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 HYQVIA [Immune Globulin Infusion 10% (Human) with Recombinant Human Hyaluronidase]

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 HYQVIA. 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 HYQVIA.

Patient's Clinical History

[Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with [primary immunodeficiency disease or chronic inflammatory demyelinating polyneuropathy (CIDP)] 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-CM 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 a primary immunodeficiency:
  1. Subclass deficiency or functional antibody deficiency, including any of the following:
     a. Selective IgA immunodeficiency;
     b. Selective IgM immunodeficiency;
     c. Selective IgG subclass deficiency;

d. Congenital hypogammaglobulinemia;

e. Immunodeficiency with near/normal IgM (absent IgG, IgA) (ie, hyper IgM syndrome);

f. Severe combined immunodeficiency disorders (eg, X-SCID, jak3, ZAP70, ADA, PNP, RAG defects, ataxia telangiectasia, Wiskott-Aldrich syndrome, DiGeorge syndrome);

g. Subclass deficiency or functional antibody deficiency

2. Hypogammaglobulinemia (below normal for age)
3. One of the following (a or b):

a. One documented, very serious, laboratory-proven bacterial infection within the preceding 6 months;

b. Two or more bacterial infections in the preceding year requiring IV antibiotic infusion therapy in the home or in the hospital

- If applicable, test results that support diagnosis of CIDP:
  1. Electromyography
  2. Other nerve conduction studies
  3. CSF analysis
  4. Nerve biopsy
  5. MRI
  6. NF155 levels
  7. CNTN1 levels
- Extenuating circumstances that would preclude alternatives to HYQVIA
- 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 HYQVIA is [XX mg/X mL and XX U/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 HYQVIA. [Summarize your recommendation. Include your professional opinion of your patient's likely prognosis or disease progression without HYQVIA 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 HYQVIA, clinical notes/medical records, diagnostic test results, US Food and Drug Administration approval letter for HYQVIA, scans showing progressive disease, relevant peer-reviewed articles, and pathology reports.]

Reference: 1. Hyqvia. Prescribing information. Baxalta US Inc; 2020.