Xembify connexions™

# PATIENT ASSISTANCE PROGRAM APPLICATION

- **This form includes sections for the patient and the prescriber to complete and sign. The patient must also enroll in Xembify Connexions.**
- Return the completed form by FAX to 1-877-375-0758 or EMAIL to grifolsconnexions@cardinalhealth.com.
- If you prefer, you may MAIL the completed form to: Xembify Connexions, 2730 South Edmonds Ln, Suite 300, Lewisville, TX 75067.
- If you have any questions, please call **1-844-MYXEMBIFY (1-844-699-3624)**, Monday to Friday, 8 AM to 8 PM ET.

The Patient Assistance Program enables eligible patients to receive medication at no cost. Patients must be diagnosed with primary immunodeficiency (eligible diagnosis codes available upon request), be a US citizen or legal resident (excluding Puerto Rico and US territories), and meet financial eligibility requirements.

## PATIENT INFORMATION

Name: _____ Date of Birth: / /

*First* *Last* *MM/DD/YYYY*

*Address: _____ *City: _____ *State: _____ *ZIP: _____

**Optional Information*

Please check one: ☐ I currently have prescription drug coverage OR ☐ I certify that I have no insurance

Are you currently receiving prescription reimbursement, in whole or in part, by any of the following:

☐ Medicaid ☐ Medicare ☐ Medigap ☐ VA ☐ DOD ☐ Tricare

☐ Other federal or state funded program (please specify:) _____

Patient must be a **US citizen** or **legal resident of the US**, excluding Puerto Rico and US territories.

A Connexions representative will review all information to confirm eligibility and contact you if additional information is necessary.

## PATIENT CONSENT

I agree that I have no insurance coverage for XEMBIFY® (immune globulin subcutaneous human—klhw) 20% at this time and insufficient financial resources to pay for the prescribed medication. I hereby permit my healthcare providers, physicians, or third-party service providers to disclose, share, and use the information on these forms and other information pertaining to me, to the minimum extent necessary, for adjudication of the application, as requested by the Xembify Connexions Patient Assistance Program. I verify that the information provided in this application is complete and accurate to the best of my knowledge. I understand that if my health insurance coverage or employment status changes, I will notify the Xembify Connexions Patient Assistance Program promptly of such change. I understand that this may affect my eligibility to participate in the program before my eligibility period ends. I also understand that any and all information that I provide may be shared with my treating physician. I understand that this authorization will remain in effect throughout my participation in the program. I understand that I am approved for the calendar year and must re-affirm my status as requested and/or re-apply at the end of the calendar year to continue my participation in the program. I understand that my access to XEMBIFY within the program may be delayed depending on the number of participants and the availability of drug product for the program. The Xembify Connexions Patient Assistance Program may be discontinued or modified at any time, without notice. I understand that I am under no obligation to use or purchase any product or service as a condition of receipt of free product from Grifols, the manufacturer of XEMBIFY. I shall not seek reimbursement from any sources for the free product that I receive, and acknowledge that neither I nor any provider is entitled to reimbursement for free product. Free product is nontransferable.

Grifols or its authorized third-party agency may use my date of birth or Social Security number and/or additional demographic information as needed to access my credit information and information derived from public or other sources to estimate my income.

Grifols may obtain information from my credit profile from Experian Health for the purpose of verifying my income eligibility for the Xembify Connexions Patient Assistance Program.

I understand that Grifols or its third-party vendor administering the program may ask me for a copy of my IRS 1040 form or other proof of income for the purpose of verifying my eligibility for the program at any time. I agree to provide any requested financial documentation in a timely manner.

**Patient Name**: _____ PATIENT SIGNATURE: _____ Date: _____

**Patient Representative**: _____ REPRESENTATIVE SIGNATURE: _____ Date: _____

*Name and relationship*

**Financial documentation demonstrating household income is also required with your submission. Please review a detailed list of the acceptable documents on the following page.**

**Please see Important Safety Information on page 3 and see accompanying full Prescribing Information for XEMBIFY.**

GRIFOLS

*Continued on page 2*

Xembify® (immune globulin subcutaneous human-klhw) 20%

## FINANCIAL DOCUMENTATION

Financial documentation demonstrating household income is required. Acceptable forms of income documentation include:

- Copy of W-2 or most recently filed US Income Tax Return (IRS Form 1040, 1040A, 1040EZ, 1040NR or 1040PR)
- Copy of most recent pay stub plus most recently filed US Income Tax Return
- Copy of transcript received through submission of IRS 4506-T (request for transcript form is not accepted)
- Copy of most recent Social Security/Disability monthly check, award letter, benefit statement, or 1099
- Copy of Unemployment Determination Letter

## PHYSICIAN/PRESCRIBER ATTESTATION

My signature certifies that I am licensed to practice medicine under state law. I certify that the information provided in this document is complete and accurate to the best of my knowledge. I verify that, to the best of my knowledge, this patient has no prescription insurance coverage for the product prescribed, including all public programs, and the patient has insufficient financial resources to pay for the prescribed medication. I confirm that the patient prescription is for on-label use. I understand Grifols reserves the right to modify or terminate this program at any time. Furthermore, my signature certifies that these goods will not be sold or offered for sale, trade, or barter and will not be returned for credit. I understand that Grifols reserves the right to recall the product, if necessary.

I further certify that if any units of product are shipped to me under the Patient Assistance Program for this patient, they will be provided to the above-named patient only for his or her treatment and will not be sold or otherwise distributed. I further certify that no patient or third party will be charged for the product. Additionally, no units of product will be submitted for Medicare, Medicaid, or any public or private third-party reimbursement, or returned for credit.

I will supervise the patient's overall treatment plan, to include periodically verifying continued use of the provided product and resubmitting current prescriptions. I understand eligibility under this program is subject to Grifols approval and the patient's continuing compliance with all eligibility requirements, as set by Grifols from time to time.

I agree to allow Grifols or its authorized agent to review the medical, financial, and insurance records for this patient at any time for the purposes of verifying the patient's eligibility status for the Patient Assistance Program and the patient's receipt of any product provided to him or her through the Patient Assistance Program.

**Physician Name**: _____ PHYSICIAN SIGNATURE: _____ Date: _____

A physician's signature is required to assure that both parties are informed about the patient's enrollment in the Patient Assistance Program.

**Please see Important Safety Information on page 3 and see accompanying full Prescribing Information for XEMBIFY**

**What is XEMBIFY®?**
XEMBIFY® (immune globulin subcutaneous human–klhw) is a 20% immune globulin used in the 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 (formation of blood clots within blood vessels) may occur with immune globulin products, including XEMBIFY. Before you take XEMBIFY, talk to your doctor if you:**
  - **Are older**
  - **Are sedentary (need to lie down or sit down) for long periods of time**
  - **Are taking estrogen-containing medicines (birth control pills, hormone replacement therapy)**
  - **Have a permanent intravenous (IV) catheter**
  - **Have hyperviscosity of the blood (diseases such as multiple myeloma or other causes of elevated proteins in the blood)**
  - **Have cardiovascular (heart) problems or previous history of stroke**
- **Thrombosis may occur even if you don't have any risk factors**
- **If you are at risk of thrombosis, your doctor may prescribe XEMBIFY at the minimum dose and infusion rate. Make sure you drink plenty of fluid before taking XEMBIFY. Make sure your doctor is checking you regularly for signs and symptoms of thrombosis and is checking your blood viscosity if you are at risk of hyperviscosity**

**Who should not use XEMBIFY?**

- XEMBIFY should not be used if you have had a severe allergic reaction to human immune globulin, or if you have been told by a doctor that you are IgA deficient and have developed antibodies to IgA and hypersensitivity after exposure to a previous plasma product

**What are possible serious side effects of XEMBIFY?**

- **Aseptic meningitis syndrome (AMS).** Aseptic meningitis is a non-infectious inflammation of the membranes that cover the brain. It causes a severe headache syndrome, which may occur with human immune globulin treatment, including XEMBIFY. If you are showing signs and symptoms of AMS, your doctor may conduct a thorough neurological evaluation including spinal tap (sampling fluid which surrounds the spinal cord) to rule out other causes of meningitis. Stopping human immune globulin treatment has resulted in the end of signs and symptoms within several days. Treatment may include analgesics (pain medicines) and/or a special procedure known as a "blood patch" to stop headache
- **Hypersensitivity.** Severe allergic reactions may occur with immune globulin products, including XEMBIFY. If you have a severe allergic reaction, stop the infusion immediately and get medical attention. XEMBIFY contains IgA. If you have known antibodies to IgA, you may have a greater risk of developing potentially severe allergic reactions
- **Kidney problems or failure.** Kidney problems or failure may occur with use of human immune globulin products, especially those containing sucrose (sugar). XEMBIFY does not contain sucrose. If you have kidney disease or diabetes with kidney involvement, your doctor should perform a blood test to assess your hydration level and kidney function before beginning immune globulin treatment and at appropriate intervals thereafter. If your doctor determines that kidney function is worsening, they may discontinue treatment
- **Hemolysis.** Your doctor should monitor you for symptoms of hemolysis (destruction of red blood cells causing anemia, or low red blood cell count). If your doctor suspects hemolysis, they should perform additional tests to confirm
- **Transfusion-related acute lung injury (TRALI).** TRALI is a rare but serious syndrome characterized by sudden acute respiratory distress following transfusion. If your doctor suspects TRALI, they will monitor you for any other lung issues. TRALI may be managed with oxygen therapy
- **Transmissible infectious agents.** Because XEMBIFY is made from human blood, it may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases or CJD have been associated with the use of XEMBIFY
- **Interference with lab tests.** Because XEMBIFY contains a variety of antibodies, blood tests to determine antibody levels may be falsely elevated. Be sure to tell your doctor or lab technician that you are using XEMBIFY

**What are other possible side effects of XEMBIFY?**

- In clinical studies of XEMBIFY, some patients experienced local side effects (at the injection site) including pain, redness, puffiness, bruising, nodules, itching, firmness, scabbing and swelling at the site on the skin where the injection occurred. Some patients experienced non-injection-site side effects including cough and diarrhea
- Use of XEMBIFY may interfere with the immune response to virus vaccines, such as vaccines for measles, mumps, rubella and varicella. Tell your doctor you are taking XEMBIFY before getting vaccinations

**Please see accompanying full Prescribing Information for XEMBIFY.**

**You are encouraged to report negative side effects of prescription drugs to the FDA.**
**Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

GRIFOLS



Xembify® (immune globulin subcutaneous human-klhw) 20%