Drafting a Formulary Exception Request Letter

This document was developed to provide guidance when drafting a Formulary Exception Request Letter.

It is provided for informational purposes only and does not guarantee coverage or reimbursement. Healthcare providers make the ultimate determination as to when to use a specific product, based on clinical appropriateness for a patient. Third-party payment for medical products and services is affected by numerous factors, and Grifols cannot make any representation or guarantee concerning reimbursement or coverage for any service or product.

Providers, patients, and their legal representatives are encouraged to contact third-party payers for specific information on their coverage policies.* **For additional support, please contact Xembify Connexions™ at 1-855-XEMBIFY.**

A formulary exception is a type of coverage determination. It is used when a drug is not included on a health plan's formulary, is subject to a National Drug Code (NDC) block, or when a plan has not yet reviewed or listed the drug and NDC.

Plans frequently provide specific formulary exception request templates that must be used when making the request. These forms may be downloaded from each plan's website. Please remember to follow the plan's processes and procedures when they are provided.*

This resource is designed to help you and your staff with the process of drafting a Formulary Exception Request Letter. A checklist is included below that may be helpful when creating this letter. In addition, a sample letter (in template format) is attached to this document and includes information that plans often require to process requests. Typically, the patient's medical records and a Letter of Medical Necessity (LMN) are submitted with the letter. The formulary exception letter may originate from the patient, HCP, or legal representative. Both the prescriber and patient should sign the letter.

- ☐ Include the full name of the patient, plan identification number, and date of birth
- ☐ Include prescriber name, National Provider Identifier (NPI), specialty, address, phone/fax number, email, and date of submission
- ☐ Provide XEMBIFY® (immune globulin subcutaneous human–klhw) physical characteristics and safety/adverse event profile from package insert
- ☐ Explain why the plan's preferred formulary agents are not appropriate for this patient and provide a recommendation summary, including professional opinion of the patient's likely prognosis or disease progression without XEMBIFY treatment
- ☐ Include a Letter of Medical Necessity (see additional resources for examples)

*The Centers for Medicare & Medicaid Services (CMS) provides specific information of particular importance to beneficiaries receiving Part D drug benefits through a Part D plan and/or benefits through Medicare Part B Durable Medical Equipment (DME). Please visit the following link to download forms and instructions concerning Part D grievances, coverage determinations (including exceptions), and appeals processes. https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/coveragedeterminationsandexceptions.html. For Medicare Part B please consult the appropriate regional DME Medicare Administrative Contractor or Medicare Advantage plan.

Sample Letter of Formulary Exception Request

[Date]

[Payer Name]

ATTN: [Medical Director]
[Payer Contact Name, if available]
[Payer Address]

Re: Formulary Exception Request Letter for XEMBIFY® (immune globulin subcutaneous human–klhw) 20%

Patient: [Patient First and Last Name]
Date of Birth: [MM/DD/YYYY]
Weight: [kg]
Subscriber Identification Number: [Insurance ID Number]
Subscriber Group Number: [Insurance Group Number]
Case Identification Number: [Case ID Number]
Dates of Service: [Dates]

Dear [Contact Name/Medical Director]:

My name is [Name], and I am [board certification or relationship to patient]. I am writing to request a formulary exception on behalf of [Patient name], who is currently a member of [Name of health plan]. The request is for XEMBIFY® (immune globulin subcutaneous human–klhw) 20%. Treatment with XEMBIFY [dose and frequency] is medically appropriate and necessary for this patient who has been diagnosed with primary humoral immunodeficiency disease, [ICD-10 code]. However, XEMBIFY is not included on your plan's formulary list. I am requesting that the plan allow a formulary exception and remove any relevant NDC* blocks so that XEMBIFY can be made available to my patient as a preferred treatment.

Previous Treatments
[In this section, explain why the plan's preferred formulary agents are not appropriate for this patient. Include any previous treatments, start/stop dates, and reasons for discontinuation where applicable including any unplanned physician, urgent care, emergency department visits, or inpatient hospitalizations.]

Clinical Rationale for XEMBIFY
[In this section, provide clinical rationale for XEMBIFY including patient's medical history and diagnosis, condition, and the full Prescribing Information supporting the use of XEMBIFY, and a statement summarizing the recommended treatment plan.]

*XEMBIFY NDCs include: 13533-0810-05; 13533-0810-10; 13533-0810-20; 13533-0810-50.

For additional support, contact Xembify Connexions™ at 1-844-MYXEMBIFY (1-844-699-3624).
Please see Important Safety Information on the last 2 pages of this letter and refer to full Prescribing Information for complete prescribing details.

Sample Letter of Formulary Exception Request

XEMBIFY Characteristics
Indication – Primary humoral immunodeficiency disease in patients 2 years of age and older
IgA content is 68±19 µg/mL and the average IgM content is <4 µg/mL.[†]
Formulation – No sugar, trace amounts of sodium, stabilized with glycine, close to physiologic osmolality
Manufacturing steps with capacity to inactivate/remove pathogens – Caprylate precipitation/depth filtration, caprylate incubation, depth filtration, column chromatography, low pH incubation, TSE removal

[†]Alonso W, Vandeberg P, Lang J, et al. Immune globulin subcutaneous, human 20% solution (Xembify®), a new high concentration immunoglobulin product for subcutaneous administration. Biologicals. 2020;64:34-40.

Summary of Recommendation
[In this section, provide a summary of your recommendation, including peer-to-peer discussions and your professional opinion of the patient's likely prognosis or disease progression without XEMBIFY treatment.]

Sincerely,

[Prescriber name and signature]
[Prescriber medical specialty]
[National Provider Identifier]
[Practice Name, address, phone/fax and email]

[Patient name and signature]

Enclosure(s)
[List enclosures which may include Prescribing Information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed articles, FDA approval letter, scans showing progressive disease, and pathology reports.]

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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.

GRIFOLS

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