BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.90.067

| | | | |
|---|---|---|---|
| **Section:** | Prescription Drugs | **Effective Date:** | January 1, 2026 |
| **Subsection:** | Topical Products | **Original Policy Date:** | November 10, 2023 |
| **Subject:** | Bimzelx | **Page:** | 1 of 10 |

***Last Review Date:*** December 12, 2025

# Bimzelx

## Description

### Bimzelx (bimekizumab-bkzx)

**Background**
Bimzelx (bimekizumab-bkzx) is subcutaneous injectable treatment that helps regulate inflammation in patients with moderate to severe plaque psoriasis (PsO), active psoriatic arthritis (PsA), active non-radiographic axial spondyloarthritis (nr-axSpA), active ankylosing spondylitis (AS), and moderate to severe hidradenitis suppurativa (HS). Bimzelx is a humanized immunoglobulin IgG1/K monoclonal antibody with two identical antigen binding regions that selectively bind to interleukin 17A (IL-17A), interleukin 17F (IL-17F), and interleukin 17-AF cytokines, and inhibits their interaction with the IL-17 receptor complex. IL-17A and IL-17F are naturally occurring cytokines that are involved in normal inflammatory and immune responses. Bimzelx inhibits the release of proinflammatory cytokines and chemokines (1).

**Regulatory Status**
FDA-approved indications: Bimzelx is a humanized IL-17A and IL-17F antagonist indicated for the treatment of: (1)

- Moderate to severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy.
- Adults with active psoriatic arthritis (PsA).
- Adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
- Adults with active ankylosing spondylitis (AS).
- Adults with moderate to severe hidradenitis suppurativa (HS).

Bimzelx may increase the risk of suicidal ideation and behavior. Patients with new or worsening symptoms of depression, suicidal ideation, or other mood changes should be referred to a mental health professional, as appropriate. Prescribers should also weigh the risks and benefits of treatment with Bimzelx in patients with a history of severe depression and/or suicidal ideation or behavior (1).

Bimzelx may increase the risk of infection. Patients should seek medical advice if signs and symptoms of clinically important infection occurs. Patients should also be evaluated for tuberculosis (TB) infection prior to initiating treatment. Do not administer to patients with active TB infection. Initiate treatment for latent TB prior to administering Bimzelx (1).

Elevations in serum transaminases can occur with Bimzelx use. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and according to routine patient management (1).

Inflammatory bowel disease (IBD) has been reported with IL-17 inhibitors. Use of Bimzelx should be avoided in patients with active IBD. Monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening signs and symptoms occur (1).

The safety and effectiveness of Bimzelx have not been evaluated in pediatric patients (1).

**Related policies**
Cosentyx, Siliq, Taltz

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Bimzelx may be considered **medically necessary** if the conditions indicated below are met.

Bimzelx may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Moderate to severe plaque psoriasis (PsO)
    a. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
        i. If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
    b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Patients < 120 kg weight: 320 mg every 8 weeks
        ii. Patients ≥ 120 kg weight: 320 mg every 4 weeks
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

2. Active psoriatic arthritis (PsA)
    a. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
    b. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
    c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

3. Active non-radiographic axial spondyloarthritis (nr-axSpA)
    a. Patient has objective signs of inflammation
    b. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
    c. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
    d. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

4. Active ankylosing spondylitis (AS)

a. Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal anti-inflammatory drugs (NSAIDs)
b. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
c. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

5. Moderate to severe hidradenitis suppurativa (HS)
    a. Prescriber will not exceed the FDA labeled maintenance dose of 320 mg every 4 weeks

**AND ALL** of the following for **ALL** indications:
a. Result for latent TB infection is negative **OR** result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
b. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
d. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

**Diagnoses**

Patient must have **ONE** of the following with provided documentation (e.g., medical records, laboratory reports):

1. Plaque psoriasis (PsO)
    a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
        i. Patients < 120 kg weight: 320 mg every 8 weeks
        ii. Patients ≥ 120 kg weight: 320 mg every 4 weeks

   b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
2. Psoriatic arthritis (PsA)
   a. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
   b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
3. Non-radiographic axial spondyloarthritis (nr-axSpA)
   a. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
   b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
4. Ankylosing spondylitis (AS)
   a. Prescriber will not exceed the FDA labeled maintenance dose of 160 mg every 4 weeks
   b. Patient **MUST** have tried the preferred product(s) (see Appendix 2) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
5. Hidradenitis suppurativa (HS)
   a. Prescriber will not exceed the FDA labeled maintenance dose of 320 mg every 4 weeks

**AND ALL** of the following for **ALL** indications:

a. Condition has shown improvement or stabilization
b. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
d. **NOT** given concurrently with live vaccines

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

## Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Quantity**

| Diagnosis | Strength | Quantity |
|---|---|---|
| Plaque psoriasis (PsO) Weight < 120 kg | 160 mg/mL | 20 injections (injection at Weeks 0, 4, 8, 12, 16, then every 8 weeks) |
| | 320 mg/2 mL | 10 injections (injection at Weeks 0, 4, 8, 12, 16, then every 8 weeks) |
| Plaque psoriasis (PsO) Weight ≥ 120 kg | 160 mg/mL | 28 injections (injection at Weeks 0, 4, 8, 12, 16, then every 4 weeks) |
| | 320 mg/2 mL | 14 injections (injection at Weeks 0, 4, 8, 12, 16, then every 4 weeks) |
| Psoriatic arthritis (PsA) | 160 mg/mL | 13 injections (injection every 4 weeks) |
| Non-radiographic axial spondyloarthritis (nr-axSpA) | 160 mg/mL | 13 injections (injection every 4 weeks) |
| Ankylosing spondylitis (AS) | 160 mg/mL | 13 injections (injection every 4 weeks) |
| Hidradenitis suppurativa (HS) | 160 mg/mL | 36 injections (injection at Weeks 0, 2, 4, 6, 8, 10, 12, 14, 16, then every 4 weeks) |
| | 320 mg/2 mL | 18 injections (injection at Weeks 0, 2, 4, 6, 8, 10, 12, 14, 16, then every 4 weeks) |

**Duration** 12 months

## Prior – Approval *Renewal* Limits

**Quantity**

| Diagnosis | Strength | Quantity |
|---|---|---|
| Plaque psoriasis (PsO) Weight < 120 kg | 160 mg/mL | 2 injections per 56 days |
| | 320 mg/2 mL | 1 injection per 56 days |
| Plaque psoriasis (PsO) Weight ≥ 120 kg | 160 mg/mL | 4 injections per 56 days |
| | 320 mg/2 mL | 2 injections per 56 days |
| Psoriatic arthritis (PsA) | 160 mg/mL | 2 injections per 56 days |
| Non-radiographic axial spondyloarthritis (nr-axSpA) | 160 mg/mL | 2 injections per 56 days |
| Ankylosing spondylitis (AS) | 160 mg/mL | 2 injections per 56 days |
| Hidradenitis suppurativa (HS) | 160 mg/mL | 4 injections per 56 days |
| | 320 mg/2 mL | 2 injections per 56 days |

**Duration** 18 months

## Rationale

**Summary**

Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis (PsA), active non-radiographic axial spondyloarthritis (nr-axSpA), active ankylosing spondylitis (AS) and moderate to severe hidradenitis suppurativa (HS). It is administered as an injection under the skin. Bimzelx has been associated with an increased risk of suicidal ideation and behavior, increased risk of infection, elevated serum transaminases, and inflammatory bowel disease (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Bimzelx while maintaining optimal therapeutic outcomes.

**References**

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; November 2024.

## Policy History

| Date | Action |
|---|---|
| November 2023 | Addition to PA |
| March 2024 | Annual review |
| October 2024 | Per PI update, added indications PsA, nr-axSpA, and AS. Added 320 mg/2 mL to quantity chart |
| December 2024 | Annual review |
| January 2025 | Per PI update, added indication HS |
| March 2025 | Annual review |
| December 2025 | Annual review. Added documentation requirement. Revised Appendix 2 |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.**

## Appendix 1 - List of DMARDs

**Conventional disease-modifying antirheumatic drugs (DMARDs)**

| Generic Name | Brand Name |
|---|---|
| azathioprine | Azasan, Imuran |
| cyclophosphamide | Cytoxan |
| cyclosporine | Neoral, Gengraf, Sandimmune |
| hydroxychloroquine | Plaquenil |
| leflunomide | Arava |
| methotrexate | Rheumatrex, Trexall |
| mycophenolate | Cellcept |
| sulfasalazine | Azulfidine, Sulfazine |

**Biological disease-modifying antirheumatic drugs (DMARDs)***

| Generic Name | Brand Name |
|---|---|
| abatacept | Orencia |
| adalimumab | Humira |
| anakinra | Kineret |
| bimekizumab-bkzx | Bimzelx |
| brodalumab | Siliq |
| certolizumab | Cimzia |
| etanercept | Enbrel |
| golimumab | Simponi/Simponi Aria |
| guselkumab | Tremfya |
| infliximab | Remicade |
| infliximab-dyyb | Zymfentra |
| ixekizumab | Taltz |
| risankizumab-rzaa | Skyrizi |
| rituximab | Rituxan |
| sarilumab | Kevzara |
| secukinumab | Cosentyx |
| spesolimab-sbzo | Spevigo |
| tildrakizumab-asmn | Ilumya |
| tocilizumab | Actemra |
| ustekinumab | Stelara |
| vedolizumab | Entyvio |

**Targeted synthetic disease-modifying antirheumatic drugs (DMARDs)***

| Generic Name | Brand Name |
|---|---|
| apremilast | Otezla |

| | |
|---|---|
| baricitinib | Olumiant |
| deucravacitinib | Sotyktu |
| tofacitinib | Xeljanz/XR |
| upadactinib | Rinvoq |

*Refer to respective drug policy for biosimilars

## Appendix 2 - List of Preferred Products

List of preferred products:
https://info.caremark.com/content/dam/enterprise/caremark/microsites/dig/pdfs/pa-fep/fep-misc/FEP_IndicationMedChx.pdf

Refer to formulary documents for confirmation of coverage:
https://www.fepblue.org/pharmacy/prescriptions#drug-lists