Effective Date: 05/01/2024
Reviewed: 02/2024, 1/2025, 2/2025 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

1. Treatment of moderate to severe plaque psoriasis (PsO) in adult patients who are candidates for systemic therapy or phototherapy
2. The treatment of adults with active psoriatic arthritis (PsA).
3. The treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
4. The treatment of adults with active ankylosing spondylitis (AS).
5. The treatment of adults with moderate to severe hidradenitis suppurativa (HS).

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

II. 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.

III. CRITERIA FOR INITIAL APPROVAL

Universal Criteria

1. Member must be 18 years of age or older
2. 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), Ustekinumab (e.g., Stelara, Wezlana, etc.), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)
3. 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.

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. Member has documentation of 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. Documentation that 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 and at least a 6-month trial of ustekinumab biosimilar 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), Tremfya (guselkumab), or Otezla (apremilast).

Psoriatic Arthritis (PsA)

Authorization of 6 months may be granted for treatment of active psoriatic arthritis (PsA) when the following is met:

1. Bimzelx is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. Documented moderate to severe active disease and member meets either of the following criteria:
    a. If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
    b. If member has peripheral arthritis, member has experienced an inadequate response to a ≥ 3 consecutive month trial a trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, unless intolerance experienced
3. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab and at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

Non-Radiographic Axial Spondyloarthritis (nr-axSpA)

Authorization of 6 months may be granted for treatment of active ankylosing spondyloarthritis in members 18 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology
2. Documented active disease for AS or (nr-axSpA)
3. Member has objective signs of inflammation noted by an elevation of C-reactive protein (CRP) above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI)
4. Member is without definitive radiographic evidence of structural damage on sacroiliac joints
5. Member has experienced an inadequate response or has a contraindication to TWO (2) NSAIDs
6. Member has experienced an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

Ankylosing Spondylitis (AS)
Authorization of 6 months may be granted for treatment of active ankylosing spondylitis in members 18 years of age or older when all of the following criteria are met:
1. Bimzelx is prescribed by, or in consultation with, a specialist in rheumatology.
2. Member has documented active disease
3. Member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs) over 4 weeks (in total) unless use is contraindicated.
4. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

Hidradenitis Suppurativa (HS)
Authorization of 6 months may be granted for treatment of active hidradenitis suppurativa in members 18 years of age or older when all of the following criteria are met:
1. Prescribed by, or in consultation with, a specialist in dermatology.
2. Member has documented moderate to severe hidradenitis suppurativa when either of the following is met:
    a. Member has experienced an inadequate response to oral antibiotics for at least 90 days.
    b. Member has an intolerance or contraindication to oral antibiotics.
3. Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

IV. CONTINUATION OF THERAPY

Plaque Psoriasis (PsO)
Authorization of 12 months may be granted for all adult members (including new members) with documentation of 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.

Psoriatic Arthritis (PsA)
Authorization of 12 months may be granted for all members (including new members) with documentation who are using the requested medication for active psoriatic arthritis 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 there is improvement in any of the following from baseline:
1. Number of swollen joints
2. Number of tender joints

3. Dactylitis
4. Enthesitis
5. Skin and/or nail involvement
6. Disease activity scoring tool [e.g., defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria.]

Non-Radiographic Axial Spondylarthritis (nr-axSpA)
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active non-radiographic axial spondylarthritis and who achieve or maintain positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
1. Total back pain
2. Physical function
3. Reduction of C-reactive protein
4. Disease activity scoring tool [e.g., ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)]

Ankylosing Spondylitis (AS)
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis and who achieve or maintain positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
1. Functional status
2. Total spinal pain
3. Inflammation (e.g., morning stiffness)
4. Disease activity scoring tool [e.g., ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 2 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)]

Hidradenitis Suppurativa (HS)
Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe hidradenitis suppurativa 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 any of the following is met:
1. Reduction in abscess and inflammatory nodule count from baseline
2. Reduced formation of new sinus tracts and scarring
3. Decrease in frequency of inflammatory lesions from baseline
4. Reduction in pain from baseline
5. Reduction in suppuration from baseline
6. Improvement in frequency of relapses from baseline
7. Improvement in quality of life from baseline
8. Improvement on a disease severity assessment tool from baseline

V. DOSAGE AND ADMINISTRATION

Indication	Dose
Plaque Psoriasis	Induction: 320mg SC at weeks 0, 4, 8, 12, and 16 Maintenance: 320mg SC every 8 weeks Note: For members ≥ 120 kg, consider a dose of 320mg SC every 4 weeks after week 16
Psoriatic Arthritis	Maintenance: 160mg SC every 4 weeks. Note: Members with coexisting moderate to severe plaque psoriasis, use the dosage and administration for plaque psoriasis.
Non-Radiographic Axial Spondylarthritis	Maintenance: 160mg SC every 4 weeks.
Ankylosing Spondylitis	Maintenance: 160mg SC every 4 weeks.
Hidradenitis Suppurativa	Induction: 320mg SC at weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16. Maintenance: 320mg SC every 4 weeks.

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

QUANITY LIMITS:

- Bimzelx 160mg/ml has a quantity limit of 1 syringe/autoinjector pen or 1 ml per 28 days (daily dose of 0.036).
- Bimzelx 320mg/2ml has a quantity limit of 1 syringe/autoinjector pen or 2ml per 56 days (daily dose of 0.036)

- **For plaque psoriasis or psoriatic arthritis with coexisting plaque psoriasis**, a quantity limit exception will be provided for the induction regimen of 5 initial loading doses of 320mg/2ml per 28 days (daily dose of 0.072). A quantity limit exception of 320mg/2ml per 28 days (daily dose of 0.072) may be provided for the maintenance dose for plaque psoriasis or psoriatic arthritis with coexisting plaque psoriasis if member weighs ≥120 kg with documentation of weight and medical rationale provided.

- **For hidradenitis suppurativa**, a quantity limit exception will be provided for the induction regimen of two doses of 320mg/2ml per 28 days (daily dose of 0.143) for 16 weeks, and 320mg/2ml per 28 days (daily dose of 0.072) for the maintenance dose.

VI. REFERENCES

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