



# Guide to Coverage and Reimbursement

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**GRIFOLS**

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

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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

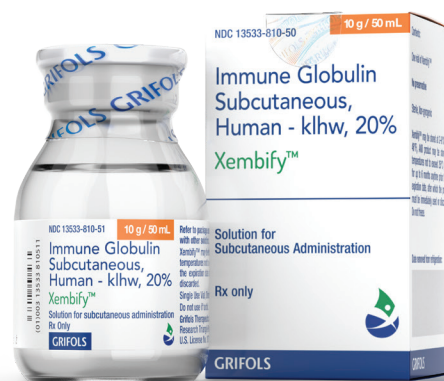
XEMBIFY is approved for subcutaneous infusion only. Before switching to XEMBIFY, healthcare professionals should obtain a patient's serum IgG trough level to guide subsequent dose adjustments.

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), 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 of the 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) CODES\*

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

The HCPCS J1558 code for XEMBIFY 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 XEMBIFY HCPCS code. Use J1558-JB on claims billed to the DME Medicare Administration 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 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 <sup>†</sup>	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)

\*Centers for Medicare and Medicaid Services (CMS). HCPCS file located at: <https://www.cms.gov/medicare/coding/medhcpcsgeninfo>.

<sup>†</sup>Use the Outer Package 11-digit NDC number for billing purposes.

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

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

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

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

\*Optum, for Hospitals and Payers, Volumes 1, 2, and 3 (with ICD-10-CM), publisher of the  
 official code set issued by the Department of Health and Human Services.

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

**G11 HEREDITARY ATAXIA**

<b>G11.3*</b>	Cerebellar ataxia with defective DNA repair Ataxia-telegiectasia
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**D82 IMMUNODEFICIENCY ASSOCIATED WITH OTHER MAJOR DEFECTS**

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

**D83 COMMON VARIABLE IMMUNODEFICIENCY**

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

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

**CURRENT PROCEDURAL TERMINOLOGY (CPT<sup>®</sup>) CODES\***

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

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

## HOME INFUSION SERVICES

HCPCS / CPT*	DESCRIPTION
S9338 <sup>†</sup>	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
G0089 <sup>‡</sup>	Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes
G0069 <sup>‡</sup>	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 <sup>†</sup>	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602 <sup>†</sup>	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour

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

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

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

## DURABLE MEDICAL EQUIPMENT (DME) CODES

HCPCS CODE*	DESCRIPTION
<b>EXTERNAL INFUSION PUMP CODES</b>	
E0779 <sup>†</sup>	Ambulatory infusion pump, mechanical, reusable for infusion 8 hours or greater
E0780	Ambulatory infusion pump, mechanical, reusable, for infusion less than 8 hours
E0781 <sup>†</sup>	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
<b>EXTERNAL INFUSION PUMP SUPPLIES</b>	
A4221 <sup>†</sup>	Supplies for maintenance of non-insulin drug infusion catheter, per week (list drugs separately)
A4222 <sup>†</sup>	Infusion supplies for external drug infusion pump, per cassette or bag (list drugs separately)
K0552 <sup>†</sup>	Supplies for external non-insulin 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/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>.

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

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

## BILLING MEDICARE DME MACS\*

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 <sup>†</sup>	DESCRIPTION
J1558-JB <sup>‡</sup>	Injection, immune globulin (XEMBIFY), 100 mg.

\*Palmetto GBA (a Medicare Administrative Contractor). Instructions located at: <https://palmettogba.com/palmetto/providers.nsf/DocsCat/Providers-JM%20Part%20A-Resources-FAQs-Claims-8BFR455541?open&navmenu=%7C%7C>

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

<sup>‡</sup>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*	DESCRIPTION
0636	Pharmacy, drugs requiring detailed coding

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



# Sample CMS-1500 for XEMBIFY



## HEALTH INSURANCE CLAIM FORM

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

<input type="checkbox"/> PICA		<input type="checkbox"/> PICA	
1. MEDICARE <input type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DoD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA BLK (LUNG) <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (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 <input type="checkbox"/> F <input type="checkbox"/>	
5. PATIENT'S ADDRESS (No., Street) CITY STATE ZIP CODE TELEPHONE (Include Area Code) ( )		6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/> 7. INSURED'S ADDRESS (No., Street) CITY STATE 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		a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
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 _____		11. INSURED'S POLICY GROUP OR FECA NUMBER 11a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/> b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL _____		15. OTHER DATE MM DD YY QUAL _____	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE		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 <input type="checkbox"/> NO <input type="checkbox"/> \$ 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. _____	
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. EPDIT Family Plan I. ID. QUAL J. RENDERING PROVIDER ID. #		23. PRIOR AUTHORIZATION NUMBER _____	
25. FEDERAL TAX ID. NUMBER SSN EIN <input type="checkbox"/> <input type="checkbox"/>		26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? For 27a. date, see below. YES <input type="checkbox"/> NO <input type="checkbox"/>	
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 _____		28. TOTAL CHARGE \$ _____ 29. AMOUNT PAID \$ _____ 30. Rsvd for NUCC Use	
32. SERVICE FACILITY LOCATION INFORMATION a. NPI _____ b. _____		33. BILLING PROVIDER INFO & PH # ( ) a. NPI _____ b. _____	

NUCC Instruction Manual available at: [www.nucc.org](http://www.nucc.org)

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

### BOX 21

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

### BOX 24D

Enter the CPT and HCPCS codes that correctly describe the procedure(s) performed and the product(s) administered. Insert HCPCS code J1558. Be sure to append modifier -JB on claims submitted to the DME MACs (1 HCPCS unit equals 100 mg, therefore, 1 g equals 10 HCPCS units).

# A partnership with dedicated support

SUPPORTING PATIENTS THROUGHOUT THEIR TREATMENT



## Copay assistance

Eligible 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 partners.

## PATIENT ASSISTANCE PROGRAMS

- 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' coverage authorization and appeals
- Coding and reimbursement guidance



Eligible patients with PIDD 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<sup>®</sup> (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.

Please refer to accompanying full Prescribing Information for XEMBIFY.

**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](http://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.

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