ALASKA MEDICAID
Prior Authorization Criteria

Bimzelx®
(bimekizumab-bkzx)

FDA INDICATIONS AND USAGE[1]

Bimzelx® is a humanized interleukin-17A and F antagonist indicated for the treatment of

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

APPROVAL CRITERIA[1,2,3,4,5,6,7]

Plaque Psoriasis

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a dermatologist **AND**;
3. Patient has the diagnosis of moderate to severe plaque psoriasis and one or more of the following applies:
    a. Body Surface Area (BSA) ≥ 3% involved
    b. Psoriasis Area and Severity Index (PASI) score ≥ 10
    c. Concomitant severe psoriatic arthritis **AND**;
4. Patient has tried and failed or has a documented clinical contraindication a TNF antagonist and at least one other therapy to include at least one topical agent **AND**;
5. Prescriber has provided all the following baseline information:
    a. PASI score
    b. Current patient weight.
    c. Liver function enzymes, alkaline phosphatase, and bilirubin.

Psoriatic Arthritis

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with a dermatologist or rheumatologist **AND**;
3. Patient has a CASPAR criteria score of ≥ 3 (or equivalent) **AND**;
4. Patient has tried and failed a preferred TNF antagonist and at least one conventional agent (e.g. methotrexate, sulfasalazine, etc.) for at least three months.
5. Prescriber has provided all the following baseline information:
    a. CASPAR score (or equivalent)
    b. Current patient weight.
    c. Liver function enzymes, alkaline phosphatase, and bilirubin.

Non-radiographic Axial Spondyloarthritis

1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with a rheumatologist **AND**;
3. Patient has objective signs of inflammation, including at least one of the following:

   a) C-reactive protein [CRP] levels above the upper limit of normal
   b) Sacroiliitis on magnetic resonance imaging (MRI), indicative of inflammatory disease but without definitive radiographic evidence of structural damage on sacroiliac joints **AND;**
4. Patient has tried and failed or has a documented clinical contraindication to 2 different NSAIDs (e.g., ibuprofen, naproxen, meloxicam, etc.) for at least three months at maximal recommended or tolerated anti-inflammatory doses **AND;**
5. Patient has tried and failed or has a documented clinical contraindication to a preferred TNF antagonist for at least three months.

Ankylosing Spondylitis
1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with a rheumatologist **AND**;
3. Patient BASDAI score ≥4 with spinal pain component score ≥4 **AND**;
4. Patient has tried and failed or has a documented clinical contraindication to 2 different NSAIDs (e.g., ibuprofen, naproxen, meloxicam, etc.) for at least three months at maximal recommended or tolerated anti-inflammatory doses **AND;**
5. Patient has tried and failed or has a documented clinical contraindication to a preferred TNF antagonist for at least three months.

Hidradenitis Suppurativa
1. Patient meets FDA labeled age **AND;**
2. Prescribed by or in consultation with a dermatologist **AND**;
3. Patient has the diagnosis of moderate to severe hidradenitis suppurativa Hurley Stage II or Stage III **AND**;
4. Patient has tried and failed or has a documented clinical contraindication to both of the following for a minimum of 90 days:
   a. Oral antibiotic used for the treatment of hidradenitis suppurativa (e.g. clindamycin, metronidazole, rifampin, tetracyclines, etc.) **AND**
   b. Preferred TNF antagonist

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient has an active clinically significant infection **OR**;
3. Patient is receiving another biologic response modifying agent **OR**;
4. Patient has an active inflammatory bowel disease (IBD).

CAUTIONS[1]

- Bimzelx may be associated with an increased risk of suicidal ideation and behavior
- Avoid use in patients with active tuberculosis. Initiate treatment of latent tuberculosis prior to Bimzelx treatment
- Monitor liver function tests, alkaline phosphatase, and billirubin while undergoing Bimzelx treatment.
- Live vaccines are not recommended while undergoing Bimzelx treatment.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT[1]

- PSO: One 320mg prefilled syringe or autoinjector per 28 days
- PsA, nr-axSpA, AS: One 160mg prefilled syringe or autoinjector per 28 days
- HS:
    - Initial: One 320mg prefilled syringe or autoinjector at Week 0, 2, 4, 6, 8, 10, 12, 14, 16
    - Maintenance: One 320mg prefilled syringe or autoinjector per 28 days

REFERENCES / FOOTNOTES:

1. Bimzelx [prescribing information]. Smyrna, GA; UCB; November 2024.
2. Gordon KB, Foley P, Krueger JG, et al. Bimekizumab efficacy and safety in moderate to severe plaque psoriasis (BE READY): a multicentre, double-blind, placebo-controlled, randomised withdrawal phase 3 trial. Lancet. 2021; 397(10273):475-486. DOI: 10.1016/S0140-6736(21)00126-4.
3. Reich K, Papp KA, Blauvelt A, et al. Bimekizumab versus ustekinumab for the treatment of moderate to severe plaque psoriasis (BE VIVID): efficacy and safety from a 52-week, multicentre, double-blind, active comparator and placebo controlled phase 3 trial. Lancet. 2021; 397(10273):487-498.
4. Warren RB, Blauvelt A, Bagel J, et al. Bimekizumab versus adalimumab in plaque psoriasis. N Engl J Med 2021; 385:130-141.
5. van der Heijde D, Deodhar A, Baraliakos X, et al. Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomised controlled trials. Annals of the Rheumatic Diseases 2023;82:515-526.
6. Baraliakos X, Deodhar A, Dougados M, et al. Safety and Efficacy of Bimekizumab in Patients With Active Ankylosing Spondylitis: Three-Year Results From a Phase IIb Randomized Controlled Trial and Its Open-Label Extension Study. Arthritis Rheumatol. 2022 Dec;74(12):1943-1958.
7. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: a publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019;81(1):91-101