A patient's health insurance plan or payer may require prior authorization (PA) or supporting documentation to process and cover a claim for treatment with HIBSAGO® (bepirovirsen). A PA allows the health plan to review the reason for the requested therapy and to determine medical appropriateness. A patient-specific Letter of Medical Necessity will help explain the physician's rationale and clinical decision-making in choosing HIBSAGO. Please note that some health plans have specific forms that must be completed in order to request PA or to document medical necessity.

The following Letter of Medical Necessity template for HIBSAGO can be customized based on your patient's medical history and demographic information.

SAMPLE LETTER OF MEDICAL NECESSITY

[Date]
[Plan/Payer Name]
[Payer street address]
[Payer city, state, ZIP code]
Re: Letter of Medical Necessity [NDC] [Drug Name, Billing Unit]
Patient: [Patient Full Name]
Group/Policy Number: [Patient group & policy number]
Date(s) of Service: [Date(s)]
Diagnosis: [Code & Description]

Dear [Insert payer contact name and/or department]:

I am writing on behalf of my patient, [patient name/policy number], to document medical necessity for treatment with HIBSAGO® (bepirovirsen). The patient will be treated with HIBSAGO for [diagnosis].

This letter serves to document that [patient name] needs HIBSAGO, and that HIBSAGO is medically necessary for [him/her] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatments.

HIBSAGO is indicated [in combination with nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) therapy for treatment of chronic hepatitis B virus (HBV) infection in adult patients without cirrhosis: who have been on NrtI therapy for at least 6 months and have suppressed HBV deoxyribonucleic acid (DNA), and who have HBV surface antigen (HBsAg) levels less than or equal to 3,000 IU/mL as determined by an FDA-authorized test].

[Patient name] is a/an [age]-year-old [male/female] diagnosed with [diagnosis]. [Patient name] has been in my care since [date]. As a result of [diagnosis], my patient [enter a brief description of patient history]. Additionally, [patient name] has tried [previous management strategies] and [outcomes]. The patient is currently on [current therapy] for the treatment of [diagnosis]. The attached medical records document [patient name]'s clinical condition and medical necessity for treatments with HIBSAGO.

Based on the above facts, I am confident that you will agree that HIBSAGO is indicated and medically necessary for this patient. The plan of treatment is to initiate HIBSAGO [300 mg subcutaneously twice weekly during Weeks 1 and 2, with 3 to 4 days between each dose, followed by 300 mg subcutaneously once weekly during Weeks 3 through 24. Each 300 mg dose is administered as two 150 mg subcutaneous injections]. HIBSAGO will be administered by [the patient/a caregiver/trained healthcare professional] at [site of service], with dosage adjustments made as clinically indicated per the Prescribing Information. Please consider coverage of HIBSAGO on [patient name]'s behalf and approve use and subsequent payment as planned.

Please refer to the enclosed Prescribing Information for HIBSAGO. If you have any further questions regarding this matter, please do not hesitate to call me at [physician telephone number].

Thank you for your prompt attention to this matter.

Sincerely,
[Physician's name], [degree initials], [physician's practice name]

Suggested Enclosures

- Medical records and clinical notes and labs
- FDA approval letter available at: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=browseByLetter.page&productLetter=h
- Prescribing Information (PI) - please also visit: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Hibsago/pdf/HIBSAGO-PI-MG-IFU.PDF
- Important Safety Information

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