ON OFFICE LETTERHEAD INCLUDING PROVIDER NAME AND ADDRESS

SAMPLE LETTER OF MEDICAL NECESSITY

[Date]

[Payer Name]

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

Re: Letter of Medical Necessity for CUVITRU [Immune Globulin Subcutaneous (Human)] 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]
Date(s) of Service: [Dates]

Dear [Contact Name/Medical Director]:

I am writing on behalf of my patient, [patient name], to document the medical necessity of treatment with CUVITRU. This letter provides information about my patient's medical history and diagnosis and includes a statement summarizing my treatment plan. On behalf of my patient, I am requesting approval for use and subsequent payment for treatment with CUVITRU.

Patient's Clinical History

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

- [Diagnosis (including date) and relevant ICD-10 code
- 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
- If applicable, test results that support diagnosis of primary humoral immunodeficiency disease, such as 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)
    - 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 CUVITRU
- Social and family information]

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

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

Treatment Plan

The recommended dose of CUVITRU is [XX mg/X mL] administered subcutaneously.[1] The regimen is [insert specifics].

Summary of Recommendation

In the best interest of my patient, I appreciate your immediate review and ask for approval and subsequent payment for treatment with CUVITRU. [Summarize your recommendation. Include your professional opinion of your patient's likely prognosis or disease progression without CUVITRU treatment and any relevant peer-to-peer discussions.]

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 Signature]
[Prescriber Name]
[Prescriber Medical Specialty]
[National Provider Identifier]
[Practice Name, Address, Phone/Fax Number, and Email Address]

Enclosure(s)

[List enclosures, which may include the Prescribing Information for CUVITRU, clinical notes/medical records, diagnostic test results, US Food and Drug Administration approval letter for CUVITRU, scans showing progressive disease, relevant peer-reviewed articles, and pathology reports.]

Reference: 1. CUVITRU [Prescribing Information]. Lexington, MA: Baxalta US Inc.