Xembify connexions™

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

PATIENT ASSISTANCE PROGRAM APPLICATION

- **Please complete all sections of this form and FAX to 1-877-375-0758.**
- If you prefer, you may mail this form to: Xembify Connexions, PO Box 31137, Bethesda, MD 20824.
- Should you have any questions about the application or process, please call **1-844-MYXEMBIFY (1-844-699-3624)**.

Patient Assistance Program is for on-label use for patients with primary immunodeficiency disease (PIDD), and may help eligible patients receive their medication at no cost.

PATIENT INFORMATION

First Name: Last Name: Date of Birth: (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:
(select all that apply) ☐ 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 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 this 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 non-transferable.

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 and 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 (print): Date:

Patient Signature: Date:

Patient Representative (name and relationship):

Representative Signature: Date:

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Please see Important Safety Information on the reverse side and see accompanying full Prescribing Information for XEMBIFY.

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

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.

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PATIENT ASSISTANCE PROGRAM – PRESCRIBER THERAPY ATTESTATION

- **Please complete all sections of this form and FAX to 1-877-375-0758.**
- If you prefer, you may mail this form to: Xembify Connexions, PO Box 31137, Bethesda, MD 20824.
- Should you have any questions about the application or process, please call **1-844-MYXEMBIFY (1-844-699-3624).**

Patient Assistance Program is for on-label use for patients with primary immunodeficiency disease (PIDD).
Please contact Connexions for a full list of approved diagnosis codes.

PATIENT INFORMATION

First Name: Last Name:

Does the patient have prescription drug coverage? ☐ Yes ☐ No

Is the patient currently receiving prescription reimbursement, in whole or in part, by any of the following:

(select all that apply) ☐ 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 the patient if additional information is necessary.

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 for PIDD. 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 XEMBIFY® (immune globulin subcutaneous human–klhw) 20% 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(s) provided to him or her through the Xembify Connexions Patient Assistance Program.

Physician Name (print): Date:

Physician Signature: Date:

Please see Important Safety Information on the reverse side and refer to accompanying full Prescribing Information for XEMBIFY.

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

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, hypercoagulable conditions, history of venous or arterial thrombosis, use of 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

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.

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.

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.

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 ≥ 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).

Please see accompanying full Prescribing Information for XEMBIFY.

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