Xembify® connexions

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

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):

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) 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 PAP 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.

GRIFOLS

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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 ≥ 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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