

Commercial PA Criteria Effective: February 8, 2024

Prior Authorization: Bimzelx

Products Affected: Bimzelx® (Bimekizumab-bkzx subcutaneous injection)

<u>Medication Description</u>: Bimzelx, an interleukin (IL)-17A and 17F blocker, is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Covered Uses:

1. Moderate to severe plaque psoriasis

Exclusion Criteria:

- 1. Concurrent use with other Biologics or DMARDs
- 2. Inflammatory Bowel Disease (i.e., Crohn's disease, ulcerative colitis)

Required Medical Information:

- 1. Diagnosis
- 2. Previous therapies tried and failed

Prescriber Restriction:

1. The medication is prescribed by or in consultation with a dermatologist

Age Restriction: 18 years of age or older

Coverage Duration:

Initial: 3 months Continuation: 1 year

Other Criteria: Initial Approval Criteria

1. Plaque Psoriasis

Initial Therapy. Approve if the patient meets the following criteria (A AND B)

- A. Patient meets ONE of the following conditions (i OR ii):
 - i. Patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; **OR**

<u>Note</u>: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.

ii. Patient has a contraindication to methotrexate, as determined by the prescriber; AND



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B. Patient must have a trial and documented failure of, or intolerance to, **TWO** of the following medications

<u>Note</u>: Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumabadbm, adalimumab-fkjp, adalimumab-aaty, adalimumab-ryvk, Simlandi, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as **ONE** product.

Plaque Psoriasis (TWO of the following)				
Enbrel				
Adalimumab Product				
Otezla				
Skyrizi SC				
Stelara SC				
Sotyktu				
Taltz				
Tremfya				

Continuation

- A. Patient has been established on therapy for at least 90 days; AND Note: A patient who has received < 90 days of therapy or who is restarting therapy is reviewed under Initial Therapy criteria.
- B. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Bimzelx) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
- *C.* Compared with baseline (prior to receiving Bimzelx), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

References:

1. Bimzelx[®] subcutaneous injection [prescribing information]. Smyrna, GA: UCB; October 2023

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/08/2024
2	Update	Updated Note: A trial of multiple adalimumab products counts as ONE product. To include; Examples of adalimumab products include Humira, Abrilada, adalimumab-adaz, adalimumab-adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry. A trial of multiple adalimumab products counts as ONE product. Renewal criteria addition of patient established for at least 3 months of therapy.	Other Criteria Renewal Criteria	5/17/2024

3	Update	For Plaque Psoriasis, Simlandi and adalimumab-ryvk were added to the list of Preferred adalimumab products that may have been tried prior to Bimzelx. Sotyktu was added as a product that may have been tried prior to Bimzelx. Documentation of previous trials remains required.	Other Criteria	6/7/2024
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June 2024