



COMPOSING A LETTER OF MEDICAL NECESSITY*

A letter of medical necessity (LMN) explains the prescribing healthcare professional's (HCP) rationale and clinical decision-making when choosing a treatment.[†] LMNs are often required by health insurance plans when submitting a request for an appeal, formulary exception, and/or tiering exception.

This resource provides information on the process of drafting an LMN, including a checklist and sample letter containing information health plans often require.

When requesting BIMZELX for your patient, follow the patient's plan requirements, which may require specific forms for documenting an LMN; otherwise, treatment may be delayed.

Use of the information in this letter does not guarantee that the health plan will provide reimbursement for BIMZELX and is not intended to be a substitute for, or an influence on, the physician's independent medical judgment.

LMN considerations



- ✓ **Include the patient's** full name, plan identification number, gender, date of birth, and the case identification number if a decision has already been rendered
- ✓ **Note the severity of the patient's condition using the plan's preferred scoring system.** Common scoring systems used depend on the patient's diagnosis
- ✓ **Provide a copy of the patient's records** with the following details:
 - The patient's history, diagnosis with specific International Classification of Diseases (ICD) code(s), and present-day condition and symptoms
 - The patient's recent history of infection(s), along with any allergies and existing comorbidities
- ✓ **Document prior treatments and the duration of each,** including start/stop dates and reason(s) for discontinuation
 - Document any other patient characteristics and/or clinical considerations relevant to BIMZELX therapy
- ✓ **Attach clinical documentation that supports your recommendation;** this information may be found in the BIMZELX Prescribing Information and/or clinical peer-reviewed literature

*The information in this guide is presented for informational purposes only and is not intended to provide reimbursement or legal advice. HCPs are encouraged to contact third-party payers for specific information about their current coverage policies. For other questions, please call BIMZELX Navigate™ at **1-866-4-BIMZELX (1-866-424-6935)**.

[†]For Medicare beneficiaries, there are specific requirements that need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit [CMS.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf](https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf).



SAMPLE LETTER OF MEDICAL NECESSITY

The purpose of an LMN is to explain the prescribing HCP's rationale and clinical decision-making when choosing BIMZELX for a patient. LMNs are often required by plans when submitting a request for a formulary/medical exception, tiering exception, or an appeal.

You may choose to use this template to assist in completing your request. Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.

SAMPLE LETTER OF MEDICAL NECESSITY

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[Date] Re: [Patient's name]
 [Prior authorization department] [Plan identification number]
 [Name of health plan] [Date of birth]
 [Mailing address] [Case identification number]

To whom it may concern:

I am writing to provide additional information to support my claim for [patient's name's] treatment of [indication] with BIMZELX[®] (bimekizumab-bkzx). In brief, treatment with BIMZELX [dose, frequency] is medically appropriate and necessary for this patient. This letter outlines the patient's medical history and previous treatments that support my recommendation for treatment with BIMZELX.

- [Patient's gender and age]
- [Patient's relevant history, findings, and diagnosis; previous treatment of BIMZELX]
- [Past treatment start/stop date and patient's response to these therapies]
- [Brief description of the patient's recent symptoms or conditions]

_____ Indicate here, by adding a checkmark, that the patient does not have active tuberculosis or other serious infections (required by some health plans). If the patient has any serious infections, please list them below:

Infection name and affected part(s) of body	Treatment type(s)	Treatment start/stop dates	Anticipated resolution date

Summary of your professional opinion:

[Insert rationale for prescribing BIMZELX here, including your professional opinion of the patient's likely prognosis or disease progression without BIMZELX treatment.]

Provide supporting references for your recommendation:

[Provide clinical rationale for treatment; this information may be found in the BIMZELX Prescribing Information and/or clinical peer-reviewed literature.]

Physician contact information:

The ordering physician is [physician name, NPI #]. The prior authorization decision may be faxed to [fax #]. Please send a copy of the coverage determination decision to [patient's name, street address, city, state, ZIP]. Please feel free to contact me, [physician's name], at [office phone number] for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,
 [Physician's name and signature] [Patient's name and signature]

[Physician's medical specialty]
 [Physician's NPI #]
 [Physician's practice name]
 [Phone #]
 [Fax #]

Consider including the patient's medical records and supporting documentation:

- Clinical evaluation
- Scoring forms
- Photos of affected areas, where relevant
- Drug name and strength, dosage form, and therapeutic outcome

HELP CLEAR THE WAY WITH BIMZELX Navigate™*



BIMZELX Navigate helps make the treatment journey smooth from the start for your patients.

Start your patients on BIMZELX Navigate today

Here Is How!

- 1** Enroll your patients at BIMZELXhcp.com.
 - 2** Then, log in to the BIMZELX Navigate HCP Portal, click the **"Add a Patient"** button in the top right, and fill out the patient information.
- or
- Fax a completed BIMZELX Navigate enrollment form to **844-628-3299**.

Patients Get Support

- Easy enrollment and onboarding support for **streamlined product access—with no prior authorization (PA) needed** for eligible, commercially insured patients if there is a delay or denial in insurance coverage^{††}
- Eligible, commercially insured patients may **pay only \$5 per dose once insurance coverage is approved or just \$15 per dose** for up to 2 years while insurance coverage is pending[‡]
- Innovative tracking tools and resources available online at [My Navigate Portal](#)
- Nurse Navigators for **assistance throughout the patient journey**[§]

*The BIMZELX Navigate program is provided as a service of UCB and is intended to support the appropriate use of BIMZELX. The BIMZELX Navigate program may be amended or cancelled at any time without notice. Some program and eligibility restrictions may apply.

†Prior to second dose, a PA will be needed.

‡For eligible, commercially insured patients only. Eligible patients who have a delay or denial of coverage may pay as little as \$15 per dose of BIMZELX for up to two years or until the patient's commercial insurance plan approves coverage, whichever comes first. Eligible, commercially insured patients may pay \$5 per dose. Please see full eligibility requirements and terms at BIMZELXhcp.com.

§Nurse Navigators do not provide medical advice and will refer patients to their healthcare professional for any treatment-related questions.

 Inspired by patients.
Driven by science.

Please see Important Safety Information on next page. Please click to access the full [Prescribing Information](#), or visit BIMZELXhcp.com.



INDICATION

BIMZELX is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

Suicidal Ideation and Behavior

BIMZELX[®] (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections

BIMZELX may increase the risk of infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities

Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase and bilirubin at baseline, periodically during treatment with BIMZELX and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

Inflammatory Bowel Disease

Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

Immunizations

Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.

MOST COMMON ADVERSE REACTIONS

Most common adverse reactions ($\geq 1\%$) are upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

Please click to access the full [Prescribing Information](#), or visit [BIMZELXhcp.com](https://www.bimzelxhcp.com).



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Sincerely,

[Physician's name and signature]

[Patient's name and signature]

[Physician's medical specialty]

[Physician's NPI #]

[Physician's practice name]

[Phone #]

[Fax #]