SAMPLE LETTER OF MEDICAL NECESSITY OR MEDICAL EXCEPTION

This sample letter is provided for your guidance only. It includes examples of information you may wish to include when a patient's insurance company/payer requests a letter of medical necessity or letter of medical exception.

Use of the information in this sample letter does not guarantee reimbursement or coverage and is not intended to be a substitute for or to influence your independent medical judgment as a physician. You may modify this sample content or write your own letter. The payer sometimes may require that you complete payer-specific form(s).

Please see full Prescribing Information for complete prescribing details including Boxed Warning, contraindications and dosing and administration information.

Tips for drafting a Letter of Medical Necessity or Medical Exception

- To help avoid denials, familiarize yourself with the payer's specific guidelines before submitting your request.
- Know and meet all deadlines for submitting any required forms or documents to the payer.
- If your request is approved, check with the payer to determine length of the approval.
- It is helpful to keep complete records, including a copy of the materials you send, and a log of telephone calls made to the payer.
- Recommended information to include:
    1. Patient information including insurance information
    2. Indication for the medication being prescribed
    3. A summary of the patient's diagnosis including:
        - Diagnosis code(s)
        - Severity of the patient's condition
        - Prior treatment(s) including the duration and patient response to each treatment
    4. The clinical rationale for treatment including clinical trial data supporting FDA approval of the drug and administration and dosing information
    5. A summary of your recommendation
    6. Additional enclosures, which may include, where applicable:
        - Prescribing Information
        - Relevant peer-reviewed articles
        - Clinical practice guidelines
        - Clinical notes/medical records
        - Diagnostic test results
        - FDA approval letter

⇒ **Please remove this box and all content above before saving your document.**

[Insert Your Practice/Physician Letterhead]
[Insert Date]

ATTN: [Insert Medical Director/Payer Contact Name]
[Insert Medical Director/Payer Contact Title]
[Insert Payer Company Name]
[Insert Payer Street Address]
[Insert Payer City, State ZIP Code]

RE: Letter of Medical Necessity/Exception for YIMMUGO® [Immune Globulin Intravenous Human-dira, 10% Liquid]

Insured Patient:
Date of Birth:
Subscriber ID Number:
Subscriber Group Number:
Case ID Number:

Dear [Insert Contact Name]:

I am the treating physician for [Insert Patient Name], who has been diagnosed with [Insert Diagnosis], ICD-10-CM [Insert Code]. I am writing to request [approval/a step therapy override/a medical exception] for YIMMUGO as the prescribed treatment for my patient's condition.

I believe YIMMUGO is medically necessary for this patient based on my practice experience, the patient's clinical history as described below, and the drug's clinical and safety profile. In a Phase III clinical study, YIMMUGO resulted in fewer than one serious bacterial infection (SBI—defined as bacterial pneumonia, bacteremia/septicemia, osteomyelitis/septic arthritis, visceral abscesses, or bacterial meningitis) per person-year over a 12-month period (Section 14 of Prescribing Information). YIMMUGO demonstrated a low rate of discontinuation due to adverse events (2/67 patients or 3%) and only 2% of infusions (22/923) were associated with a headache (Section 6.1 of Prescribing Information). To increase the safety margin, the YIMMUGO manufacturing process includes a unique combination of steps designed to inactivate adventitious viruses, remove specific proteins such as IgA, FXIa and other thrombogenic factors, and remove properdin which is an activator of the complement system and can lead to unwanted side effects (Section 11 of Prescribing Information and Duellberg C, et al. *Drugs in R&D*. 2023. https://doi.org/10.1007/s40268-023-00430-w). For these reasons, I recommend YIMMUGO for my patient over the preferred brands.

Summary of patient's medical history

- [Patient's diagnosis, date of diagnosis, relevant symptom information, condition/severity, and history]
- [Past history of diabetes, hypertension, cardiovascular disease, or other conditions that increase risk for thrombosis]
- [Past history of IVIG infusion-related reactions such as headache and fever]
- [Previous therapies used for this condition with treatment duration and treatment response/lack of response]

Rationale for treatment

- [Summary of your professional opinion of the patient's prognosis and need for YIMMUGO]
- [Rationale for YIMMUGO based on product properties and the patient's medical history]
- [Relevant clinical trial data supporting approval of YIMMUGO]

Additional supportive information (enclosed)

- YIMMUGO Prescribing Information at https://www.yimmugo.us/download/YIMMUGO-PI.pdf
- YIMMUGO Efficacy, Safety, and Pharmacokinetics Clinical Trial at https://onlinelibrary.wiley.com/doi/epdf/10.1111/vox.13337
- [Relevant supportive clinical documentation such as history and physical, progress notes, treatment history, outcomes]
- [Supportive peer-reviewed journal articles or clinical guidelines]

In summary, based on the patient's medical scenario, I believe YIMMUGO is medically necessary for this patient as described above, and I request coverage for their treatment. Please call my office at [Insert primary phone number] if I can be of further assistance or if you require additional information. Thank you for your consideration and I look forward to receiving timely approval of this request on behalf of my patient.

Sincerely,

[Insert Physician Name, Title, and Participating Provider Number]
[Signature]