bimekizumab-bkzx (Bimzelx®)

Policy # 00873
Original Effective Date: 04/08/2024
Current Effective Date: 04/08/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider bimekizumab-bkzx (Bimzelx®)‡ for the treatment of moderate to severe plaque psoriasis to be **eligible for coverage.****

Patient Selection Criteria

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

- Patient has a diagnosis of moderate to severe plaque psoriasis; AND
- Patient is 18 years of age or older; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has failed to respond to an adequate trial of one of the following treatment modalities unless there is clinical evidence or patient history that suggests the use of these treatments will be ineffective or cause an adverse reaction to the patient:
  - Ultraviolet B; OR
  - Psoralen positive Ultraviolet A; OR
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin); AND

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: a preferred adalimumab product (i.e. Humira®, adalimumab-adbm)‡, etanercept (Enbrel®)‡, apremilast (Otezla®)‡, ustekinumab (Stelara®)‡, secukinumab (Cosentyx®)‡, guselkumab (Tremfya®)‡, or risankizumab (Skyrizi®)‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, adalimumab-adbm) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR®)‡ or apremilast (Otezla); AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of bimekizumab-bkzx (Bimzelx) when any of the following criteria are not met to be **not medically necessary.****

- Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
- Patient has failed to respond to an adequate trial of one of the following treatment modalities:
  - Ultraviolet B; OR
  - Psoralen positive Ultraviolet A; OR
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin)
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: a preferred adalimumab product (i.e. Humira, adalimumab-adbm), etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara), secukinumab (Cosentyx), guselkumab (Tremfya), or risankizumab (Skyrizi)

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of bimekizumab-bkzx (Bimzelx) when the patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

Background/Overview

Bimzelx is an interleukin-17A and 17F blocker indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Bimzelx is a humanized immunoglobulin (IgG) monoclonal antibody that inhibits the release of proinflammatory cytokines and chemokines by selectively binding to and neutralizing IL-17A, IL-17F and IL-17AF cytokines. Bimzelx is supplied as a 160 mg/mL single dose prefilled syringe or autoinjector. The recommended dosing for Bimzelx is 320 mg (two 160 mg injections) administered subcutaneously (SC) at Weeks 0, 4, 8, 12, and 16 and then once every 8 weeks (Q8W) thereafter. For patients who weigh ≥ 120 kg, consider a dose of 320 mg once every 4 weeks (Q4W) after Week 16.

Plaque Psoriasis

Psoriasis is a common skin condition caused by an increase in production of skin cells and characterized by frequent episodes of redness, itching and thick, dry silvery scales on the skin. It is most commonly seen on the trunk, elbows, knees, scalp, or lower back. Plaques can also occur on thinner and more sensitive skin, such as body folds and facial and genital regions, which may be more difficult to treat. This condition can appear suddenly or gradually and may affect people of any age. The average age of onset is 33 years. The severity of disease is classified by disease location, the amount of the body affected by the psoriasis, and impact on quality of life. Mild to moderate psoriasis can be managed with topical treatments. Typical treatments for severe cases of plaque psoriasis include ultraviolet therapy or systemic therapies such as methotrexate or cyclosporine. Systemic therapy can also be used for localized disease involving areas such as scalp, palms and soles, and genitals, or psoriasis unresponsive to topical therapy. Newer biologic therapies are also approved for the treatment of plaque psoriasis.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Bimzelx is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Bimzelx was evaluated in three Phase III, randomized, double-blind, multicenter, pivotal studies and one non-pivotal study in adults with plaque psoriasis. Each study assessed induction therapy at Week 16 and maintenance therapy using Q4W or Q8W dosing. Three of the studies used another biologic as an active comparator (BE-VIVID vs. Stelara [ustekinumab SC injection], BE-SURE vs. adalimumab SC injection [Humira, biosimilars], and BE-RADIANT vs. Cosentyx [secukinumab SC injection]). Primary endpoints of the trials included the proportion of patients reporting 90% or greater improvement in the Psoriasis Area and Severity Index score from baseline (PASI 90) and Investigator's Global Assessment (IGA) score of 0 or 1 (indicating clear or almost clear skin). The pivotal trials included: BE-VIVID, BE-SURE, and BE-READY. The results of the BE-VIVID trial, which included 567 patients, found a higher proportion of patients on Bimzelx achieved a PASI 90 at Week 16 (85% vs. 50% with Stelara and 5% with placebo; $P < 0.0001$ for Bimzelx vs. both comparisons). IGA response was also more common at Week 16 with Bimzelx (84% vs. 53% with Stelara and 5% with placebo; $P < 0.0001$ for Bimzelx vs. both comparisons). A total of 478 patients were enrolled in the BE-SURE trial which demonstrated superiority of Bimzelx at Week 16 and Week 24. A higher proportion of patients on Bimzelx achieved a PASI 90 at Week 16 (86% vs. 47% with adalimumab; $P < 0.001$ for noninferiority and superiority). IGA 0/1 was also more common at Week 16 with Bimzelx (85% vs. 57% with adalimumab; $P < 0.001$ for noninferiority and superiority). At Week 56, PASI 90 response was achieved in a similar proportion of patients taking maintenance dosing with Bimzelx Q4W (85%) and Q8W (83%). PASI 90/100 was achieved at Week 56 in 82%/67% of patients who switched from adalimumab to Bimzelx at Week 24. The results of the BE-READY trial, which included 435

patients randomized to treatment with Bimzelx or placebo, showed the PASI 90 response at Week 16 was higher with Bimzelx (91%) compared with placebo (1%) [P < 0.001]. IGA 0/1 was also more common at Week 16 with Bimzelx (93% vs. 1% with placebo; P < 0.001).

References

1. Bimzelx [package insert]. UCB, Inc. Smyrna, Georgia. October 2023.
2. Bimzelx Drug Evaluation. Express Scripts. October 25, 2023.

Policy History

Original Effective Date: 04/08/2024
Current Effective Date: 04/08/2024
03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 03/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.