Original Effective Date: 03/07/2024
Current Effective Date: 12/17/2025
Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
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, Psoriatic Arthritis, Non-Radiographic Axial Spondyloarthritis, Ankylosing Spondylitis, Hidradenitis Suppurativa

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. ALL INDICATIONS:
   1. 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

2. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B, tuberculosis, etc.), including clinically important localized infections, according to the FDA label
AND
3. 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).
MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix.

B. CHRONIC PLAQUE PSORIASIS:
1. Documented diagnosis of moderate to severe psoriasis (BSA ≥ 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 or serious side effects 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, or number of sessions.
OR
(c) Documentation of contraindication to systemic therapy and phototherapy
NOTE: Contraindications to phototherapy 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]

C. PSORIATIC ARTHRITIS (PsA):
1. Documentation of active psoriatic arthritis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Documented treatment failure, serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
OR
(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function- limiting PsA at a few sites or rapidly progressive disease]
OR
(c) Documentation member has severe psoriasis [PASI ≥12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]
AND
4. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3

months) of ONE FORMULARY OR PREFERRED TNF-inhibitor

D. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS:
1. Documented diagnosis of adult-onset axial spondyloarthritis
   AND
2. Documentation that C-reactive protein (CRP) levels are above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease
   AND
3. Documentation that there is no definitive radiographic evidence of structural damage on sacroiliac joints
   AND
4. Documentation member has active disease and prescriber provides baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
   AND
6. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor

E. MODERATE TO SEVERE ANKYLOSING SPONDYLITIS:
1. Documented diagnosis of ankylosing spondylitis
   AND
2. Documentation of treatment failure, serious side effects or clinical contraindication to TWO NSAIDs (e.g., ibuprofen, naproxen, etodolac, meloxicam, indomethacin) for ≥3 consecutive months at maximal recommended or tolerated anti- inflammatory doses
   AND
3. FOR MEMBER WITH PROMINENT PERIPHERAL ARTHRITIS: Documentation of treatment failure, serious side effects or clinical contraindication to a trial (≥3 consecutive months) of methotrexate OR sulfasalazine
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
   AND
5. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor

F. HIDRADENITIS SUPPURATIVA:
1. Documented diagnosis of Hidradenitis suppurativa Hurley stage II (moderate recurrent) or stage III (severe diffuse) disease
   AND
2. Documentation indicating the member has been counseled on the use of general supportive measures (e.g., education and support, avoidance of skin trauma, hygiene, dressings, smoking cessation, weight management, diet)
   AND
3. (a) Documentation of treatment failure with or a clinical contraindication to a 3-month trial of the following:
   (i) Oral antibiotic (e.g., minocycline, doxycycline, clindamycin/rifampin) AND
   (ii) Antiandrogen (e.g., finasteride)
   AND
   (b) Documentation of treatment failure with or a clinical contraindication to intralesional corticosteroids
   AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

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 [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

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

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Plaque Psoriasis:
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

Psoriatic Arthritis, Non-Radiographic Axial Spondyloarthritis, Ankylosing Spondylitis: 160 mg by subcutaneous injection every 4 weeks
NOTE: For psoriatic arthritis with coexisting moderate to severe plaque psoriasis, use the dosage and administration for plaque psoriasis.

Hidradenitis Suppurativa:
320 mg (two 160 mg injections) by subcutaneous injection at Week 0, 2, 4, 6, 8, 10, 12, 14 and 16, then every 4 weeks thereafter

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 (PSO) in adults who are candidates for systemic therapy or phototherapy, adults with active psoriatic arthritis (PsA), adults with active non-radiographic axial spondyloarthritis (nraxSpA) with objective signs of inflammation, adults with active ankylosing spondylitis (AS), and adults with moderate to severe hidradenitis suppurativa (HS).

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

Illinois (Source: Illinois General Assembly)

"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

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."

APPENDIX 1:

Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

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.

Drug and Biologic Coverage Criteria

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.

Approval for Bimzelx (bimekizumab) was expanded to Psoriatic Arthritis, Non-Radiographic Axial Spondyloarthritis, and Ankylosing Spondylitis in 2024.

The 2023 EULAR updated guideline for the management of psoriatic arthritis (PsA) focused on non-topical management and addressed considerations for treatment in the context of the spectrum of PsA as well as comorbidities that may be present. For biologic therapies, the guidelines recommend TNF inhibitors as the first-line biologic treatment for most patients, particularly those with peripheral arthritis, axial disease, or enthesitis. IL-17 inhibitors (secukinumab, ixekizumab) and IL-17A/F inhibitors (bimekizumab) are also recommended as alternatives, especially in cases of insufficient response to TNF inhibitors or contraindications. IL-12/23 inhibitors (ustekinumab) and IL-23 inhibitors (guselkumab, risankizumab) are considered for those with inadequate responses to prior biologics. Regular monitoring of disease activity and adjustment of therapy based on efficacy and safety is emphasized, with a goal of achieving minimal disease activity or remission.

Bimzelx (bimekizumab) is also approved for the treatment of adults with moderate to severe hidradenitis suppurativa. The safety and efficacy of Bimzelx for HS were assessed in two Phase 3 multicenter, randomized, double blind, placebo-controlled trials (HS-1 and HS-2) in 1,014 adult subjects with moderate to severe HS of at least 6 months with Hurley Stage II or Hurley Stage III disease, and with ≥5 inflammatory lesions, and a history of inadequate response to a course of systemic antibiotics. The primary efficacy endpoint in both trials was the Hidradenitis Suppurativa Clinical Response 50 (HiSCR50) at Week 16, defined by at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess or draining tunnel count relative to baseline. Secondary endpoints included the proportion of subjects who achieved HiSCR75 and HS-specific skin pain response as assessed by a 0 to 10 numeric rating scale (NRS). In both trials, a higher proportion of Bimzelx treated subjects achieved HiSCR50 and HiSCR75 compared to placebo. Bimzelx was associated with an improvement in patient reported worst skin pain (lesion pain) based on the achievement of a reduction of at least 3 points (as measured on a 0 to 10 NRS) compared to placebo at Week 16.

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. Avoid use in patients with active TB. Initiate treatment of latent TB prior to Bimzelx treatment. Avoid use of Bimzelx in patients with active Inflammatory Bowel Disease (IBD). Avoid use of Bimzelx in patients with acute liver disease or cirrhosis as they may be at increased risk for severe hepatic injury. Avoid the use of live vaccines in patients treated with Bimzelx.

Exclusions/Discontinuation:
Treatment with Bimzelx was associated with increased incidence of liver enzyme elevations compared to treatment with placebo in randomized clinical trials. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline, periodically during treatment with Bimzelx and according to routine patient management. Permanently discontinue use of Bimzelx in patients with causally - associated combined elevations of transaminases and bilirubin.
Patients with acute liver disease or cirrhosis may be at increased risk for severe hepatic injury; avoid use of Bimzelx in these patients.

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

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Bimzelx SOAJ 160MG/ML, 320MG/2ML auto-injector
Bimzelx SOSY 160MG/ML, 320MG/2ML prefilled syringe

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Appendix Contraindications/Exclusions/ Discontinuation	Q4 2025

REVISION- Notable revisions: Diagnosis Required Medical Information Quantity FDA-Approved Uses Background References	Q1 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements Quantity FDA-Approved Uses Appendix Background Contraindications/Exclusions/Discontinuation References	Q4 2024
NEW CRITERIA CREATION	Q1 2024