Mass General Brigham
Health Plan

Bimzelx (bimekizumab-bkzx)
Effective 01/01/2027

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	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

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)
- Adults with moderate to severe hidradenitis suppurativa (HS)

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

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

Moderate to Severe Plaque Psoriasis (PsO)

1. Diagnosis of moderate to severe plaque psoriasis
2. 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 or targeted synthetic therapy as first-line therapy

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

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.

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. Member has 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

Hidradenitis suppurativa (HS)

1. Member has a diagnosis of moderate to severe hidradenitis suppurativa (Hurley stage II or III)

Continuation of Therapy

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

1. Submission of medical records (e.g. chart notes) documenting an improvement in the member's condition, as evidenced by low disease activity or improvement in signs and symptoms of the condition

Limitations

1. Initial approvals and reauthorizations will be granted for 24 months.
2. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Bimzelx autoinjector	1 injection per 28 days
Bimzelx prefilled syringe	1 injection per 28 days

References

1. Bimzelx (bimekizumab-bkzx) [prescribing information]. Smyrna, GA: UCB; November 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.
04/09/2025 – Reviewed and updated for April P&T. Added diagnosis of hidradenitis suppurativa for the policy. Specified quantity limitations. Effective 07/01/2025.
06/11/2025 – Reviewed and updated for June P&T. Effective 7/1/2025: Updated approval length to 24 months. Effective 9/1/2025: Added Sotyktu as a previous trial option for the diagnosis of plaque psoriasis.
09/10/2025 - Reviewed and updated at September P&T. Added Yesintek as an Ustekinumab trial option. Effective 10/15/2025.
10/08/2025 – Reviewed and updated at October P&T. Updated policy to reflect that Selarsdi, Steqeyma and Yesintek are the preferred Ustekinumab trial options. Updated preferred adalimumab products to Humira, Hadlima, Simlandi and Yuflyma. Updated policy to reflect that policy only applies to the pharmacy benefit. Minor verbiage updates to trial language for ankylosing spondylitis and nr-axSpA; intent remains the same. Effective 01/01/2026.
01/14/2026 – Reviewed and updated at January P&T. Updated policy to include Otezla XR as a trial option for plaque psoriasis and psoriatic arthritis. Effective 02/01/2026.
03/11/2026 – Reviewed and updated for March P&T. Administrative update - changing verbiage in reauthorization criteria from “documentation is submitted” to “submission of medical records (e.g., chart notes…” and updating language for members who are new to the Plan. Effective 05/01/2026.
04/15/2026 – Reviewed and updated at April P&T. Updated criteria for psoriatic arthritis to include Sotyktu as a previous trial option. Updated previous trial language for plaque psoriasis, allowing for bypassing conventional therapy if member has severe psoriasis that warrants a biologic DMARD or targeted synthetic therapy as first-line therapy. Effective 08/16/2026.
09/09/2026 – Reviewed and updated at September P&T. Removing biologic trial requirements from criteria. Effective 01/01/2027.