Original Effective Date: 03/07/2024
Current Effective Date: 03/07/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 10/2024
Policy Number: C27172-A

Bimzelx (bimekizumab-bkzx)

PRODUCTS AFFECTED

Bimzelx (bimekizumab-bkzx)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Plaque Psoriasis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CHRONIC PLAQUE PSORIASIS:
   1. Documented diagnosis of moderate to severe psoriasis (BSA $\geq$ 3%) OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
      AND

2. (a) Documentation of treatment failure, serious side effects, or clinical contraindication to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
   OR
   (b) Documentation of treatment failure to Phototherapy for ≥ 3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)
   AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
4. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
   **MOLINA REVIEWER NOTE: TB SKIN TEST (TST, PPD) AND TB BLOOD TEST (QuantiFERON TB Gold, T-Spot) are not required or recommended in those without risk factors for tuberculosis
   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment
   AND
5. Member is not on concurrent treatment or will not be used in combination with TNF-inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4 inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
   AND
6. Prescriber attests member does not have an active infection, including clinically important localized infections
   AND
7. Prescriber attests to obtaining baseline liver enzymes, alkaline phosphatase, and bilirubin and to perform periodic testing during treatment and according to routine patient management per FDA label
   AND
8. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

CONTINUATION OF THERAPY:

A. CHRONIC PLAQUE PSORIASIS:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

AND

3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms
   AND
4. Prescriber attests to performing periodic liver enzymes, alkaline phosphatase, and bilirubin testing during treatment and according to routine patient management per FDA label
   AND
5. (a) Prescriber attests, or clinical reviewer has found, member has had a negative TB screening* or TB test (if indicated)** result within the last 12 months for initial and continuation of therapy requests
   *MOLINA REVIEWER NOTE: TB SCREENING assesses patient for future or ongoing TB exposure or risk and includes reviewing if they have been exposed to tuberculosis, if they have resided or traveled to areas of endemic tuberculosis, if patient resides or works in a congregate setting (e.g., correctional facilities, long-term care facilities, homeless shelters), etc.
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   OR
   (b) For members who have a positive test for latent TB, provider documents member has completed a treatment course (a negative chest x-ray is also required every 12 months) OR that member has been cleared by an infectious disease specialist to begin treatment

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified dermatologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
320 mg (two 160 mg injections) by subcutaneous injection at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter.
For patients weighing ≥120 kg, consider a dose of 320 mg every 4 weeks after Week 16

PLACE OF ADMINISTRATION:
The recommendation is that subcutaneous injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Antipsoriatic - Systemic

FDA-APPROVED USES:
Indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Plaque psoriasis is a chronic, immune-mediated, hyperproliferative skin condition that is characterized by well-demarcated, thick, oval circular plaques with an appearance that can vary by skin type. It is a T-lymphocyte mediated inflammatory skin disorder characterized by recurrent exacerbations and remission. Plaque psoriasis is the most common subtype, affecting 80-90% of patients with psoriasis. In the United States, 7.5 million people have psoriasis. The severity of plaque psoriasis is generally defined by the total body surface area (BSA) involved, although different definitions have been proposed. The joint American Academy of Dermatology-National Psoriasis Foundation (JAAD-NPF) guidelines consider BSA involvement of 10% as mild, moderate, and severe disease, respectively. The exact cause of plaque psoriasis is not known, but risk factors may include genetics, family history, as well as environmental and behavioral factors such as cold or dry weather conditions, stress, smoking, obesity, and heavy alcohol use. People with plaque psoriasis are at an increased risk of developing other health conditions including cardiovascular disease, inflammatory bowel disease, diabetes, and depression. Additionally, about one-third of patients with plaque psoriasis go on to develop psoriatic arthritis.

Current treatment includes topical therapy, systemic agents, phototherapy, targeted immunomodulators (TIMs) including biologics that target IL-17, IL-23, IL-12/IL-23, or tumor necrosis factor (TNF)-alpha; and oral agents including the PDE4 inhibitors, and combinations of these therapies.

The approval of bimekizumab, an IL-17A and F antagonist, was supported by data from three phase 3, multicenter, randomized, double-blind, placebo- and active comparator- controlled, parallel-group studies (BE READY, BE VIVID, and BE SURE) that evaluated efficacy and safety of bimekizumab in adult subjects with moderate to severe chronic plaque psoriasis. The studies were conducted on 1480 adults with moderate to severe PsO. Treatment with bimzelx dosed every 4 weeks, achieved clear or almost clear skin in 85%-91% patients at week 16, with 59%-68% achieving completely clear skin. Bimzelx showered superior efficacy compared to Stelara, Humira, and Cosentyx in the BE VIVID, BE SURE, and BE RADIANT trials, respectively. Long-term data showed most patients maintained high levels of clinical response

through 3 years and was generally well tolerated but had an oral candidiasis rate of about 9%.The most common adverse reactions reported with treatment were upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Bimzelx (bimekizumab) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Bimzelx (bimekizumab) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:
If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regular scheduled time.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Bimzelx SOAJ 160MG/ML auto-injector
Bimzelx SOSY 160MG/ML prefilled syringe

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2024