	MM	DD	YY	MM	DD	YY	MM	DD	YY	MM	DD	YY	MM	DD	YY
1	MM DD YYYY	MM DD YYYY																		
2	MM DD YYYY	MM DD YYYY																		
3	MM DD YYYY	MM DD YYYY																		
4																				
5																				
6																				

25. FEDERAL TAX I.D. NUMBER SSN EIN
 26. PATIENT'S ACCOUNT NO.
 27. ACCEPT ASSIGNMENT? (or gov't 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 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 subcutaneous infusion use the JB modifier J1561-JB (1 HCPCS unit equals 500 mg, therefore, 1 g equals 2 units).

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.

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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.

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 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.

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