Neighborhood Health Plan OF RHODE ISLAND™

Effective Date: 05/01/2024
Reviewed: 02/2024, 1/2025, 2/2025, 7/2025, 8/2026 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 Indications

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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

For all indications

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member is free of any clinically important active infection, including clinically important localized infections; AND
- Member has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; AND
- Member will not receive live vaccines during therapy; AND
- Bimzelx will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab(e.g., Hadlima), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, and Yesintek, etc.), Tremfya (guselkumab), Icotyde (icotrokinra), Ilumya (tildrakizumab), Skyrizi (risankizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), tofactinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.).

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 4 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology; AND
3. Documentation has been submitted of one or more of the following:
    a. BSA affected is at least 10%; OR
    b. Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
    c. Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene); AND
4. Documentation has been submitted that the member meets any of the following criteria:
    a. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine, or acitretin); OR
    b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
    c. Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND
5. Documentation has been submitted that the member meets all of the following criteria:
    a. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab AND a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; AND
    b. Member has also had an inadequate response, intolerance, or contraindication to at least a 6-month trial of one of the following: Cosentyx (secukinumab), Ilumya (tildrakizumab), Tremfya (guselkumab), or Otezla (apremilast).

B. Active psoriatic arthritis (PsA)

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

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND Member has documented moderate to severe active disease and documentation has been submitted that the member meets either of the following criteria:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response, intolerance, or contraindication to methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.); OR
        ii. Member has enthesitis or predominantly axial disease; OR
    b. Member has severe disease; AND
3. Documentation has been submitted that the 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.

C. Non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 6 months may be granted for treatment of active non-radiographic axial spondyloarthritis when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in rheumatology; AND

3. Member has documented active disease with 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) and member is without definitive radiographic evidence of structural damage on sacroiliac joints; AND
4. Documentation has been submitted of all of the following:
   i. Member has had an inadequate response, intolerance, or contraindication to at least two (2) NSAIDs; AND
   ii. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

D. 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. Member is 18 years of age or older; AND
2. Bimzelx is prescribed by, or in consultation with, a specialist in rheumatology.
3. Member has documented active disease
4. Documentation has been submitted of all of the following:
   i. Member has had an inadequate response, intolerance, or contraindication to at least two (2) NSAIDs; AND
   ii. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses.

E. Moderate to severe hidradenitis suppurativa (HS)

Authorization of 6 months may be granted for treatment of moderate to severe hidradenitis suppurativa when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Member has documented moderate to severe disease; AND
4. Documentation has been submitted that the member meets both of the following criteria:
   a. Member has had an inadequate response, intolerance, or contraindication to oral antibiotics for at least 90 days; AND
   b. 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 at maximum tolerated doses.

III. CONTINUATION OF THERAPY

A. Moderate to severe 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 (e.g., reduction in BSA from baseline) or improvement in signs and symptoms of the condition (e.g., itching, redness, flaking, scaling, burning, cracking, pain).

**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.*

B. Active 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. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)
9. 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.]

C. Active ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis or non-radiographic axial spondyloarthritis 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. Swollen joints
5. Tender joints
6. C-reactive protein (CRP)
7. 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)]

D. Moderate to severe hidradenitis suppurativa (HS)

Authorization of 6 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

IV. QUANTITY 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.

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.

VI. REFERENCES

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