



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.

Table of contents

INTRODUCTION	3
CODING FOR GAMUNEX-C	
HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODES	4
NATIONAL DRUG CODES (NDCs)	4
INTERNATIONAL CLASSIFICATION OF DISEASE (ICD-10-CM) CODES	5-6
CURRENT PROCEDURAL TERMINOLOGY (CPT) CODES	6
HOME INFUSION SERVICES	7
DURABLE MEDICAL EQUIPMENT (DME) CODES	7
HOSPITAL REVENUE CODE	7
SAMPLE CLAIM FORMS	8-9
GAMUNEX-C SUPPORT PROGRAM	10
IMPORTANT SAFETY INFORMATION	11-12

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 polyneuropathy
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

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 aplasia/hypoplasia 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.

Sample CMS-1500 For GAMUNEX-C

IV ADMINISTRATION

HEALTH INSURANCE CLAIM FORM									
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12									
☐ PICA ☐ PICA									
1. MEDICARE (Medicare#)		2. MEDICAID (Medicaid#)		3. TRICARE (ID#/DoD#)		4. CHAMPVA (Member ID#)		5. GROUP HEALTH PLAN (ID#)	
6. FECA BLK LUNG (ID#)		7. OTHER (ID#)		8. 1a. INSURED'S LD. NUMBER (For Program in Item 1)		9. 1b. INSURED'S NAME (Last Name, First Name, Middle Initial)		10. 1c. INSURED'S ADDRESS (No., Street)	
11. 2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		12. 3. PATIENT'S BIRTH DATE (MM DD YY)		13. 4. INSURED'S NAME (Last Name, First Name, Middle Initial)		14. 5. INSURED'S ADDRESS (No., Street)		15. 6. PATIENT RELATIONSHIP TO INSURED (Self, Spouse, Child, Other)	
16. 5. PATIENT'S ADDRESS (No., Street)		17. 6. PATIENT RELATIONSHIP TO INSURED (Self, Spouse, Child, Other)		18. 7. INSURED'S ADDRESS (No., Street)		19. 8. RESERVED FOR NUCC USE		20. 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	
21. CITY		22. STATE		23. CITY		24. STATE		25. 10. IS PATIENT'S CONDITION RELATED TO:	
26. ZIP CODE		27. TELEPHONE (Include Area Code)		28. ZIP CODE		29. TELEPHONE (Include Area Code)		30. a. EMPLOYMENT? (Current or Previous)	
31. 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		32. 10. IS PATIENT'S CONDITION RELATED TO:		33. 11. INSURED'S POLICY GROUP OR FECA NUMBER		34. 12. INSURED'S DATE OF BIRTH (MM DD YY)		35. 13. INSURED'S SEX (M, F)	
36. a. OTHER INSURED'S POLICY OR GROUP NUMBER		37. a. EMPLOYMENT? (Current or Previous)		38. a. INSURED'S DATE OF BIRTH (MM DD YY)		39. 14. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.		40. 15. OTHER CLAIM ID (Designated by NUCC)	
41. b. RESERVED FOR NUCC USE		42. b. AUTO ACCIDENT? (YES, NO)		43. b. OTHER CLAIM ID (Designated by NUCC)		44. c. INSURANCE PLAN NAME OR PROGRAM NAME		45. d. IS THERE ANOTHER HEALTH BENEFIT PLAN? (YES, NO)	
46. c. RESERVED FOR NUCC USE		47. c. OTHER ACCIDENT? (YES, NO)		48. d. INSURANCE PLAN NAME OR PROGRAM NAME		49. 10d. CLAIM CODES (Designated by NUCC)		50. 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
51. d. INSURANCE PLAN NAME OR PROGRAM NAME		52. 10d. CLAIM CODES (Designated by NUCC)		53. 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.		54. 14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (MM DD YY)		55. 15. OTHER DATE (MM DD YY)	
56. 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.		57. SIGNED		58. DATE		59. 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM MM DD YY TO MM DD YY)		60. 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	
61. 14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (MM DD YY)		62. 15. OTHER DATE (MM DD YY)		63. 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM MM DD YY TO MM DD YY)		64. 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		65. 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM MM DD YY TO MM DD YY)	
66. 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		67. 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM MM DD YY TO MM DD YY)		68. 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		69. 20. OUTSIDE LAB? (YES, NO)		70. 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E))	
71. 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		72. 20. OUTSIDE LAB? (YES, NO)		73. 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E))		74. 22. RESUBMISSION CODE		75. 23. PRIOR AUTHORIZATION NUMBER	
76. 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E))		77. 22. RESUBMISSION CODE		78. 23. PRIOR AUTHORIZATION NUMBER		79. 24. A. DATE(S) OF SERVICE (From MM DD YY To MM DD YY)		80. 25. FEDERAL TAX ID. NUMBER	
81. 24. A. DATE(S) OF SERVICE (From MM DD YY To MM DD YY)		82. 25. FEDERAL TAX ID. NUMBER		83. 26. PATIENT'S ACCOUNT NO.		84. 27. ACCEPT ASSIGNMENT? (YES, NO)		85. 28. TOTAL CHARGE	
86. 25. FEDERAL TAX ID. NUMBER		87. 26. PATIENT'S ACCOUNT NO.		88. 27. ACCEPT ASSIGNMENT? (YES, NO)		89. 28. TOTAL CHARGE		90. 29. AMOUNT PAID	
91. 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.)		92. 32. SERVICE FACILITY LOCATION INFORMATION		93. 33. BILLING PROVIDER INFO & PH #		94. 30. Rsvd for NUCC Use		95. 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.)	
96. 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.)		97. 32. SERVICE FACILITY LOCATION INFORMATION		98. 33. BILLING PROVIDER INFO & PH #		99. 30. Rsvd for NUCC Use		100. 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.)	
101. SIGNED		102. DATE		103. a. NPI		104. b. NPI		105. c. NPI	

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		2		3a PAT. CNTL. # b. MED. REC. #		4		5		6		7	
8 PATIENT NAME		9 PATIENT ADDRESS		10		11		12		13		14	
10 BIRTHDATE		11 SEX		12 DATE		13 ADMISSION 13 HR		14 TYPE		15 SRC		16 DHR	
17 STAT		18		19		20		21		22		23	
24		25		26		27		28		29		30	
31 OCCURRENCE DATE		32		33 OCCURRENCE DATE		34		35		36		37	
38		39		40		41		42		43		44	
45		46		47		48		49		50		51	
52		53		54		55		56		57		58	
59		60		61		62		63		64		65	
66		67		68		69		70		71		72	
73		74		75		76		77		78		79	
80		81		82		83		84		85		86	
87		88		89		90		91		92		93	
94		95		96		97		98		99		100	

PAGE 1 OF 1 CREATION DATE 12/15/2015

50 PAYER NAME 51 HEALTH PLAN ID 52 REL. ID 53 PRIOR PAYMENTS 54 EST. AMOUNT DUE 55 NPI 56 OTHER 57 PRIV ID 58 INSURED'S NAME 59 P. REL. 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 A B C D E F G H I J K L M N O P Q R S T U V W X Y Z 68 69 ADMIT DX 70 PATIENT REASON DX 71 PPS CODE 72 ECI 73 74 PRINCIPAL PROCEDURE DATE 75 OTHER PROCEDURE DATE 76 ATTENDING NP1 77 OPERATING NP1 78 OTHER NP1 79 OTHER NP1 80 REMARKS 81 CC a b c d 82 LAST FIRST LAST FIRST LAST FIRST LAST FIRST 83 THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF

UB-04 CMS-1450 APPROVED OMB NO. 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.

Gamunex Connexions[®] Support Program

ACCESS, SUPPORT, AND RESOURCES FOR YOUR PATIENTS



Gamunex Connexions is a support program that provides financial and logistical assistance to ensure a smooth experience with GAMUNEX-C for patients.

COPAY ASSISTANCE PROGRAM

- For eligible patients* with commercial or private insurance, copay assistance up to \$10,000 per calendar year is available to help with copayments, coinsurance, and deductibles.
- To request copay assistance, the infusion provider or specialty pharmacy enters the patient's information in the Gamunex Connexions copay assistance portal.
- The team at Gamunex Connexions is available to answer questions about accessing the Copay Assistance Program.

PATIENT ASSISTANCE PROGRAM (PAP)

- For eligible patients without insurance, the PAP provides medication free of charge.
- Requirements for qualification include:
 - Total household income less than or equal to 400% of the federal poverty level
 - Patient is uninsured or has an insurance plan that does not cover specialty pharmaceuticals
 - Prescribed GAMUNEX-C for PIDD
 - Resident of the United States, excluding territories
 - Patient may not be enrolled in a government-funded healthcare program, such as Medicare, Medigap, Medicaid, VA, DOD, or Tricare

*Subject to terms and conditions.

To access support for your patients and
the healthcare team, call Gamunex Connexions[™]

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

Monday through Friday,
8 AM to 8 PM ET

www.gamunex-c.com/en/hcp/cidp/gamunex-support-program

Important Safety Information

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

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

GRIFOLS