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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Topical Products	**Original Policy Date:**	November 10, 2023
Subject:	Bimzelx	**Page:**	1 of 10

Last Review Date: March 7, 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:

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** diagnoses:
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

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

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** diagnoses:
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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Strength	Quantity
Plaque psoriasis (PsO)	160 mg/mL	20 injections

Weight < 120 kg		(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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.

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
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

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Plaque Psoriasis (PsO) **Age 18+**	*must try **TWO** preferred products: Enbrel Humira** Otezla Skyrizi Stelara (SC) Taltz Tremfya	*must try ONE preferred product: Enbrel Humira**
Psoriatic arthritis (PsA) **Age 18+**	*must try **TWO** preferred products: Enbrel Humira** Otezla Rinvoq Skyrizi Stelara (SC) Taltz Tremfya Xeljanz/XR	*must try **ONE** preferred product: Enbrel Humira**
Non-radiographic axial spondyloarthritis (nr-axSpA)	*must try **TWO** preferred products: Cimzia Rinvoq Taltz	No preferred products
Ankylosing spondylitis (AS)	*must try **TWO** preferred products: Enbrel Humira** Rinvoq Taltz	*must try **ONE** preferred product: Enbrel Humira**

**Including all preferred biosimilars (see reference product criteria)