

Guide to Coverage and Reimbursement

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



Table of contents

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

The information contained in this guide is provided for informational purposes only and is subject to change. 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 patient. This guide is not intended to provide specific guidance on how to use, 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 make any representation or guarantee concerning reimbursement or coverage for any service or item.



Introduction

Grifols has developed the Guide to Coverage and Reimbursement for XEMBIFY to assist its customers in understanding third-party payment for XEMBIFY.

XEMBIFY (immune globulin subcutaneous, human- klhw) is a 20% immune globulin solution for subcutaneous injection indicated for treatment of Primary Humoral Immunodeficiency (PIDD) in patients 2 years of age and older. This includes, but is not limited to congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

XEMBIFY is contraindicated in patients who have had an anaphylactic or severe systemic reaction to human immunoglobulin or inactive ingredients of XEMBIFY such as polysorbate 80. 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 XEMBIFY

XEMBIFY is approved for subcutaneous infusion only. Before switching to XEMBIFY, healthcare professionals should obtain a patient's serum IgG trough level to guide subsequent dose adjustments.

When switching from an IVIG to XEMBIFY: calculate the dose by using a dose adjustment factor of 1.37. Begin XEMBIFY one week after the last IVIG infusion.

Establish initial; weekly dose by converting the monthly (or every 3 weeks) IVIG dose into an equivalent weekly dose and increase it by the dose adjustment factor 1.37.

For frequent dosing (2 to 7 times per week) you divide the calculated weekly dose by the desired number of times per week. When switching from immune globulin subcutaneous (human) treatment (IGSC), the weekly dose (grams) should be the same as the weekly dose prior IGSC treatment (grams).

Administration of XEMBIFY may occur in up to 6 infusion sites simultaneously, with at least 2 inches (5 cm) between sites avoiding bony areas, scars, areas of inflammation, superficial infection, or blood vessels.



Please see Important Safety Information on pages 11 to 12 and refer to the accompanying full Prescribing Information for XEMBIFY.



Coding for XEMBIFY

This section describes codes most relevant to provider claims for XEMBIFY.

XEMBIFY is administered subcutaneously via an external subcutaneous infusion pump. The most common setting of care is the patient's home; however, there may be some use in the physician office or Hospital Outpatient Department (HOPD), for example, for training and instructional purposes.

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) CODES¹

HCPCS CODE	DESCRIPTION
J1558	Injection, immune globulin (XEMBIFY), 100 mg.

NATIONAL DRUG CODES (NDCs)

NDCs are typically 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. XEMBIFY has the following NDCs:

OUTER PACKAGE NDC*	INNER PACKAGE NDC
13533-0810-05 (1 g)	13533-810-06 (1 g)
13533-0810-10 (2 g)	13533-810-11 (2 g)
13533-0810-20 (4 g)	13533-810-21 (4 g)
13533-0810-50 (10 g)	13533-810-51 (10 g)

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

^{&#}x27;Centers for Medicare and Medicaid Services (CMS). HCPCS file located at: https://www.cms.gov/medicare/coding/medhcpcsgeninfo.

1-844-MYXEMBIFY (1-844-699-3624)

to receive personalized assistance.

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

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

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 (lgG) 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

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

 $^{^2 \}mbox{Optum},$ 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.

evere combined immunodeficiency SCID) with reticular dysgenesis evere combined immunodeficiency SCID) with low T- and B-cell numbers evere combined immunodeficiency SCID) with low or normal B-cell numbers develop for syndrome furine nucleoside phosphorylase PNP] deficiency
evere combined immunodeficiency SCID) with low or normal B-cell numbers Major histocompatibility complex
Agior histocompatibility complex
Purine nucleoside phosphorylase PNP] deficiency
PNP] deficiency Major histocompatibility complex
Major histocompatibility complex
lass I deficiencey
Najor histocompatibility complex lass II deficiencey
ctivated Phosphoinositide 3-kinase Delta Syndrome [APDS]
Other combined immunodeficiencies
Combined immunodeficiency, Inspecified Severe combined Inmunodeficiency disorder [SCID]

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

1-844-MYXEMBIFY (1-844-699-3624)

to receive personalized assistance.

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
D82.4*	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

CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODES³

CPT CODE	DESCRIPTION
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)
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)

 $^{{}^3} Optum\ Current\ Procedural\ Coding\ Expert,\ publisher\ of\ CPT,\ a\ registered\ trademark\ of\ the\ AMA.$

^{*}Indicates ICD-10 codes covered by Medicare Part B/DME for XEMBIFY

1-844-MYXEMBIFY (1-844-699-3624) to receive personalized assistance.

HOME INFUSION SERVICES

HCPCS / CPT⁴	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 or other subcutaneous infusion drug or biological 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

 $^{^{\}star}$ This code is not for use on Medicare claims, but may be covered by payers other than 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 non-insulin 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 non-insulin drug infusion pump, syringe type cartridge, sterile, each

 $^{^*\}text{External Infusion Pump types covered for XEMBIFY by Medicare Part B/DME Local Coverage Determination (L33794) and Article (A52507)}$

[†]May be accepted by Medicare.

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



1-844-MYXEMBIFY (1-844-699-3624)

to receive personalized assistance.

BILLING MEDICARE DME MACS⁵

The Medicare Part B Durable Medical Equipment (DME) benefit covers subcutaneously infused drugs requiring an external infusion pump for administration. Suppliers submit Part B DME claims to the appropriate DME Medicare Administrative Contractor (MAC) using the electronic version of the CMS-1500 claim form (see sample claim form on page 10). References to the CMS-1500 claim form use the paper format's identifiers but will guide electronic claims submissions as well.

HCPCS CODE ⁶	DESCRIPTION
J1558-JB*	Injection, immune globulin (XEMBIFY), 100 mg.

^{*}To specify SC administration, Medicare requires that modifier –JB accompany the HCPCS code J1558 on claims billed to the DME Medicare Administrative Contractors (MACs).

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 XEMBIFY:

REVENUE CODE ⁷	DESCRIPTION
0636	Pharmacy, drugs requiring detailed coding

 $^{^5} Palmetto GBA (a Medicare Administrative Contractor). Instructions located at: https://palmettogba.com/palmetto/providers.nsf/DocsCat/Providers~JM%20Part%20 A~Resources~FAQs~Claims~8BFR455541?open&navmenu=%7C%7C$

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

⁷National Uniform Billing Committee (NUBC) guidance located at: http://www.nubc.org/.



Sample CMS-1500 for XEMBIFY

PEALTH INSURANCE CLAIM FORM APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12		CARNER —→	Enter the appropriate diagnosis code(from page 5 or 6, and link each to the procedur
PICA		PICA T	performed.
1. MEDICARE MEDICAID TRICARE CHAMP\ (Medicare#) (Medicaid#) (ID#/DoD#) (Member.	— HEALTH PLAN — BLK LLING —	1a. INSURED'S I.D. NUMBER (For Program in Item 1)	p =
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)	3. PATIENT'S BIRTH DATE SEX	4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSURED	7. INSURED'S ADDRESS (No., Street)	
	Self Spouse Child Other 8. RESERVED FOR NUCC USE		
OTTY	8. RESERVED FOR NUCC USE	CITY STATE NO.	
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:		BOX 24D
		a. NSURANCE PLAN NAME OR PROGRAM NAME d. IS THERE ANOTHER HEALTH BENEFIT PLAN?	Enter the CPT a
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) YES NO	a. NSURED'S DATE OF BIRTH SEX	HCPCS codes t
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)	correctly descr
c. RESERVED FOR NUCC USE	c, OTHER ACCIDENT?	c. INSURANCE PLAN NAME OR PROGRAM NAME	the procedure
	YES NO		performed and
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.	the product(s)
12, PATIENTS OR AUTHORIZED PERSONS SIGNATURE: I authorize the to process this claim. I also request payment of government benefits either below. SIGNED	to myself or to the party who accepts assignment	payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED SORNED	administered. Insert HCPCS of J1558. Be sure
	OTHER DATE MM DD YY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY	append modifi
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17.	a. NPI	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY	-JB on claims
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	5. NPI	20. OUTSIDE LAB? \$ CHARGES	submitted to the
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to sen	rice line helow (24F)	YES NO 22. RECORD ORIGINAL REF. NO	DME MACs
A. L. B. L. C. L	vice line below (24E) ICD Ind.	ORIGINAL REF. NO.	
E. L G. L	н. 🗀	23 PRIOR AUTHORIZATION NUMBER	(1 HCPCS unit
I.	EDURES, SERVICES, OR SUPPLIES E.	F. G. H. I. J. Z. DAYS EPSUT ID BENDERING	equals 100 mg
From	ain Unusual Circumstances) PCS MODIFIER POINTER	S CHARGES ON S CHA	therefore, 1 g
MM DD YYYY MM DD YYYY		NPI NPI	equals 10 HCP
AAAA DD boood AAAA DD boood		N N	units).
MM DD YYYY MM DD YYYY		S CHARGES UNITS PRO QUAL. RENDERING PROVIDER ID, # NPI	
MM DD YYYY MM DD YYYY		NPI NPI	
		NPI NPI	
		N	
		S S S S S S S S S S S S S S S S S S S	
	100000000000000000000000000000000000000	NPI NPI	
25. FEDERAL TAX LD. NUMBER SSN EIN 26. PATIENT'S	ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO	28. TOTAL CHARGE	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that estatements on the reverse apply to this bill and are made a part thereof.)	ACILITY LOCATION INFORMATION	33, BILLING PROVIDER INFO & PH # ()	
SIGNED DATE a. N	D b.	a. NP b.	
DATE	2/ 5/ 05 55/// 05 5//05	100001/50 01/0 0000 11/0 5001/1 1500 (00 10)	



A partnership with dedicated support

SUPPORTING PATIENTS THROUGHOUT THEIR TREATMENT





Copay assistance

Patients may receive up to \$10,000 over 12 months on their prescription for XEMBIFY.



Dedicated support program

Partnering with you and your PIDD patients to ensure ongoing access and continuity of care.



Access to XEMBIFY

Call Xembify Connexions at 1-888-MYXEMBIFY to access XEMBIFY through our distribution patners.

PATIENT ASSISTANCE PROGRAMS WITH MAXIMUM SUPPORT

- · Copay assistance program covers deductibles, copayment, and coinsurance medication costs for XEMBIFY
- · Eligibility—patients must be enrolled in Xembify Connexions and have commercial insurance that:
 - Covers medication costs for XEMBIFY
 - · Allows for copay or coupon assistance
- · Provides uninsured PIDD patients access to the therapy they need

OFFICE SUPPORT

- Supporting you and your office with guidance on coverage authorization, reimbursement, and access to XEMBIFY
- · Sample letters and checklists to help you and your staff with your patients' coveravge authorization and appeals
- Coding and reimbursement guidance



Eligible PIDD patients may pay as little as ZERO COPAY for XEMBIFY!*

*Subject to terms and conditions.

1-844-MYXEMBIFY 1-844-699-3624

XEMBIFY.com

Please see Important Safety Information on pages 11 to 12 and refer to the accompanying full Prescribing Information for XEMBIFY.



INDICATION

XEMBIFY™ (immune globulin subcutaneous human–klhw) is a 20% immune globulin indicated for treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older. XEMBIFY is for subcutaneous administration only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- Thrombosis may occur with immune globulin products, including XEMBIFY. Risk factors may include: advanced age, prolonged immobilization, estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- For patients at risk of thrombosis, administer XEMBIFY 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 of hyperviscosity.

Contraindications

XEMBIFY 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 a history of hypersensitivity.

Warnings and Precautions

Hypersensitivity. Severe hypersensitivity reactions may occur with immune globulin products, including XEMBIFY. In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. XEMBIFY contains IgA. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Thrombosis. Thrombosis may occur following treatment with immune globulin products, including XEMBIFY. Thrombosis may occur in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

Aseptic meningitis syndrome (AMS). AMS may occur with human immune globulin treatment, including XEMBIFY. Conduct a thorough neurological exam on patients exhibiting signs and symptoms to rule out other causes of meningitis. Discontinuation of treatment has resulted in remission within several days without sequelae.

Renal dysfunction/failure. Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with use of human immune globulin products, especially those containing sucrose. XEMBIFY does not contain sucrose. Ensure patients are not volume-depleted prior to starting infusion. In patients at risk due to preexisting renal insufficiency or predisposition to acute renal failure, assess renal function prior to the initial infusion of XEMBIFY and again at appropriate intervals thereafter. If renal function deteriorates, consider discontinuation.

Hemolysis. XEMBIFY may contain blood group antibodies that may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for clinical signs and symptoms of hemolysis. If signs and symptoms are present after infusion, perform confirmatory lab testing.



Transfusion-related acute lung injury (TRALI). Noncardiogenic pulmonary edema may occur in patients following treatment with immune globulin products, including XEMBIFY. Monitor patients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of antineutrophil and anti-HLA antibodies in both the product and patient serum. TRALI may be managed using oxygen therapy with adequate ventilatory support.

Transmissible infectious agents. Because XEMBIFY 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. No cases of transmission of viral diseases, vCJD, or CJD have ever been associated with the use of XEMBIFY.

Interference with lab tests. After infusion of XEMBIFY, passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.

Adverse Reactions

The most common adverse reactions in \geq 5% of subjects in the clinical trial were local adverse reactions, including infusion-site erythema (redness), infusion-site pain, infusion-site swelling (puffiness), infusion-site bruising, infusion-site nodule, infusion-site pruritus (itching), infusion-site induration (firmness), infusion-site scab, infusion-site edema, and systemic reactions including cough and diarrhea.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (eg, measles, mumps, rubella, and varicella).



Go to www.xembify.com for additional resources and updates.

Please contact Xembify Connexions at 1-844-MYXEMBIFY (1-844-699-3624) for more information about financial support for patients with PIDD.

Please see Important Safety Information on pages 11 to 12 and refer to the accompanying full Prescribing Information for XEMBIFY.

