# Bimzelx (bimekizumab-bkzx)

## NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

## BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

## DESCRIPTION

The intent of the Bimzelx drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies while steering utilization to the most cost-effective medication within the therapeutic class. For this program, Adalimumab-aacf, Enbrel, Cosentyx, Otezla, Rinvoq, Simponi, Skyrizi, Otulfi (ustekinumab-aauz), Tremfya, and Xeljanz/Xeljanz XR are the preferred products and will apply to members requesting treatment for an indication that is FDA-approved for the preferred product. The criteria will require the use of two of the health plan's preferred products before the use of non-preferred products unless there are clinical circumstances that exclude the use of all the preferred products, the patient is currently receiving treatment with the non-preferred drug and experience a positive therapeutic outcome, or there is only one preferred product for an indication.

FDA-Approved Indications

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

## POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

**A)** Plaque psoriasis (PsO)
1. Initial requests:
    i. Chart notes or medical record documentation of affected area(s) and body surface area (BSA) affected.
    ii. Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation of decreased body surface area (BSA) affected and/or improvement in signs and symptoms.

**B)** Ankylosing spondylitis (AS), axial non-radiographic spondyloarthritis (nr-axSpA), psoriatic arthritis (PSA), and hidradenitis suppurativa (HS)
1. Initial requests: Chart notes, medical record documentation, or claims history supporting previous medications tried (if applicable), including response to therapy. If therapy is if not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Must meet BOTH the Preferred Drug Plan Design and Criteria for Initial Approval/Continuation of Therapy when both are applicable.

Preferred Drug Plan Design

**A) Moderate to severe plaque psoriasis (adults)**
1. Criteria for initial approval on moderate to severe plaque psoriasis in adults will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Adalimumab-aacf, Enbrel, Otezla, Skyrizi, Otulfi (ustekinumab-aauz), and Tremfya)
    b) Member has a clinical reason to avoid Enbrel and Adalimumab-aacf (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Otezla, Skyrizi, Otulfi (ustekinumab-aauz), and Tremfya)
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**B) Moderate to severe psoriatic arthritis**
1. Criteria for initial approval on moderate to severe psoriatic arthritis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Enbrel, Adalimumab-aacf, Rinvoq, Otulfi (ustekinumab-aauz), Simponi, Skyrizi, Otezla, Tremfya, and Xeljanz/Xeljanz XR)
    b) Member has a clinical reason to avoid TNF-inhibitors (Enbrel, Adalimumab-aacf, and Simponi) (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Otulfi (ustekinumab-aauz), Skyrizi, Otezla, Tremfya, Rinvoq and Xeljanz/Xeljanz XR)
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**C) Active ankylosing spondylitis**

1. Criteria for initial approval on moderate to active ankylosing spondylitis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with Cosentyx and another of the preferred products (Enbrel, Adalimumab-aacf, Rinvoq, Simponi, and Xeljanz/Xeljanz XR)
    b) Member has a clinical reason to avoid TNF-inhibitors (Enbrel, Adalimumab-aacf, and Simponi) (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with TWO of the preferred products (Cosentyx and either Xeljanz or Rinvoq)
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**D) Non-radiographic axial spondyloarthritis**

1. Criteria for initial approval on non-radiographic axial spondyloarthritis will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with one of the preferred products (Cosentyx and Rinvoq)
    b) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

**E) Hidradenitis Suppurativa**

1. Criteria for initial approval on hidradenitis suppurativa will only apply when at least ONE of the following criteria are met:
    a) Member has had an inadequate response to treatment or intolerable adverse event with TWO of the preferred products (Cosentyx and either Enbrel or Adalimumab-aacf)
    b) Member has a clinical reason to avoid Enbrel and Adalimumab-aacf (See Appendix A) AND has had an inadequate response to treatment or intolerable adverse event with Cosentyx
    c) Member is currently receiving treatment with the requested product through insurance (excludes obtainment as samples or via manufacturer's patient assistance programs) and experiencing a positive therapeutic outcome

Note: Submission of chart notes detailing the outcomes of treatment, intolerable adverse event(s) experienced, contraindication(s), or exclusion(s) to treatment with preferred product(s) is required (where applicable).

Prescriber Specialties (initial approvals only)

This medication must be prescribed by or in consultation with one of the following:

A. Plaque psoriasis: dermatologist
B. Psoriatic arthritis and hidradenitis suppurativa: rheumatologist or dermatologist
C. Ankylosing spondylitis and axial non-radiographic spondyloarthritis: rheumatologist

Criteria for Initial Approval

**A) Moderate to severe plaque psoriasis**

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Sotyktu, Otezla) indicated for the treatment of moderate to severe plaque psoriasis.

2. Authorization of 12 months may be granted for adult members for the treatment of moderate to severe plaque psoriasis when any of the following criteria is met:
    a. Crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
    b. At least 10% of the body surface area (BSA) is affected.
    c. At least 3% of body surface area (BSA) is affected and the member meets any of the following criteria:
        i. Member has had an inadequate response or intolerance to either phototherapy (e.g., UVB, PUVA) or pharmacologic treatment with methotrexate, cyclosporine or acitretin.
        ii. Member has a clinical reason to avoid pharmacologic treatment with methotrexate, cyclosporine and acitretin (see Appendix B).

**B) Active psoriatic arthritis (PsA)**

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Otezla) indicated for active psoriatic arthritis.

2. Authorization of 12 months may be granted for adult members for treatment of active psoriatic arthritis when either of the following criteria is met:
    a) Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response to methotrexate, leflunomide, or another conventional synthetic drug (e.g., sulfasalazine) administered at an adequate dose and duration.
        ii. Member has an intolerance or contraindication to methotrexate or leflunomide (see Appendix B), or another conventional synthetic drug (e.g., sulfasalazine).
        iii. Member has enthesitis or predominantly axial disease.
    b) Member has severe disease.

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

1. Authorization of 12 months may be granted for adult members who have previously received a biologic or targeted synthetic drug (e.g., Rinvoq, Xeljanz) indicated for active non-radiographic ankylosing spondylitis or active axial spondyloarthritis.

2. Authorization of 12 months may be granted for adult members for treatment of active ankylosing spondylitis or active axial spondyloarthritis when either of the following criteria is met:
    a. Member has experienced an inadequate response to at least two non-steroidal anti-inflammatory drugs (NSAIDs).
    b. Member has an intolerance or contraindication to two or more NSAIDs.

**D) Moderate to severe hidradenitis suppurativa (HS)**

1. Authorization of 12 months may be granted for adult members who have previously received a biologic indicated for treatment of moderate to severe hidradenitis suppurativa.

2. Authorization of 12 months may be granted for adult members for treatment of moderate to severe hidradenitis suppurativa when either of the following is met:
    a) Member has experienced an inadequate response to oral antibiotics used for the treatment of hidradenitis suppurativa for at least 90 days (e.g., clindamycin, metronidazole, moxifloxacin, rifampin, tetracyclines).
    b) Member has an intolerance or contraindication to oral antibiotics used for the treatment of hidradenitis suppurativa.

Continuation of Therapy

**A) Plaque psoriasis (PsO)**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain 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 body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (e.g., itching, redness, flaking, scaling, burning, cracking, pain)

**B) Psoriatic arthritis (PsA)**

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain 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)

**C) Ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (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 active 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)

**D) Moderate to severe 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

Other
Member has had a documented negative tuberculosis (TB) test (which can include a tuberculosis skin test [TST] or an interferon-release assay [IGRA])* within 12 months of initiating therapy for persons who are naïve to biologic drugs or targeted synthetic drugs associated with an increased risk of TB.

* If the screening testing for TB is positive, there must be further testing to confirm there is no active disease (e.g., chest x-ray). Do not administer the requested medication to members with active TB infection. If there is latent disease, TB treatment must be started before initiation of the requested medication.

Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Bimzelx is considered **not medically necessary** for members who do not meet the criteria set forth above.

*Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.*

Non-Formulary Exception Criteria
Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

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

Quantity Limits

| Trade Name | Generic Name | Quantity Limit |
|---|---|---|
| Bimzelx | bimekizumab-bkzx | **Plaque Psoriasis**<br>Initiation of therapy (adults): 5 x 320mg/2mL syringes or auto-injectors per 28 days for the first 119 days (17 weeks)<br>Maintenance (adults): 2 x 160mg/mL syringes or auto-injectors per 56 days<br>1 x 320mg/2 mL syringe or auto-injector per 56 days<br><br>**Psoriatic Arthritis**<br>Maintenance (adults): 1 x 160mg/mL syringe or auto-injector per 28 days |

| Trade Name | Generic Name | Quantity Limit |
|---|---|---|
| | | Note: for patients with coexisting moderate to severe plaque psoriasis, use the dosage and administration for plaque psoriasis<br><br>**Non-Radiographic Axial Spondyloarthritis**<br>Maintenance (adults): 1 x 160mg/mL syringe or auto-injector per 28 days<br><br>**Ankylosing Spondylitis**<br>Maintenance (adults): 1 x 160 mg/mL syringe or auto-injector per 28 days<br><br>**Hidradenitis Suppurativa**<br>Initiation of therapy (adults): 9 x 320mg/2 mL syringe or auto-injector for the first 119 days (17 weeks)<br>Maintenance (adults): 1 x 320mg/2 mL syringe or auto-injector per 28 days |

Appendix

**Appendix A: Clinical reasons to avoid TNF-inhibitors**

1. History of demyelinating disorder
2. History of congestive heart failure
3. History of hepatitis B infection
4. Autoantibody formation/lupus-like syndrome
5. Risk of lymphoma

**Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin**

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Risk of treatment-related toxicity
4. Drug interaction
5. Pregnancy or currently planning pregnancy
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

## PROCEDURES AND BILLING CODES

**To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- N/A

## REFERENCES


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## POLICY HISTORY

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