UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2334-4
Program	Prior Authorization/Medical Necessity
Medication	Bimzelx® (bimekizumab-bkzx)
P&T Approval Date	4/2024, 6/2024, 10/2024, 1/2025
Effective Date	4/1/2025

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, adults with active psoriatic arthritis, adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation adults with active ankylosing spondylitis, and adults with moderate to severe hidradenitis suppurativa.

2. Coverage Criteria[a]:

A. Plaque Psoriasis (PsO)

1. **Initial Authorization**

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

(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) **One** of the following:

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

i. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
ii. Cimzia (certolizumab)
iii. Cosentyx (secukinumab)
iv. Enbrel (etanercept)
v. Skyrizi (risankizumab)
vi. Sotyktu (deucravacitinib)
vii. Stelara (ustekinumab)
viii. Tremfya (guselkumab)

-OR-

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

i. Patient is currently on Bimzelx therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a UCB sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Bimzelx*

-AND-

(4) 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-

(5) Prescribed by or in consultation with a dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a UCB sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bimzelx** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Bimzelx therapy

-AND-

(2) 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)]

Authorization will be issued for 12 months.

B. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. Bimzelx will be approved based on the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

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

(a) History of failure to a 3 month trial of methotrexate at 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 psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Cosentyx (secukinumab), adalimumab, Simponi (golimumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Otezla (apremilast), Skyrizi (risankizumab), Rinvoq (upadacitinib), Enbrel (etanercept)]

-AND-

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

(a) History of failure, contraindication, or intolerance to **two** of the following preferred products (document drug, date, and duration of trial):

i. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
ii. Cimzia (certolizumab)
iii. Cosentyx (secukinumab)
iv. Enbrel (etanercept)
v. Rinvoq (upadacitinib)
vi. Simponi (golimumab)
vii. Skyrizi (risankizumab)
viii. Stelara (ustekinumab)
ix. Tremfya (guselkumab)
x. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

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

i. Patient is currently on Bimzelx therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a UCB sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Bimzelx*

-AND-

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

-AND-

(5) Prescribed by or in consultation with **one** of the following:

(a) Rheumatologist
(b) Dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a UCB sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bimzelx** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Bimzelx therapy

-AND-

(2) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis (AS)

1. **Initial Authorization**

a. **Bimzelx** will be approved based on the following criteria:

(1) Diagnosis of active ankylosing spondylitis

-AND-

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

(a) History of failure to two NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., adalimumab, Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Enbrel (etanercept)].

-AND-

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

(a) History of failure, contraindication, or intolerance to **two** of the following preferred products (document drug, date, and duration of trial):

i. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
ii. Cimzia (certolizumab)
iii. Cosentyx (secukinumab)
iv. Enbrel (etanercept)
v. Rinvoq (upadacitinib)
vi. Simponi (golimumab)
vii. Xeljanz/Xeljanz XR (tofacitinib)

-OR-

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

i. Patient is currently on Bimzelx therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a UCB sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Bimzelx*

-AND-

(4) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Cosentyx

(secukinumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(5) Prescribed by or in consultation with a rheumatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a UCB sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bimzelx** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Bimzelx therapy

-AND-

(1) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

1. **Initial Authorization**

a. **Bimzelx** will be approved based on the following criteria:

(1) Diagnosis of active non-radiographic axial spondyloarthritis

-AND-

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

(a) History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of non-radiographic axial spondyloarthritis as

documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g. Cimzia (certolizumab), Cosentyx (secukinumab), Rinvoq (upadacitinib)].

-AND-

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

(a) History of failure, contraindication, or intolerance to **two** of the following preferred products (document drug, date, and duration of trial):

i. Cimzia (certolizumab)
ii. Cosentyx (secukinumab)
iii. Rinvoq (upadacitinib)

-OR-

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

i. Patient is currently on Bimzelx therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a UCB sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Bimzelx*

-AND-

(4) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Cosentyx (secukinumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-AND-

(5) Prescribed by or in consultation with a rheumatologist

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a UCB sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bimzelx** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Bimzelx therapy

-AND-

(1) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

E. Hidradenitis Suppurativa (HS)

1. **Initial Authorization**

a. **Bimzelx** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

-AND-

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

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

i. History of failure to at least **one** oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

ii. History of failure, contraindication, or intolerance to **both** of the following preferred products (document drug, date, and duration of trial):
- One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
- Cosentyx (secukinumab)

-OR-

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

i. Patient is currently on Bimzelx therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a UCB sponsored program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Bimzelx*

-AND-

(3) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]

-AND-

(4) Prescribed by or in consultation with a dermatologist

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from a UCB sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Bimzelx** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Bimzelx therapy.

-AND-

(2) Patient is not receiving Bimzelx in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Cosentyx (secukinumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Simponi (golimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib)]

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.

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.
- Supply limits may be in place.

4. Reference:

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; November 2024
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.
10/2024	Updated step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote. Added Sotyktu as step therapy agent for PsO. Changed number of step requirement to two and added continutation of care if already on Bimzelx. Removed notation of exclusion. Added coverage criteria for PsA, AS, and nr-axSpA. Updated background and reference.
1/2025	Added criteria for hidradenitis suppurativa. Updated background and reference.