Mass General Brigham
Health Plan

Bimzelx (bimekizumab-bkzx)
Effective 01/01/2025

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions			

Overview

Bimzelx (bimekizumab-bkzx) is a humanized interleukin-17A and F antagonist indicated for the treatment of:

- Moderate to severe plaque psoriasis in adult patients 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)

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all the following diagnosis-specific criteria are met:

Moderate to Severe Plaque Psoriasis (PsO)

1. Diagnosis of moderate to severe plaque psoriasis
2. Member has at least 3% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected
3. Member meets ONE of the following criteria:
    a. Minimum duration of 4-week trial and failure, contraindication, or intolerance to ONE of the following topical therapies
        i. Corticosteroids (e.g., betamethasone, clobetasol)
        ii. Vitamin D analogs (e.g., calcitriol, calcipotriene)
        iii. Tazarotene
        iv. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
        v. Anthralin

vi. Coal tar

b. Member has severe psoriasis that warrants a biologic DMARD as first-line therapy.

4. Trial and failure, intolerance, or contraindication to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira (Abbvie), Hadlima, Adalimumab-adaz, Adalimumab-fkjp, Amjevita (Nuvaila)
    d. Otezla
    e. Skyrizi
    f. Stelara, Wezlana
    g. Taltz
    h. Tremfya

Active Psoriatic Arthritis (PsA)

1. Diagnosis of active psoriatic arthritis
2. The member meets ONE of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement
3. Trial and failure, intolerance, or contraindication to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira (Abbvie), Hadlima, Adalimumab-adaz, Adalimumab-fkjp, Amjevita (Nuvaila)
    d. Otezla
    e. Rinvoq/Rinvoq LQ
    f. Simponi
    g. Skyrizi
    h. Stelara, Wezlana
    i. Taltz
    j. Tremfya
    k. Xeljanz/XR

Active ankylosing spondylitis

1. Diagnosis of active ankylosing spondylitis
2. The member has had minimum duration of 1-month trial and failure, contraindication or intolerance to TWO different non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses.
3. Trial and failure, intolerance, or contraindication to TWO of the following:
    a. Cimzia
    b. Enbrel
    c. Humira (Abbvie), Hadlima, Adalimumab-adaz, Adalimumab-fkjp, Amjevita (Nuvaila)
    d. Rinvoq
    e. Simponi

f. Taltz
g. Xeljanz/XR

Non-Radiographic axial spondyloarthritis (nr-axSpa)

1. Diagnosis of active non-radiographical axial spondyloarthritis
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints)
3. The member has minimal 1- month duration trial and failure, contraindication or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses
4. Trial and failure, intolerance, or contraindication to TWO of the following:
    a. Cimzia
    b. Rinvoq
    c. Taltz

Continuation of Therapy

Requests for reauthorizations for all diagnoses will be granted when the following criteria are met:

1. Documentation is submitted supporting improvement in member's condition as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.

References

1. Bimzelx (bimekizumab-bkzx) [prescribing information]. Smyrna, GA: UCB; October 2024.
2. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.
3. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Review History

3/10/2024: Created and Reviewed at March P&T, Effective 4/1/2024
10/9/2024 – Reviewed and updated at October P&T. Added approval criteria for psoriatic arthritis, ankylosing spondylitis, and nr-axSpA. Updated criteria for plaque psoriasis to require trial and failure with two biologics; added Otezla, Wezlana, Taltz, and Amjevita (Nuvaila) to the list of preferred biologic step options. Updated reauthorization criteria to require documentation of clinical response to therapy. Effective 1/1/2025.