Bimzelx® (bimekizumab-bkzx)

BIMZELX® (BIMEKIZUMAB-BKZX) FREQUENTLY ASKED QUESTIONS (FAQs) FOR SPECIALTY PHARMACIES

PSO | PsA | nr-axSpA | AS | HS

Specialty Pharmacy

INDICATIONS AND FORMULATIONS

What is BIMZELX indicated for?

BIMZELX® (bimekizumab-bkzx) is indicated for the treatment of adult patients with:

- **Moderate-to-severe plaque psoriasis (PSO)** who are candidates for systemic therapy or phototherapy
- **Active psoriatic arthritis (PsA)**
- **Active non-radiographic axial spondyloarthritis (nr-axSpA)** with objective signs of inflammation
- **Active ankylosing spondylitis (AS)**
- **Moderate-to-severe hidradenitis suppurativa (HS)**

What are the available dosing forms and strengths for BIMZELX?

BIMZELX is available in the following strengths and forms:

	BIMZELX Autoinjector	BIMZELX Prefilled Syringe
Dermatology	 Carton of two (2) 160 mg/mL single-dose autoinjectors **NDC:** 50474-0781-85	 Carton of two (2) 160 mg/mL single-dose prefilled syringes **NDC:** 50474-0780-79
Dermatology	 Carton of one (1) 320 mg/2 mL (160 mg/mL) single-dose autoinjector **NDC:** 50474-0782-84	 Carton of one (1) 320 mg/2 mL (160 mg/mL) single-dose prefilled syringe **NDC:** 50474-0783-78
Rheumatology	 Carton of one (1) 160 mg/mL single-dose autoinjector **NDC:** 50474-0781-84	 Carton of one (1) 160 mg/mL single-dose prefilled syringe **NDC:** 50474-0780-78

Please see Important Safety Information on page 9, refer to full Prescribing Information provided by the UCB representative, and visit BIMZELXhcp.com.

DOSING AND ADMINISTRATION

What is the dosing regimen for BIMZELX?

Dermatology

Dosing for Patients With Moderate-to-Severe Psoriasis (PSO)

The recommended dosage of BIMZELX is 320 mg (can be given as either 2 subcutaneous injections of 160 mg each or 1 subcutaneous injection of 320 mg) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter.

INITIATION DOSE

WEEK 0	WEEK 4	WEEK 8	WEEK 12	WEEK 16
320 mg	320 mg	320 mg	320 mg	320 mg
2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL

MAINTENANCE DOSE

Q8W

320 mg

2 x 160 mg/mL OR 1 x 320 mg/2 mL

For patients weighing 120 kg (264.5 lb) or more, consider a dose of 320 mg every 4 weeks after Week 16

Dosing for Patients With Moderate-to-Severe Hidradenitis Suppurativa (HS)

The recommended dosage of BIMZELX is 320 mg (can be given as either 2 subcutaneous injections of 160 mg each or 1 subcutaneous injection of 320 mg) at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter.

INITIATION DOSE

WEEK 0	WEEK 2	WEEK 4	WEEK 6	WEEK 8
320 mg	320 mg	320 mg	320 mg	320 mg
2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL

WEEK 10	WEEK 12	WEEK 14	WEEK 16
320 mg	320 mg	320 mg	320 mg
2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL	2 x 160 mg/mL OR 1 x 320 mg/2 mL

MAINTENANCE DOSE

Q4W

320 mg

2 x 160 mg/mL OR 1 x 320 mg/2 mL

DOSING AND ADMINISTRATION

What is the dosing regimen for BIMZELX (continued)?

Rheumatology

Dosing for Patients With PsA*, nr-axSpA, and AS

The recommended dosage of BIMZELX is 160 mg (given as 1 subcutaneous injection) every 4 weeks

*For PsA patients with coexisting moderate-to-severe PSO, use the dosing regimen for PSO.

How should patients be instructed to inject BIMZELX?

BIMZELX is administered under the skin (subcutaneously) by autoinjector or prefilled syringe. BIMZELX is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject after training in subcutaneous injection technique.

BIMZELX can be self-administered in the thighs or abdomen, or administered by an HCP or caregiver in the back of the upper arm. BIMZELX should not be injected into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis. Choose a different site on the body for each injection. Do not use the same injection site two times in a row.

Instruct patients and/or caregivers to review injection training resources at https://www.bimzelxinjectiontraining.com

For full injection instructions, refer patients to the Instructions for Use.

It's important to **instruct patients switching from the 1 mL autoinjector to the 2 mL autoinjector** that there are differences in the administration instructions and to **carefully read the Instructions for Use for the 2 mL autoinjector.**

DOSING AND ADMINISTRATION (CONTINUED)

How should BIMZELX be stored?

- **Cartons should be refrigerated between 2°C and 8°C (36°F and 46°F).** When necessary, BIMZELX prefilled syringes or autoinjectors may be stored at room temperature up to 25°C (77°F) in the original carton for a single period of up to 30 days. Once BIMZELX prefilled syringes or autoinjectors have been stored at room temperature, do not place back in refrigerator.
- Keep in original carton to protect from light. Do not freeze. Do not use beyond expiration date.

What is the shelf life for BIMZELX?

- The shelf life of BIMZELX is 36 months (expires 3 years from the date of manufacture).

Is BIMZELX available for me to order?

BIMZELX is operating with an open distribution model. Any Specialty Pharmacy can order and dispense BIMZELX.

Click or scan to download the BIMZELX Wholesale Order Entry Form

CLINICAL

When were the BIMZELX indications approved?

UCB announced that BIMZELX was approved for the treatment of moderate-to-severe HS on November 20, 2024. The BIMZELX rheumatology (PsA, nr-axSpA, AS) indications were approved on September 21, 2024. The BIMZELX moderate-to-severe PSO indication was approved in October 2023.

What is the mechanism of action of BIMZELX?

IL-17A and IL-17F are naturally occurring cytokines that can **drive chronic inflammation and damage across multiple tissues**.

- **BIMZELX selectively inhibits both IL-17F and IL-17A and provides more inhibition of inflammation.**
- Please see Section 12.1 (Mechanism of Action) in full Prescribing Information at BIMZELX.com for more information.

What are the most common side effects of BIMZELX?

Most common (≥ 1%) adverse reactions in plaque psoriasis and hidradenitis suppurativa include upper respiratory infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

Most common (≥ 2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.

Most common (≥ 2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.

Most common (≥ 2%) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.

Are there drug interactions with BIMZELX?

Avoid use of live vaccines in patients treated with BIMZELX. Patients treated with BIMZELX may receive inactivated or non-live vaccinations.

- Healthy individuals who received a single dose of 320 mg of BIMZELX 2 weeks before receiving vaccination with an inactivated seasonal influenza vaccine had similar antibody responses as compared to individuals who did not receive BIMZELX before vaccination.
- The effectiveness of inactivated seasonal influenza vaccines and other inactivated and non-live vaccines has not been evaluated in patients treated with BIMZELX.

What are the warnings related to BIMZELX?

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 definitively 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, instruct to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

BIMZELX may increase the risk of infections, including serious 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.

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. 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 receiving BIMZELX for signs and symptoms of active TB during and after treatment.

Elevated serum transaminases were reported in clinical trials. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline, periodically during treatment, 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 the use of BIMZELX in patients with acute liver disease or cirrhosis.

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.

Please see Important Safety Information on page 9, refer to full Prescribing Information provided by the UCB representative, and visit BIMZELXhcp.com.

Bimzelx® (bimekizumab-bkzx)

PATIENT SUPPORT SERVICES

What is BIMZELX Navigate®?

BIMZELX Navigate provides access, affordability, and treatment support for eligible patients.

Bimzelx® (bimekizumab-bkzx) Navigate

What type of patient access and treatment support services are available?*

BIMZELX Navigate offers a wide range of resources—from quick product access for eligible patients to personalized onboarding support—to get patients on treatment as smoothly as possible.

BIMZELX Navigate Bridge†,‡

Eligible, commercially insured patients whose prescription is initially **denied or delayed by insurance** may be eligible to receive BIMZELX at **$15** per dose for up to 2 years or until the patient's commercial insurance plan approves coverage, whichever comes first.

BIMZELX Navigate Savings§

Once insurance approval is obtained, commercially insured patients may be eligible to receive BIMZELX for as little as **$5** per dose.

*Please see full eligibility and terms at www.bimzelx.com/patient-support/navigate-benefits.
†To facilitate enrollment into BIMZELX Bridge, two (2) prescriptions are requested when prescribing to non-Bridge dispensing Specialty Pharmacy; alternatively submit BIMZELX Patient Enrollment Form.
‡For eligible, commercially insured patients only. Eligible, commercially insured patients whose prescription is initially denied or delayed by insurance may be eligible to receive BIMZELX at $15 per dose for up to 2 years or until insurance coverage is approved, whichever comes first. Please see full eligibility and terms at www.bimzelx.com/patient-support/navigate-benefits.
§Eligible, commercially insured patients may pay as little as $5 per dose. Please see full eligibility requirements and terms at www.bimzelx.com/patient-support/navigate-benefits.

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PATIENT SUPPORT SERVICES (CONTINUED)

How can eligible, commercially insured patients enroll in BIMZELX Navigate Bridge?

If the healthcare provider sends the prescription directly to BIMZELX Navigate (Hub), they will automatically enroll eligible patients into BIMZELX Navigate Bridge. **Select Specialty Pharmacies within the enhanced network are contracted to dispense BIMZELX on behalf of the BIMZELX Navigate Bridge program directly to patients.**

Non-Bridge Dispensing Specialty Pharmacies can facilitate enrollment into BIMZELX Navigate Bridge using one of the following options:

- **Submit to UCB Navigate™ Pharmacy** (NPI #1891487138):
  Transfer prescription to the BIMZELX hub
  Phone: 407-502-5899
  Fax: 913-548-0896

- **Specialty Pharmacy Rx Transfer:**
  Transfer prescription to the Specialty Pharmacy Bridge-Dispensing Network*

Bimzelx Navigate Bridge-Dispensing Specialty Pharmacies*

Specialty Pharmacy†	Phone Number	Fax Number
altScripts Specialty Pharmacy	1-414-385-9500	1-414-385-7200
Amber Specialty Pharmacy	1-888-370-1724	1-402-896-3774
Ardon Health Specialty Pharmacy	1-855-425-4085	1-855-425-4096
BioPlus Specialty Pharmacy	1-888-292-0744	1-800-269-5493
CVS Specialty Pharmacy	1-800-237-2767	1-800-323-2445
Encore Pharmacy	1-817-335-5712	1-866-326-9731
Meijer Specialty Pharmacy	1-855-263-4537	1-734-391-2365
Polaris Specialty Rx	1-855-797-0857	1-800-781-3364
Publix Specialty Pharmacy	1-855-797-8254	1-863-413-5723
Senderra Specialty Pharmacy	1-855-460-7928	1-888-777-5645
Sterling Specialty Pharmacy	1-888-618-4126	1-866-588-0371

*Any specialty pharmacy can order/dispense BIMZELX.
†These pharmacies are subject to change.

PATIENT SUPPORT SERVICES (CONTINUED)

How can specialty pharmacies help eligible, commercially insured patients enroll in BIMZELX Navigate Savings?

There are two ways to assist patients with Savings Program enrollment:

Enroll patient into BIMZELX Navigate Savings program (requires patient authorization)*

ENROLL PATIENT

OR

If the patient prefers to self-enroll, direct them to text "savings" to 46341 or visit ucbsavings.com

*Certain restrictions apply. BIMZELX Navigate Savings is available for eligible, commercially insured patients only, with approved coverage. Please see full Eligibility Criteria on page 9.

What are the eligibility qualifications for BIMZELX Navigate Bridge?

- For initial enrollment into the program, eligible patients must be experiencing a delay in, or have been denied, coverage for BIMZELX by their commercial insurance plan. To maintain eligibility in the program, the following are required: (1) a prior authorization request has been submitted and/or coverage remains unavailable for the patient; and (2) if the prior authorization is denied by the payer, the prescriber must submit an appeal within the first one hundred eighty (180) days of the prior authorization denial and, thereafter, a PA, appeal, or medical exception (as required by the payer) must be submitted every one hundred eighty (180) days.

Certain restrictions apply. Please see full Eligibility Criteria on page 9. This offer is not available for patients eligible for Medicare, Medicaid, or any other form of government insurance coverage. Uninsured patients may be eligible for the UCB Patient Assistance Program.

What are the enrollment qualifications for patient assistance programs (PAPs)?

A **PAP may be available to patients with limited or no health insurance coverage who meet specific eligibility requirements**. To be eligible for a PAP, patients must:

- Have a **valid prescription** from a US HCP for on-label indication
- **Reside within the United States,** including the District of Columbia or US Territory
- Have a **total household income that does not exceed 500% of the federal poverty limit** (see https://www.healthcare.gov/glossary/federal-poverty-level-FPL)

Contact **UCBCares®** by visiting **askucbcares.com** or calling **1-844-599-CARE (2273)** for more information.

Is patient service mandated through BIMZELX Navigate?

No, HCPs may also submit the prescription to their SP of choice.

For additional information regarding patient support services, visit BIMZELXhcp.com or call BIMZELX Navigate at 1-866-4-BIMZELX (1-866-424-6935).

Please see Important Safety Information on page 9, refer to full Prescribing Information provided by the UCB representative, and visit BIMZELXhcp.com.

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*__BIMZELX Navigate® Bridge (the "Program"):__ If you, the patient, have commercial insurance and a valid prescription for BIMZELX® (bimekizumab-bkzx) consistent with FDA-approved product labeling, you may be eligible to receive BIMZELX for $15 per dose for up to two (2) years or until your commercial insurance plan approves coverage for the drug, whichever comes first. For enrollment into the Program, you must be experiencing a delay in, or have been denied, coverage for BIMZELX by your commercial insurance plan. A prior authorization ("PA") must be submitted before shipment of the second prescription fill. To maintain eligibility in the Program, if the PA is denied by the payer, an appeal must be submitted within one hundred eighty (180) days following the PA denial and, thereafter, a PA, appeal, or medical exception (as required by the payer) must be submitted every one hundred eighty (180) days. The Program is not available (1) if you are enrolled in any state, federal, or government-funded healthcare program, including but not limited to Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE/CHAMPUS, any state prescription drug assistance program, or the Government Health Insurance Plan in Puerto Rico, (2) if your insurance approves coverage for the drug, (3) if you are uninsured or cash-paying, or (4) where otherwise prohibited by law. No purchase necessary. Product shall be dispensed pursuant to Program rules and federal and state laws. You may be asked to re-verify insurance coverage status during participation in the Program. The Program is not health insurance, nor is participation a guarantee of insurance coverage. This Program cannot be combined with any other program, discount, discount card, coupon, or similar offer for BIMZELX. You, or your healthcare provider on your behalf, must not submit any claim for reimbursement from your health insurance, any third party or any health savings, flexible spending, or other healthcare reimbursement accounts for any amount of the savings received through the Program. UCB, Inc. reserves the right to end or amend this Program without notice.

†__BIMZELX Navigate® Savings (the "Savings Program"):__ You, the patient, may receive BIMZELX® (bimekizumab-bkzx) for as little as $5 per dose if you have commercial insurance coverage that covers BIMZELX and a valid prescription for BIMZELX consistent with FDA-approved product labeling. The Savings Program is not available (1) for prescriptions that are reimbursed, in whole or in part, under any state, federal, or government-funded healthcare program, including but not limited to Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE/CHAMPUS, any state prescription drug assistance program, or the Government Health Insurance Plan in Puerto Rico, (2) where your commercial insurance plan reimburses for the entire cost of the drug, (3) if you are uninsured or cash-paying, or (4) where otherwise prohibited by law. Product shall be dispensed pursuant to Savings Program rules and federal and state laws. The value of the Savings Program is exclusively for your benefit and is intended to be credited in full toward your out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. You may not seek reimbursement from your health insurance, any third party, or any health savings, flexible spending, or other healthcare reimbursement accounts, for any amount of the savings received through the Savings Program. You are responsible for complying with any applicable limitations and requirements of your health plan related to the use of the Savings Program. This Savings Program cannot be combined with any other savings, free trial, or similar offer for the specified prescription. UCB, Inc. reserves the right to amend or end this Savings Program at any time without notice. Subject to the prior sentence, this Savings Program expires at 11:59 p.m. on December 31. You may re-enroll in the Savings Program each year, subject to program requirements.

UCBCares® About People

For additional information, contact **UCBCares®** at **1-844-599-CARE (2273).**

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 definitively 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, instruct 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, including serious 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 (≥ 1%) adverse reactions in plaque psoriasis and hidradenitis suppurativa include upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

Most common (≥ 2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.

Most common (≥ 2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.

Most common (≥ 2%) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.

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