CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Bimzelx (bimekizumab-bkzx)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Bimzelx, initially approved by the FDA in 2023, is an interleukin-17 A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. 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. Psoriasis is recognized as the most prevalent immune-mediated inflammatory disease with plaque psoriasis being the most common. Plaque psoriasis presents with large oval-circular plaques over the scalp, trunk, legs and arms. It is marked by periods of acute flares and relapses.

Bimzelx (bimekizumab-bkzx) will be considered for coverage when the following criteria are met:

Plaque Psoriasis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member has tried and failed to respond to treatment with at least one of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus); AND
5. Member has tried and failed, or unable to tolerate a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin) for at least 12 weeks; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** Administer 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing ≥ 120 kg, consider a dosage of 320 mg every 4 weeks after Week 16. Quantity Limit: 2 mL per 28 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease (such as BSA improvement or decrease in pain, itching or scaling, etc.).

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Bimzelx (bimekizumab-bkzx) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/02/2023	New policy for Bimzelx created.

References:

1. Bimzelx [prescribing information]. Smyrna, GA: UCB Inc.; 2023.
2. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. *J Am Acad Dermatol.* 2020;82(6):1445-1486.
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(4):1029-1072.
4. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. *J Am Acad Dermatol.* 2019;81(3):775-804

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