UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1437-3
Program	Prior Authorization/Notification
Medication	Bimzelx® (bimekizumab-bkzx)
P&T Approval Date	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 both of the following criteria:

      (1) Diagnosis of moderate to severe plaque psoriasis

      -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.

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

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(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 **both** of the following criteria:

      (1) Diagnosis of active psoriatic arthritis

      -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.

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 **both** of the following criteria:

      (1) Diagnosis of active ankylosing spondylitis

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-AND-

(2) 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.

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

   Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis (nr-axSpA)

1. **Initial Authorization**

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

      (1) Diagnosis of non-radiographic axial spondyloarthritis

      -AND-

      (2) 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.

2. **Reauthorization**

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

      (1) Documentation of positive clinical response to Bimzelx therapy

      -AND-

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(2) 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. <u>Hidradenitis Suppurativa (HS)</u>

1. **<u>Initial Authorization</u>**

a. **Bimzelx** will be approved based on **<u>both</u>** of the following criteria:

(1) Diagnosis of moderate to severe hidradenitis suppurativa

-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.

2. **<u>Reauthorization</u>**

a. **Bimzelx** will be approved based on **<u>both</u>** 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.

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)

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and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or step therapy may be in place.

4. Reference:

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; November 2024

Program	Prior Authorization/Notification - Bimzelx (bimekizumab-bkzx)
Change Control	
4/2024	New program
10/2024	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.

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