UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2334-2
Program	Prior Authorization/Medical Necessity
Medication	Bimzelx® (bimekizumab-bkzx)* *Bimzelx is excluded from coverage for the majority of our benefits
P&T Approval Date	4/2024, 6/2024
Effective Date	9/1/2024

1. Background:
Bimzelx (bimekizumab-bkzx) 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.

2. Coverage Criteria[a]:

A. Authorization

1. **Bimzelx** will be approved based on the following criterion:

a. Submission of medical records (e.g., chart notes, laboratory values) documenting **all** of the following:

(1) Diagnosis of moderate to severe plaque psoriasis

-AND-

(2) **One** of the following:

(a) **All** of the following:

i. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

ii. History of failure to **one** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

-AND-

iii. History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), adalimumab, Orencia (abatacept), Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Otezla (apremilast)]

-AND-

(3) History of failure, contraindication, or intolerance to **three** of the following (document drug, date, and duration of trial):

(a) Cimzia (certolizumab)
(b) Enbrel (etanercept)
(c) One of the preferred adalimumab products[c]
(d) Skyrizi (risankizumab)
(e) Stelara (ustekinumab)
(f) Tremfya (guselkumab)
(g) Otezla (apremilast)

-AND-

(4) **One** of the following: (document date and duration of trial)

(a) History of 6 month trial of Cosentyx (secukinumab) with moderate clinical response yet residual disease activity[b]

-OR-

(b) **Both** of the following:

i. History of intolerance or adverse event to Cosentyx
ii. Physician attests that in their clinical opinion the same intolerance or adverse event would not be expected to occur with Bimzelx

-AND-

(5) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya

(tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(6) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.
[c] For a list of preferred adalimumab products please reference drug coverage tools.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Exclusion: Bimzelx is excluded from coverage for the majority of our benefits
- Supply limits may be in place.

4. Reference:

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; October 2023
2. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
3. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72.

Program	Prior Authorization/Medical Necessity - Bimzelx (bimekizumab-bkzx)
Change Control	
4/2024	New program
6/2024	Added requirement for medical record submission for all authorization criteria. Updated trial/failure criteria for Cosentyx. Removed reauthorization criteria.