

ALASKA MEDICAID
Prior Authorization Criteria

Bimzelx™
(bimekizumab-bkzx)

FDA INDICATIONS AND USAGE¹

Bimzelx is a humanized interleukin-17A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

APPROVAL CRITERIA^{1,2,3,4}

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) \geq 3% involved
 - b. Psoriasis Area and Severity Index (PASI) score \geq 10
 - c. Concomitant severe psoriatic arthritis **AND**;
4. Patient has tried and failed 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.

DENIAL CRITERIA¹

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).

CAUTIONS¹

- 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 bilirubin 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

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QUANTITY LIMIT¹

- 2 prefilled syringes or autoinjectors (160mg/ml) per 28 days

REFERENCES / FOOTNOTES:

1. Bimzelx [prescribing information]. Smyrna, GA; UCB; October 2023.
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. DOI: 10.1016/S0140-6736(21)00125-2.17;13(1):80. DOI: 10.1186/s13195-021-00813-8
4. Warren RB, Blauvelt A, Bagel J, et al. Bimekizumab versus adalimumab in plaque psoriasis. *N Engl J Med* 2021; 385:130-141. DOI: 10.1056/NEJMoa2102388.