

A patient's health insurance/payer may deny a patient request for coverage for treatment with BENLYSTA (belimumab). The decision can be appealed by a provider on behalf of the patient. When submitting an appeal to a patient's health insurance plan/payer, the provider can help explain the rationale and clinical decision-making behind the choice of a specific therapy.

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 APPEAL

[Date]

[Plan/Payer Name]

[Payer Street Address]

[Payer City, State Zip Code]

Re: Appeal Letter for [HCPCS Code] [Drug Name, Billing Unit]

Patient: [Patient Full Name]

Group/Policy Number: [Patient Group and Policy Number]

Date(s) of Service: [Date(s)]

Diagnosis: [Code & Description]

Dear [Name or Contact]:

This letter serves as a formal appeal for reconsideration of a claim for BENLYSTA (belimumab), which was provided to [patient name] on [date of service]. [Patient Name] has been under treatment for [diagnosis] since [date of onset]. [Insurance company name] has stated that BENLYSTA is not covered because [reason for denial].

Treatment Information

BENLYSTA (belimumab) is a human monoclonal antibody drug. It is the first in a new class of drugs called BLYS-specific inhibitors that recognize and inhibit the biological activity of B-lymphocyte stimulator, or BLYS.

BENLYSTA inhibits the biological activity of B-lymphocyte stimulator, or BLYS. BLYS is a naturally occurring protein discovered by HGS, which is required for the survival and development of B-lymphocyte cells into mature plasma B cells. Plasma B cells produce antibodies, the body's first line of defense against infection. In lupus and certain other autoimmune diseases, elevated levels of BLYS are believed to contribute to the production of autoantibodies – antibodies that attack and destroy the body's own healthy tissues. The results of prospective observational studies show a significant correlation of elevated levels of BLYS with SLE disease activity.

BENLYSTA acts by: (1) specifically recognizing and binding to BLYS, (2) inhibiting BLYS's stimulation of B-cell development, and (3) restoring the potential for autoantibody-producing B cells to undergo the normal process of apoptosis (programmed cell death). Preclinical and clinical studies show that BLYS antagonists such as BENLYSTA can reduce autoantibody levels in SLE. The results of three pivotal Phase 3 trials show that belimumab can reduce SLE disease activity.

Patient History and Diagnosis

[Patient Name] is a [age]-year-old [male/female] who has been under treatment for [diagnosis] since [date]. During this time, [Patient] has been treated with other therapies including [discuss previous therapies and patient's response to therapy]. [Continue with patient history and clinical support for medical necessity].

I believe it is imperative that this patient was ensured immediate access to BENLYSTA. Subsequently, it is crucial that [insurance company name] provide adequate coverage for BENLYSTA for this patient in the spirit of providing the best medical treatment available for [diagnosis].

On behalf of [Patient Name], we would appreciate your reconsideration of the claim for BENLYSTA dated [date of claim]. Please call me at [physician phone number] if I can be of further assistance or you require additional information.

Sincerely,

[Physician's Name], [Degree Initials] [Physician's Practice Name]

Suggested Enclosures:

- Medical records and clinical notes & labs
- Denial documentation (from the patient's health insurance/payer)
- 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

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