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):

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 reapply 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 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:

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

GRIFOLS

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 (Sub-Q) 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 lay 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?

- **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.
- **Aseptic meningitis syndrome (AMS).** Aseptic meningitis is a non-infectious inflammation of the meninges which 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.
- **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, your doctor 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, your doctor 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, your doctor 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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