

A patient's health insurance plan/payer may require prior authorization or supporting documentation in order to process and cover a claim for treatment with BENLYSTA (belimumab). A prior authorization 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 to explain the physician's rationale and clinical decision-making in choosing BENLYSTA. Please note that some health plans have specific forms that must be completed to request prior authorization or to document medical necessity.

The following is a template letter of appeal for BENLYSTA that can be customized based on your patient's medical history and demographic information.

SAMPLE LETTER OF MEDICAL NECESSITY

[Date]

[Contact Name of Medical Director or Other Payer Representative]

[Contact Title]

[Name of Health Insurance Company]

[Address]

[City, State, Zip]

Re: Letter of Medical Necessity for [HCPCS Code] [Drug Name, Billing Unit]

Patient: [Patient Name]

Group/policy Number: [Number]

Date(s) of service: [Dates]

Diagnosis: [Code & Description]

Dear [Contact Name or Department]:

I am writing on behalf of my patient, [Patient Name], to [Request Prior Authorization/Document Medical Necessity] for treatment with BENLYSTA (belimumab). The patient will be treated with BENLYSTA for [diagnosis]. BENLYSTA is indicated for patients aged ≥ 5 with active systemic lupus erythematosus (SLE) or active lupus nephritis who are receiving standard therapy. BENLYSTA is not recommended in patients with severe active central nervous system lupus. This letter serves to document that [Patient Name] needs BENLYSTA and that BENLYSTA is medically necessary for [him/her] as administered. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatments.

Medical History and Diagnosis

[Patient Name] is a [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 brief description of patient history]. Additionally, [Patient Name] has tried [previous therapies] and [outcomes]. The attached medical records document [Patient Name]'s clinical condition and medical necessity for treatments with BENLYSTA.

Based on the above facts, I am confident that you will agree that BENLYSTA is indicated and medically necessary for this patient. The plan of treatment is to start the patient on BENLYSTA. Administration of BENLYSTA [dosage] is planned on [date] and will be continued approximately every [frequency].

Please consider coverage of BENLYSTA on [Patient Name]'s behalf and approve use and subsequent payment for BENLYSTA as planned. Please refer to the enclosed Prescribing Information for BENLYSTA. 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 & labs
- FDA approval letter available at:
<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=browseByLetter.page&productLetter=N&ai=0>
- Prescribing Information (PI) - please also visit
https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/BENLYSTA/pdf/BENLYSTA-PI-MG-IFU.PDF for full prescription information
- Important Safety Information