Bimzelx® (bimekizumab-bkzx) Navigate

## 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 (≥ 1%) are upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex Infections, acne, folliculitis, other Candida infections, and fatigue.

# PRIOR AUTHORIZATION REQUEST & LETTER OF MEDICAL NECESSITY GUIDE

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## DRAFTING A PRIOR AUTHORIZATION REQUEST

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

Most health plans require a Prior Authorization Request (PAR) or other supporting documentation, such as a Letter of Medical Necessity (LMN), to process a claim for biologic treatments. A prior authorization allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

This resource provides a "how-to" guide or framework when drafting a PAR and LMN. Included is a list of sample payer requirements and a checklist, outlining what to include for each request. Attached to this document is a sample letter that includes information many health plans require to process the PAR and/or LMN.

**Follow the patient's plan requirements when requesting BIMZELX® (bimekizumab-bkzx); otherwise, treatment may be delayed.**

**Use of the information in this sample 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, your independent medical judgment.**

## PRIOR AUTHORIZATION REQUESTS: GUIDANCE AND RECOMMENDATIONS

1. Your BIMZELX Field Access Specialist (FAS) may be able to provide you with prior authorization requirements for specific plans and pharmacy benefit managers. BIMZELX Navigate and/or Specialty Pharmacies can assist with identifying prior authorizations, form requirements, and step edit therapies.

2. All BIMZELX prior authorization forms should be completed and submitted to the specialty pharmacy/plan by your office.

3. If you expect that a plan-specified step edit therapy will not be well tolerated by the patient, or another therapy is more appropriate for the patient, a request may be submitted to the plan to bypass this requirement. **For more information, refer to Composing a Letter of Medical Necessity below.**

4. Plans will usually allow up to three levels of appeal for prior authorization denials. The third appeal may include a review by an external review board or a hearing.

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## PRIOR AUTHORIZATION CONSIDERATIONS

- Verify and record that all of the prior authorization requirements for the plan have been met
- If applicable, provide evidence that all step edit therapy prerequisites have been met. For step edit therapy exception requests, include wording explaining why BIMZELX® is medically appropriate for the patient in place of a prerequisite/step edit therapy
- If required, use the health plan's PAR form that can be found on the plan's website. Your BIMZELX FAS and/or BIMZELX Navigate™ may be able to assist you in locating the plan-specific form
- Include relevant dosing information: length of treatment, prior medications and dosing, and dosing for the medication being requested
- Include relevant patient details: joint involvement, body surface area (BSA), difficult-to-treat areas, mobility limitations (e.g., inability to use hands during a flare), photos, and International Classification of Diseases (ICD) codes

## COMPOSING A LETTER OF MEDICAL NECESSITY

If your patient's plan requires a LMN to explain the prescribing HCP's rationale and clinical decision-making when choosing BIMZELX, you will be required to submit a request for Formulary/Medical Exception, Tiering Exception, or Appeals.

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.

**Provide a copy of the patient's records with the following details:**

### LETTER OF MEDICAL NECESSITY CONSIDERATIONS

- Assess the patient's history, diagnosis with specific ICD-10 code, and present-day condition and symptoms
- Consider the patient's recent history of infection(s), along with any allergies and existing comorbidities
- 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
- 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

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## SAMPLE PRIOR AUTHORIZATION REQUEST / LETTER OF MEDICAL NECESSITY

Use the included template to help complete your request. Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.

[Date]
[Prior authorization department]
[Name of health plan]

Re: [Patient's name]
[Plan identification number]
[Date of birth]

[Mailing address]

To whom it may concern:

This letter serves as a Prior Authorization Request for BIMZELX® (bimekizumab-bkzx) for [Patient's name] [Plan identification, and group number] for the treatment of [diagnosis and ICD code].

[Provide relevant dosing information here, including length of treatment, prior medications and dosing, diagnosis, and dosing for the medication being requested.]

[Provide patient information, including gender, age, relevant history, joint involvement, body surface area, difficult-to-treat areas, mobility limitations (e.g., inability to use hands during a flare), and a brief description of the patient's recent symptoms and 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 #, Fax#]

The prior authorization decision may be faxed to: [Fax#]

Please send a copy of coverage determination decision to [patient's name, street address, city, state, ZIP.]

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]

[Patient's name and signature]

If you need to compose a Letter of Medical Necessity, please find suggested text below:

"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."

**If this PAR letter is intended to appeal a plan's step edit requirement, please add text as follows:**

This plan currently lists [insert required step edit therapies] to be attempted prior to treatment with BIMZELX. These step edit therapies are not viable for this patient. We are requesting that the step edit therapy requirement be bypassed.

[Provide statement(s) indicating why these step edit therapy requirements are inappropriate for this patient.]

**INCLUDE 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

[Date]
[Prior authorization department]
[Name of health plan]

Re: [Patient's name]
[Plan identification number]
[Date of birth]

[Mailing address]

To whom it may concern:

This letter serves as a Prior Authorization Request for BIMZELX® (bimekizumab-bkzx) for [Patient's name] [Plan identification, and group number] for the treatment of [diagnosis and ICD code].

> [Provide relevant dosing information here, including length of treatment, prior medications and dosing, diagnosis, and dosing for the medication being requested.]
>
> [Provide patient information, including gender, age, relevant history, joint involvement, body surface area, difficult-to-treat areas, mobility limitations (e.g., inability to use hands during a flare), and a brief description of the patient's recent symptoms and 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 #, Fax#]

The prior authorization decision may be faxed to: [Fax#]

Please send a copy of coverage determination decision to [patient's name, street address, city, state, ZIP.]

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]

[Patient's name and signature]

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