Drafting a Coverage Authorization Appeal Letter

This document was developed to provide guidance when drafting a **Coverage Authorization Appeal 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 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.

If the Formulary Exception Request Letter and Letter of Medical Necessity are denied by the patient's health plan, you may submit a Coverage Authorization Appeal Letter. Depending on the plan, there may be varying levels of appeals. If you are uncertain about a plan's appeal policies, you can always refer to the plan's appeal processes and procedures.*

A Coverage Authorization Appeal Letter generally originates from the patient and the prescriber. It should be submitted with 2 additional items: the patient's medical records and a Letter of Medical Necessity (LMN).

This resource is designed to help you and your staff with the process of drafting a **Coverage Authorization Appeal Letter**. A checklist is included below that may be helpful when creating this letter on behalf of your patient and his/her medical needs. In addition, a sample letter (in template format) is attached to this document and includes information that plans often require when considering appeals.

- ☐ Include the full name of the patient, plan identification number, and date of birth
- ☐ Prescriber name, National Provider Identifier, specialty, address, phone/fax number, email, and submission date
- ☐ Provide XEMBIFY® (immune globulin subcutaneous human–klhw) characteristics including indication, IgA content, pH (after reconstitution), and half-life
- ☐ Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with case identification number from the initial denial letter
- ☐ Provide a copy of the patient's records with the following details:
    - Severity of condition at baseline, 3-month follow-up, and 6-month follow-up
    - The patient's history, diagnosis, and ICD-10 code(s)
    - The patient's recent history of other therapies including Ig dose and frequency (if applicable), list of any allergies, and existing comorbidities
    - The patient's current condition and symptoms including quality of life, and list of other key events such as hospitalizations, unplanned physician visits, required medications, side effects, etc
- ☐ Document prior treatments, duration, and rationale for why each treatment was discontinued
- ☐ Provide the clinical rationale for treatment with XEMBIFY; information may be found in the Prescribing Information and/or clinical peer-reviewed literature
- ☐ Include a Letter of Medical Necessity and explain options for therapy if XEMBIFY is not approved (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 Coverage Authorization Appeal Letter

[Date]

[Payer Name]

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

Re: Appeal for Denial of 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]:

I reviewed and recognize your guidelines for the responsible management of medications within the immunoglobulin drug class. I am writing to request that you reassess your recent denial of XEMBIFY® (immune globulin subcutaneous human–klhw) 20% coverage. I understand that the reason for your denial is [insert reason verbatim from the plan's denial letter]. However, I believe that XEMBIFY [dose, frequency] is a necessary treatment for my patient. In further support of my recommendation for XEMBIFY treatment, I have provided an overview of my patient's relevant clinical history on the following page.

Sample Coverage Authorization Appeal Letter

PATIENT HISTORY	TEST USED	DATE OF TEST
Severity of condition:		
Baseline measurement:		
3-month measurement:		
6-month measurement:		
Current measurement:		
QOL measurement:		

[In this section, list other key events such as hospitalizations, unplanned HCP visits, required medications, other treatments, and possible side effects that your patient is experiencing.]

OTHER THERAPIES	
Start date:	
Complications:	
Side effects:	
Reason(s) for discontinuation:	

Summary of Recommendation
[In this section, provide a summary of your recommendation, including peer-to-peer discussions and your professional opinion of your 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.]

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.

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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