Xembify connexions™

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

COPAY ASSISTANCE PROGRAM ENROLLMENT GUIDE

The XEMBIFY Copay Assistance Program provides financial support for eligible patients whose claims are billed under either pharmacy or medical benefit. The program is administered through Medmonk portal. It offers providers a streamlined process to register, submit claims, and assist patients with their copay needs.

FOR PHARMACY BILLING

If your patient's claim is being billed under the pharmacy benefit, submit a claim to the primary payer first. If your patient requires copay assistance, submit a secondary claim to Medmonk through your NCPDP system using the following processing information:

BIN: 016664
PCN: MEDMONK
Cardholder ID: MEDMONK

Claims must be submitted within 60 days of the dispense date.

FOR MEDICAL BILLING

If your patient's claim is being billed through the medical benefit, your facility needs to be registered with Medmonk.

If your facility has not registered with Medmonk for any product, complete a one-time provider registration by visiting **xembify.medmonk.com**. Enter the required details including facility name, NPI number, contact person for financial reimbursement, location tax ID, and facility contact details.

To submit a patient's claim for copay assistance:

1. Submit a request in the Medmonk portal with an estimated financial responsibility within 60 days of the dispense date.
2. After the primary insurance processes the claim, upload the EOB in the portal within 180 days of the date the request was submitted.

For more information or assistance, contact:

Medmonk Support: 1-866-234-3732 (Option 1) | XEMBIFY Connexions™: 1-844-699-3624 (1-888-MYXEMBIFY)

ELIGIBILITY CRITERIA FOR COPAY ASSISTANCE*

Patients can receive up to $10,000 of copay assistance per calendar year for XEMBIFY

- Eligibility:
  - Patients must provide consent to Xembify Connexions before the second and subsequent claims for copay assistance can be processed
  - Patients must have commercial insurance that covers medication costs for XEMBIFY and allows for copay assistance
  - Patients must have a diagnosis of PIDD.† Covered ICD codes are listed under Billing Information on **xembify.medmonk.com**
- The copay assistance program covers deductibles, copayment, and coinsurance for medication costs only
  - Assistance is available for the treatment of PIDD
  - No monthly caps or infusion limits

RESTRICTIONS

Patients are ineligible for copay assistance if they participate in Medicare, Medicaid, Medigap, Veterans Affairs, Department of Defense, Tricare, or any other federal or state-funded programs

This program is subject to change or discontinuation by Grifols at any time, for any reason, and with or without prior notice.
The copay portal is administered by Medmonk for the XEMBIFY Copay Assistance Program.

*See complete terms and conditions for the copay assistance program at: **https://www.xembify.com/en/hcp/xembify-connexions**
†PIDD, primary immunodeficiency disease

GRIFOLS

Please see Important Safety Information on the following page and refer to accompanying full Prescribing Information for XEMBIFY® (immune globulin subcutaneous human–klhw).

IMPORTANT SAFETY INFORMATION

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.

GRIFOLS

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