AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Bimzelx (bimekizumab-bkzx)	Page:	1 of 3
Effective Date:	5/1/2024	Last Review Date:	01/08/2024; 4/2024

Applies to:	☒Illinois	☐Florida	☐New Jersey
	☐Maryland	☐Florida Kids	☐Pennsylvania Kids
	☐Michigan	☐ Virginia	☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Bimzelx under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Bimzelx

Policy/Guideline:

The patient is unable to take THREE preferred products for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.

Documentation

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

Prescriber Specialty

This medication must be prescribed by or in consultation with a dermatologist

Criteria for Initial Approval

Plaque psoriasis (PsO):

A. Authorization may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for treatment of moderate to severe plaque psoriasis.

B. Authorization may be granted for adult members for treatment of moderate to severe plaque psoriasis when ANY of the following criteria is met:
    1. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    2. At least 10% of body surface area (BSA) is affected.
    3. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
        i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine, or acitretin.
        ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine, and acitretin (see Appendix).

Continuation of Therapy

A. Authorization 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:
    1. Reduction in body surface area (BSA) affected from baseline
    2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

Other Criteria

1. 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.
    - If the screening testing for TB is positive, there must be further testing to confirm there is no active disease.
    - Do not administer the requested medication to members with active TB infection.
    - If there is latent disease, TB treatment must be started before initiation of the requested medication.
2. Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Dosage and Administration

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

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine, or Acitretin

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy
5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 Months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; October 2023.
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3. Lebwohl M, Strober B, Menter A, et al. Phase 3 studies comparing brodalumab with ustekinumab in psoriasis. N Engl J Med. 2015;373(14):1318-1328.
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.
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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.
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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