Bimzelx®
(bimekizumab-bkzx)

BIMZELX COMBINED ACCESS MATERIALS

Bimzelx® (bimekizumab-bkzx)

CONTENTS

Bimzelx® (bimekizumab-bkzx)

LETTER OF MEDICAL NECESSITY GUIDE

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.

Letter of medical necessity—Items to consider:

- **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:
  - 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
- **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

*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.

Please see Important Safety Information on page 10.
Please click to access the full Prescribing Information, or visit BIMZELXhcp.com.

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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 or customize 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

You may choose to use or customize 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. 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.

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

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

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

Bimzelx® (bimekizumab-bkzx)

PRIOR AUTHORIZATION REQUEST GUIDE

DRAFTING A PRIOR AUTHORIZATION REQUEST*

Most health plans require a prior authorization request and supporting documentation 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 information to healthcare professionals (HCPs) for their consideration in drafting a prior authorization request, including guidance and recommendations, a checklist, and a sample letter with information health plans often require.

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.

Prior authorization requests: Guidance

- **Your BIMZELX Patient Experience Specialist** 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.
- **All completed BIMZELX prior authorization forms** should be submitted by your office to BIMZELX Navigate or your specialty pharmacy.
- **You may submit a request for the patient to bypass a required plan-specified step edit therapy if you think it won't be well tolerated or another therapy is more appropriate. For more information, refer to Composing a Letter of Medical Necessity or visit StepTherapy.com/step-therapy-legislation-by-state/.**
- **Plans will often allow up to 3 levels of appeal for prior authorization denials.** The third appeal may include a review by an external review board or hearing.

Prior authorization request: Items to consider

- ✓ **Verify and record that all of the prior authorization requirements** for the plan have been met
- ✓ **If required, use the Prior Authorization Request Form** that can be found on the health plan's website
- ✓ **If applicable, provide evidence that all step edit therapy prerequisites have been met.** For step edit therapy exception requests, explain why BIMZELX is medically appropriate for the patient in place of a prerequisite/step edit therapy

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Please see Important Safety Information on page 10.
Please click to access the full Prescribing Information, or visit BIMZELXhcp.com.

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SAMPLE PRIOR AUTHORIZATION REQUEST

Most health plans require a prior authorization request and supporting documentation to process a claim for BIMZELX.

You may choose to use or customize 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 PRIOR AUTHORIZATION REQUEST

You may choose to use or customize 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. 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.

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

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

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]

- [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].

Sincerely,

[Physician's name and signature] _____ [Patient's name and signature] _____

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

The patient's medical records and supporting documentation:

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

If this prior authorization request letter is intended to appeal a plan's step edit requirement, consider adding text as follows:

This plan currently lists 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.**

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Bimzelx® (bimekizumab-bkzx)

LETTER OF APPEAL FOR PRIOR AUTHORIZATION DENIAL GUIDE

WRITING A LETTER OF APPEAL FOR PRIOR AUTHORIZATION DENIAL*

A physician can write a letter of appeal when a patient's health insurance plan denies a prior authorization request. When doing so, the physician should refer to the plan's appeals guidelines, which may outline a specific process.

This resource provides information on the process of composing a letter of appeal for prior authorization denial, including a checklist and sample letter with information health plans often require.

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.

Letter of appeal—Items to consider:

- **The patient's** full name, plan identification number, date of birth, and case identification number
- **The healthcare professional (HCP) should note the HCP's** name and relationship to the patient, National Provider Identifier (NPI) number, specialty, address, telephone number, fax number, and date of submission
- **State the patient's current diagnosis** along with the specific International Classification of Diseases (ICD) code(s)
- **The HCP should acknowledge that he/she is familiar** with the plan's policy
- **State the reason(s)** why the prior authorization request was denied and why the HCP believes that decision should be reconsidered
- **Explain why BIMZELX is the preferred** and medically necessary treatment for the patient
- **Document the patient's prior treatments for diagnosis,** the duration and therapeutic outcome of each treatment, and the reason(s) why each was discontinued
- **Provide a copy of the patient's medical records,** including medical history, diagnosis, scoring forms, present-day condition and symptoms, photographs of affected areas, recent history of infection(s), allergies, and existing comorbidities
- **The following supporting documentation:**
  - A Letter of Medical Necessity
  - A copy of the denial letter and any medical notes in response to the denial
  - Clinical support for the HCP's recommendation (eg, clinical trial data, relevant peer-reviewed articles)

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Please see Important Safety Information on page 10.
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SAMPLE LETTER OF APPEAL FOR PRIOR AUTHORIZATION DENIAL

You may choose to use or customize 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. Additionally, please ensure you have read and reviewed the health plan's relevant policies before certifying that you have done so.

SAMPLE LETTER OF APPEAL FOR PRIOR AUTHORIZATION DENIAL

You may choose to use or customize 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. 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.

[Date]
[Name of health plan]
[Appeals Department]
[Mailing address]

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

To whom it may concern,

I am writing to file an appeal regarding a prior authorization denial and to request reconsideration of coverage for BIMZELX® (bimekizumab-bkzx) for my patient, [patient's name].

[My office/patient's name] received a notice, dated [date of denial letter], indicating that prior authorization for coverage of BIMZELX for the treatment of [diagnosis], [ICD code(s)], has been denied by [name of health plan] for the following reasons: [insert reason(s) provided in the denial letter]. After reviewing this reasoning and reading your policy regarding the responsible management of drugs in this category, I continue to believe that BIMZELX is medically appropriate and necessary for [patient], as outlined below.

Patient's diagnosis, current condition, and medical history:

[Insert paragraph detailing your diagnosis and the patient's medical history pertaining to the use of BIMZELX. Examples of information to include are:

- Patient's age/gender/length of time in your care
- Up-to-date clinical documentation
- Relevant test scores/results
- Present-day symptoms
- Area(s) of the body affected, including percent of body surface area (BSA) and any persistent troublesome areas to treat
- Recent history of infection(s), allergies, and existing comorbidities
- Current treatment for condition (if applicable) and reason(s) why this treatment is insufficient
- Impact on quality of life]

[Patient's name] has attempted the below treatment(s) in the past for [diagnosis], but those trials have failed due to [inadequate efficacy, lack of tolerability, etc].

Past Treatment(s)	Start/Stop Dates	Therapeutic Outcome	Reason(s) for Discontinuing
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]

In addition to this letter, I have enclosed a copy of [patient name's] medical records and a Letter of Medical Necessity. I have also included a copy of [journal article/clinical trial data/etc], which further supports why, in my professional opinion, BIMZELX is medically necessary for my patient's care and should be covered under [name of health plan].

Please contact me, [physician's name], at [physician's phone number] with any pending questions. Thank you for your time and consideration of this appeal.

Sincerely,

[Physician's name and signature] _____

[Patient's name and signature] _____

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

[Encl: Patient medical records, Letter of Medical Necessity, previous denial letter, medical notes in response to the denial, clinical support for this recommendation.]

NPI=National Provider Identifier.

Consider including supporting documentation, such as clinical evaluation, scoring forms, and photos of affected areas.

Please see Important Safety Information on page 10.
Please click to access the full Prescribing Information, or visit BIMZELXhcp.com.

Bimzelx® (bimekizumab-bkzx)

TIERING EXCEPTION REQUEST LETTER GUIDE

WRITING A TIERING EXCEPTION REQUEST LETTER*

A tiering exception request letter can help make BIMZELX more affordable for patients experiencing financial hardship. It's used when the medication is on a plan's formulary but is in a nonpreferred tier that has a higher copay or coinsurance. By outlining why the treatment is medically necessary for the patient, a tiering exception request letter may result in the plan granting the patient access to BIMZELX as a lower-cost preferred medication.

This resource provides information on the process of composing a tiering exception request letter, including a checklist and sample letter with information health plans often require.

When requesting BIMZELX for your patient, follow the patient's plan requirements, which may require specific forms for documenting a tiering exception request letter; 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.

Tiering exception request letter—Items to consider:

- **The patient's** full name, plan identification number, date of birth, and case identification number
- **The healthcare professional (HCP) should note the HCP's** name and relationship to the patient, National Provider Identifier (NPI) number, specialty, address, telephone number, fax number, and date of submission
- **State the patient's current diagnosis** along with the specific International Classification of Diseases (ICD) code(s)
- **Document the patient's prior treatments for diagnosis,** the duration and therapeutic outcome of each treatment, and the reason(s) each was discontinued
- **Explain why BIMZELX is the preferred** and medically necessary treatment over the plan's preferred formulary medications
- **State the main reason(s)** for requesting a tiering exception for BIMZELX
- **Provide a copy of the patient's medical records,** including medical history, diagnosis, scoring forms, present-day condition and symptoms, photographs of affected areas, recent history of infection(s), allergies, and existing comorbidities
- **The following supporting documentation:**
  - A Letter of Medical Necessity
  - A statement of financial hardship written by the patient
  - A copy of the denial letter and a response to the denial letter, if applicable

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Please see Important Safety Information on page 10.
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SAMPLE TIERING EXCEPTION REQUEST LETTER

You may choose to use or customize 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 and financial situation.

SAMPLE TIERING EXCEPTION REQUEST LETTER

You may choose to use or customize 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. 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.

[Date]
[Formulary director]
[Name of health plan]
[Mailing address]

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

To whom it may concern,

I am writing to request a tiering exception for my patient, [patient's name], who is currently a member of [name of health plan]. This request is for BIMZELX® (bimekizumab-bkzx) to be made available as a preferred prescription medication for the treatment of this patient, who has been diagnosed with [diagnosis], [ICD code(s)].

[Patient name] previously experienced successful results with BIMZELX [dose, frequency] for [enter length of time on BIMZELX], but had to discontinue treatment due to [list reason(s): eg, change in plan's formulary list or patient change in health plans during the past year].

BIMZELX, at [dosage and frequency], is medically appropriate and necessary for [patient's name], who has attempted the below treatment(s) in the past for [diagnosis]. Those trials have failed due to [inadequate efficacy, lack of tolerability, etc].

Past Treatment(s)	Start/Stop Dates	Therapeutic Outcome	Reason(s) for Discontinuing
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]

The patient's present treatment(s) are as follows:

Current Treatment(s)	Dosage	Start Date	Therapeutic Outcome
[Drug name, strength, form]	[XX]	[MM/YY]	[List treatment benefits and/or failures]
[Drug name, strength, form]	[XX]	[MM/YY]	[List treatment benefits and/or failures]

Currently, [patient's name] has the following unresolved symptoms of [diagnosis]:

- [Symptom 1]
- [Symptom 2]

In addition to this letter, I have enclosed a copy of [patient name's] medical records and a Letter of Medical Necessity. This latter letter describes how BIMZELX is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary because [explain rationale for why lower-tiered formulary drugs would be less effective than BIMZELX].

I am requesting this tiering exception because the cost associated with the assigned tier for BIMZELX would present a financial burden to [patient's name]. It would also prevent [him/her] from utilizing what I consider to be the best medication to help successfully treat [his/her] [diagnosis].

Please contact me, [physician's name], at [physician's phone number] with any pending questions.

Sincerely,

[Physician's name and signature]

[Patient's name and signature]

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

[Encl: Patient medical records, Letter of Medical Necessity, statement of financial hardship from [patient's name], previous denial letter, medical notes in response to the denial.]

Include only if patient has previously been treated with BIMZELX and has had a treatment interruption.

NPI=National Provider Identifier.

Consider including supporting documentation, such as clinical evaluation, scoring forms, and photos of affected areas.

HELP CLEAR THE WAY WITH BIMZELX Navigate®*

Bimzelx® (bimekizumab-bkzx) 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** for eligible, commercially insured patients if there is a delay or denial in insurance coverage[†‡]
- Eligible, commercially insured patients may **pay as little as $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 **patient 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.

†PA is required prior to shipment of second dose.

‡For eligible, commercially insured patients only. Under the BIMZELX Navigate Bridge program, eligible patients who have a delay or denial of coverage may pay $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 with approved coverage may pay as little as $5 per dose. Please see full eligibility requirements and terms at BIMZELX.com/patient-support/navigate-benefits.

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

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IMPORTANT SAFETY INFORMATION

INDICATIONS

BIMZELX is indicated for the treatment of adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, active ankylosing spondylitis, and moderate-to-severe plaque psoriasis (PSO) 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 (≥ 2%) adverse reactions in PsA, nr-axSpA, and AS include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections. Other most common (≥ 2%) adverse reactions specific to each indication include: urinary tract infections (PsA); cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections (nr-axSpA); injection site pain, rash, and vulvovaginal mycotic infections (AS).

Most common (≥ 1%) adverse reactions in plaque psoriasis include upper respiratory tract 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.

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SAMPLE LETTER OF MEDICAL NECESSITY

You may choose to use or customize 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. 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.

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

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

SAMPLE PRIOR AUTHORIZATION REQUEST

You may choose to use or customize 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. 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.

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

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

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]

- [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].

Sincerely,

[Physician's name and signature] _____

[Patient's name and signature] _____

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

SAMPLE LETTER OF APPEAL FOR PRIOR AUTHORIZATION DENIAL

You may choose to use or customize 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. 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.

[Date]
[Name of health plan]
[Appeals Department]
[Mailing address]

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

To whom it may concern,

I am writing to file an appeal regarding a prior authorization denial and to request reconsideration of coverage for BIMZELX® (bimekizumab-bkzx) for my patient, [patient's name].

[My office/patient's name] received a notice, dated [date of denial letter], indicating that prior authorization for coverage of BIMZELX for the treatment of [diagnosis], [ICD code(s)], has been denied by [name of health plan] for the following reasons: [insert reason(s) provided in the denial letter]. After reviewing this reasoning and reading your policy regarding the responsible management of drugs in this category, I continue to believe that BIMZELX is medically appropriate and necessary for [patient], as outlined below.

Patient's diagnosis, current condition, and medical history:

[Insert paragraph detailing your diagnosis and the patient's medical history pertaining to the use of BIMZELX. Examples of information to include are:

- Patient's age/gender/length of time in your care
- Up-to-date clinical documentation
- Relevant test scores/results
- Present-day symptoms
- Area(s) of the body affected, including percent of body surface area (BSA) and any persistent troublesome areas to treat
- Recent history of infection(s), allergies, and existing comorbidities
- Current treatment for condition (if applicable) and reason(s) why this treatment is insufficient
- Impact on quality of life]

[Patient's name] has attempted the below treatment(s) in the past for [diagnosis], but those trials have failed due to [inadequate efficacy, lack of tolerability, etc].

Past Treatment(s)	Start/Stop Dates	Therapeutic Outcome	Reason(s) for Discontinuing
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]

In addition to this letter, I have enclosed a copy of [patient name's] medical records and a Letter of Medical Necessity. I have also included a copy of [journal article/clinical trial data/etc], which further supports why, in my professional opinion, BIMZELX is medically necessary for my patient's care and should be covered under [name of health plan].

Please contact me, [physician's name], at [physician's phone number] with any pending questions. Thank you for your time and consideration of this appeal.

Sincerely,

[Physician's name and signature] _____

[Patient's name and signature] _____

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

[Encl: Patient medical records, Letter of Medical Necessity, previous denial letter, medical notes in response to the denial, clinical support for this recommendation.]

Bimzelx® (bimekizumab-bkzx)

TIERING EXCEPTION REQUEST LETTER GUIDE

SAMPLE TIERING EXCEPTION REQUEST LETTER

You may choose to use or customize 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. 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.

[Date]
[Formulary director]
[Name of health plan]
[Mailing address]

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

To whom it may concern,

I am writing to request a tiering exception for my patient, [patient's name], who is currently a member of [name of health plan]. This request is for BIMZELX® (bimekizumab-bkzx) to be made available as a preferred prescription medication for the treatment of this patient, who has been diagnosed with [diagnosis], [ICD code(s)].

[Patient name] previously experienced successful results with BIMZELX [dose, frequency] for [enter length of time on BIMZELX], but had to discontinue treatment due to [list reason(s), eg, change in plan's formulary list or patient change in health plans during the past year].

BIMZELX, at [dosage and frequency], is medically appropriate and necessary for [patient's name], who has attempted the below treatment(s) in the past for [diagnosis]. Those trials have failed due to [inadequate efficacy, lack of tolerability, etc].

Past Treatment(s)	Start/Stop Dates	Therapeutic Outcome	Reason(s) for Discontinuing
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]
[Drug name, strength, dosage, form]	[MM/YY] – [MM/YY]	[List treatment benefits and/or failures]	[List side effects, lack of efficacy, etc]

The patient's present treatment(s) are as follows:

Current Treatment(s)	Dosage	Start Date	Therapeutic Outcome
[Drug name, strength, form]	[XX]	[MM/YY]	[List treatment benefits and/or failures]
[Drug name, strength, form]	[XX]	[MM/YY]	[List treatment benefits and/or failures]

Currently, [patient's name] has the following unresolved symptoms of [diagnosis]:

- [Symptom 1]
- [Symptom 2]

In addition to this letter, I have enclosed a copy of [patient name's] medical records and a Letter of Medical Necessity. This latter letter describes how BIMZELX is medically necessary for my patient's care over the preferred drugs listed in the plan's formulary because [explain rationale for why lower-tiered formulary drugs would be less effective than BIMZELX].

I am requesting this tiering exception because the cost associated with the assigned tier for BIMZELX would present a financial burden to [patient's name]. It would also prevent [him/her] from utilizing what I consider to be the best medication to help successfully treat [his/her] [diagnosis].

Please contact me, [physician's name], at [physician's phone number] with any pending questions.

Sincerely,

[Physician's name and signature] _____

[Patient's name and signature] _____

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

[Encl: Patient medical records, Letter of Medical Necessity, statement of financial hardship from [patient's name], previous denial letter, medical notes in response to the denial.]