Effective Date: 05/01/2024
Reviewed: 02/2024 Scope: Medicaid

BIMZELX (bimekizumab-bkzx)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Treatment of moderate to severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected (if applicable).
   2. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

B. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

III. CRITERIA FOR INITIAL AND CONTINUATION OF THERAPY

For all indications:
1. Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication.

IV. CRITERIA FOR INITIAL APPROVAL

Plaque psoriasis (PsO)

Authorization of 4 months may be granted for adult members for treatment of moderate to severe plaque psoriasis when all of the following criteria is met:

1. Bimzelx is prescribed by, or in consultation with, a specialist in dermatology
2. At least 10% 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 ALL of the following:
    i. Member meets either of the following criteria:
        1. Member has had an inadequate response to at least a 3-month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
        2. Member has had an inadequate response to at least a 3-month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
    ii. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses
    iii. Member has had inadequate response, intolerance or contraindication to at least one additional medication that treats moderate to severe plaque psoriasis such as Zoryve (roflumilast), Enbrel (etanercept), Cosentyx (secukinumab), Skyrizi (risankizumab), infliximab products, Ilumya (tildrakizumab), Stelara (ustekinumab), Tremfya (guselkumab), or Otezla (apremilast).
4. Bimzelx will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), Stelara (ustekinumab), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)
5. Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [PPD], an interferon-release assay [IGRA], or a chest x-ray) within 6 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when either of the following is met:

A. Reduction in body surface area (BSA) affected from baseline
B. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)
C. If the request is for Bimzelx 320mg every 4 weeks, the provider has submitted medical rationale (including patient's current weight) for increased frequency after at least 16 weeks of starting therapy and for continuation of an escalated frequency of every 4 weeks, the patient has shown a response to therapy, as described above, and has had a clinically meaningful incremental benefit from the previous frequency of every 8 weeks.

VI. DOSAGE AND ADMINISTRATION

Indication	Dose
Plaque Psoriasis	Induction: 320mg SC at weeks 0, 4, 8, 12, and 16 Maintenance: 320mg SC every 8 weeks For patients ≥ 120 kg, consider a dose of 320mg SC every 4 weeks after week 16

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VII. QUANITY LIMITS

- Bimzelx 160mg/ml has a quantity limit of 2 syringes/autoinjector pens per 56 days (daily dose of 0.036). A quantity limit exception will be provided for initial loading dose of 2 syringes/autoinjector pens per 28 days (daily dose of 0.072) for 5 doses and may be provided for 2 syringes/autoinjector pens per 28 days (daily dose of 0.072) for maintenance dose if member weighs ≥120 kg with documentation of weight and medical rationale provided.

VIII. REFERENCES

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; October 2023.
2. Gordon KB, Foley P, Krueger JG, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial [published correction appears in Lancet. 2021 Mar 27;397(10280):1182]. *Lancet.* 2021;397(10273):475-486
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4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011;65(1):137-174.
5. 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.
6. Testing for TB Infection. Centers for Disease Control and Prevention. Retrieved on November 1, 2023 from: https://www.cdc.gov/tb/topic/basics/risk.htm.
7. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022;18(8):465-479.
8. 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. doi:10.1016/j.jaad.2020.02.044.
9. Reich K, Papp KA, Blauvelt A, et al. Bimekizumab versus ustekinumab for the treatment of moderate to severe plaque psoriasis (BE VIVID): efficacy and safety from a 52-week, multicentre, double-blind, active comparator and placebo controlled phase 3 trial. *Lancet.* 2021;397(10273):487-498.