Drafting a Letter of Medical Necessity (LMN)

This document was developed to provide guidance when drafting a Letter of Medical Necessity (LMN). 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.

Many health plans require that an LMN accompanies a Coverage Authorization Appeal Letter. The purpose of an LMN is to explain the prescribing healthcare provider's (HCP's) rationale and clinical decision-making when choosing a treatment. An LMN is often required by plans when submitting a Coverage Authorization Appeal Letter, Formulary Exception Request Letter, and Tiering Exception Request Letter.

This resource is designed to help you and your staff with the process of drafting a Letter of Medical Necessity. 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.

- ☐ Include the full name of the patient, plan identification number, date of birth, and the case identification number if a decision has already been rendered
- ☐ Include prescriber name, National Provider Identifier (NPI), specialty, address, phone/fax number, email, and date of submission
- ☐ Provide a copy of the patient's records with the following details:
    - Patient's age, weight, recent medical history, diagnosis with specific ICD-10 code, present-day condition, and symptoms including any unplanned physician, urgent care, emergency dept visit(s), or inpatient hospitalization(s) in the previous 2 years
    - Severity of the patient's condition using the plan's preferred assessment when provided
- ☐ Document prior treatments and duration including applicable product J-codes and why the prior treatment was discontinued
- ☐ Attach clinical documentation that supports your recommendations; this information may be found in the XEMBIFY® (immune globulin subcutaneous human–klhw) Prescribing Information and/or clinical peer-reviewed literature

*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 for the Part D appeals overview and other relevant information. https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/AppealsOverview.html. For Medicare Part B please consult the appropriate regional DME Medicare Administrative Contractor or Medicare Advantage plan.

Sample Letter of Medical Necessity

[Date]

[Payer Name]

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

Re: Letter of Medical Necessity 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]:

I am writing on behalf of my patient, [Patient name], to [request prior authorization of/document medical necessity for] treatment with XEMBIFY® (immune globulin subcutaneous human–klhw) 20%. This letter provides information about my patient's medical history and diagnosis and a statement summarizing my treatment plan. On behalf of my patient, I am requesting approval for use and subsequent payment for treatment.

Patient's Clinical History
[Patient's name] is a [age]-year-old [male/female] who was diagnosed on [date] with a primary humoral immunodeficiency disease. [Patient's name] underwent [describe treatments to date to include other immune globulin replacement therapies and prophylactic antibiotics].

- [Include diagnosis along with relevant ICD-10 code and dates]
- [Past treatments] and failure of past treatments (eg, number of recurrent infections/year)
- [Unplanned physician visit(s), urgent/emergency department visit(s), or inpatient hospitalization(s) in the previous 2 years]
- [If applicable, test results that support diagnosis of primary humoral immunodeficiency disease, such as
  - Quantitative serum IgM, IgG, and IgA levels, Complement (CH50, C3, C4), CBC differential, and ESR
  - B-cell functional evaluation, quantitative IgG subclasses, natural or commonly acquired antibodies (eg, isohemagglutinins, rubella, rubeola, tetanus), T-cell–dependent antigens (tetanus), T-cell independent antigens (eg, unconjugated pneumococcal vaccine, unconjugated Haemophilus influenzae type B vaccine)

Sample Letter of Medical Necessity

  - Quantification of blood T- and B-cell subpopulations by immunofluorescence assays using monoclonal Ab markers
    - » T cells: CD3, CD4, CD8, TCR alpha/beta, TCR gamma/delta
    - » B cells: CD19, CD20, CD21, Ig (mu, delta, gamma, alpha, kappa, lambda), Ig-associated molecules (alpha, beta)
  - Disease-specific analysis, MHC haplotype analysis, CD40, CD40 ligand expression, genetic analyses]
- [Extenuating circumstances that would preclude alternatives to XEMBIFY]
- [Social and family information]

[**NOTE**: If the payer has a published medical policy, include here]

[**NOTE**: If state statute exists, include here]

Treatment Plan
On July 3, 2019, the FDA approved XEMBIFY® (immune globulin subcutaneous human–klhw) 20%, for the treatment of primary humoral immunodeficiency disease in patient's 2 years of age and older. The recommended dose of XEMBIFY is XX mg/X mL administered subcutaneously. The regimen† is XXXXXXXXXX.

Summary of Recommendation
In summary, please consider coverage of XEMBIFY on behalf of [Patient name], and approve use and subsequent payment for XEMBIFY. In addition, I have enclosed the full Prescribing Information, FDA approval letter, and relevant clinical studies regarding XEMBIFY for your reference.

If you have any further questions regarding this matter, please do not hesitate to call me, [Prescriber name] at [phone number]. Thank you for your prompt attention to this matter.

Sincerely,

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

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.]

†Establish initial weekly dose by converting the monthly IVIG dose into an equivalent weekly dose and increasing it using a dose adjustment factor (1.37).
Initial weekly = prior IVIG dose (in grams) × 1.37 dose (grams)/number of weeks between IVIG doses.
Frequent dosing (2-7 times per week): Divide the calculated weekly dose by the desired number of times per week.
Switching from subcutaneous immune globulin (SCIG) treatment: weekly dose (grams) should be the same as the weekly dose of prior SCIG treatment (grams).

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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