UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 3181-3
Program	Step Therapy
Medications	Bimzelx® (bimekizumab-bkzx)
P&T Approval Date	4/2024, 10/2024, 1/2025
Effective Date	4/1/2025

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try preferred products before providing coverage for Bimzelx. Infused medications for any of the conditions referenced in this document are not part of the criteria.

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.

Adalimumab is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA, reducing signs and symptoms in adult patients with active AS, the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate, and the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

Cimzia® (certolizumab) is indicated for the treatment of adult patients with active PsA, treatment of adults with active ankylosing spondylitis (SpA), treatment of adults with moderate to severe PsO who are candidates for systemic therapy or phototherapy, and for the treatment of adults with non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation.

Simponi® (golimumab) is indicated for the treatment of adult patients with active PsA, alone or in combination with methotrexate and the treatment of adult patients with active AS.

Rinvoq® (upadacitinib) is indicated for the treatment of adults with active PsA who have an inadequate response or intolerance to one or more TNF blockers, adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers, and adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, biologic therapies for UC, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Xeljanz/Xeljanz XR® (tofacitinib) is indicated for the treatment of adult patients with active PsA and AS who have had an inadequate response or intolerance to one or more TNF blockers. The use of Xeljanz/Xeljanz XR/Xeljanz Oral Solution in combination with biologic DMARDs, biologic therapies for UC or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Stelara® (ustekinumab) is indicated for the treatment of patients 6 years of age or older with moderate to severe PsO who are candidates for phototherapy or systemic therapy and adult patients with active PsA, alone or in combination with methotrexate.

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate-to-severe PsO who are candidates for systemic therapy or phototherapy and for the treatment of adult patients with active PsA.

Skyrizi® (risankizumab-rzaa) is indicated for the treatment of moderate to severe PsO in adults who are candidates for systemic therapy or phototherapy and active PsA in adults.

Cosentyx® (secukinumab) is indicated for the treatment of moderate to severe PsO in patients 6 years and older who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of active PsA in patients 2 years of age and older, adults with active AS or non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and adults with moderate to severe hidradenitis suppurativa.

Enbrel (etanercept) is indicated for the treatment of psoriatic arthritis (PsA), ankylosing spondylitis (AS), and plaque psoriasis (PsO) in patients 4 years or older.

Sotyktu (deucravacitinib) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. <u>Plaque Psoriasis</u>

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

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

      (a) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
      (b) Cimzia (certolizumab)
      (c) Cosentyx (secukinumab)
      (d) Enbrel (etanercept)
      (e) Skyrizi (risankizumab)
      (f) Sotyktu (deucravacitinib)
      (g) Stelara (ustekinumab)
      (h) Tremfya (guselkumab)

Authorization will be issued for 12 months.

B. <u>Psoriatic Arthritis</u>

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

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

(1) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
(2) Cimzia (certolizumab)
(3) Cosentyx (secukinumab)
(4) Enbrel (etanercept)
(5) Rinvoq (upadacitinib)
(6) Simponi (golimumab)
(7) Skyrizi (risankizumab)
(8) Stelara (ustekinumab)
(9) Tremfya (guselkumab)
(10) Xeljanz/Xeljanz XR (tofacitinib)

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis

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

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

(1) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
(2) Cimzia (certolizumab)
(3) Cosentyx (secukinumab)
(4) Enbrel (etanercept)
(5) Rinvoq (upadacitinib)
(6) Simponi (golimumab)
(7) Xeljanz/Xeljanz XR (tofacitinib)

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

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

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

(1) Cimzia (certolizumab)
(2) Cosentyx (secukinumab)
(3) Rinvoq (upadacitinib)

Authorization will be issued for 12 months.

E. Hidradenitis Suppurativa (HS)

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

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

(1) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
(2) Cosentyx (secukinumab)

Authorization will be issued for 12 months.

F. Other Diagnoses

1. **Bimzelx** will be approved

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) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity, Supply limits and/or Notification may be in place.

4. References:

1. Bimzelx [package insert]. Smyrna, GA: UCB, Inc.; November 2024
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2022.
4. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; December 2023.
5. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; November 2023.
6. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; September 2022.
7. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; January 2024.
8. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; October 2023.
9. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2023.
10. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022

Program	Step Therapy - Bimzelx (bimekizumab-bkzx)
Change Control	
4/2024	New program.
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 and decreased required step agents to two. Removed exclusion notation.

	Added step therapy criteria for PsA, AS, and nr-axSpA. Updated background and reference.
1/2025	Added step therapy criteria for hidradenitis suppurativa. Updated background and reference.