Clinical Policy: Bimekizumab-bkzx (Bimzelx)

Reference Number: PA.CHIP.PHAR.660
Effective Date: 01/2026
Last Review Date: 10/2025

Description

Bimekizumab-bkzx (Bimzelx®) is a humanized interleukin-17A and F antagonist.

FDA Approved Indication(s)

Bimzelx is indicated for the treatment of:

- Moderate to severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy.
- Adult patients with active psoriatic arthritis (PsA).
- Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
- Adult patients with active ankylosing spondylitis (AS).
- Adult patients with moderate to severe hidradenitis suppurativa (HS).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that the member has met all approval criteria.

It is the policy of PA Health & Wellness® that Bimekizumab-bkzx (Bimzelx) is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Plaque Psoriasis (must meet all)**:**

1. Diagnosis of moderate-to-severe PsO as evidenced by involvement of one of the following (a or b):
   a. ≥ 3% of total body surface area;
   b. Hands, feet, scalp, face, or genital area;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b, or c):
   a. Failure of a ≥ 3 consecutive month trial of methotrexate (MTX) at up to maximally indicated doses;
   b. Member has intolerance or contraindication to MTX (*see Appendix D*), and failure of a ≥ 3 consecutive month trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   c. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
5. Member meets ONE of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a or b, *see Appendix D*):
   a. Failure of a ≥ 3 consecutive month trial of one* adalimumab product (e.g., *Hadlima™, Simlandi®, Yusimry™, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*);

b. History of failure of two TNF blockers;
**Prior authorization may be required for adalimumab product*

6. Failure of a ≥ 3 consecutive month trial of one ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*), unless clinically significant adverse effects are experienced or all are contraindicated;
**Prior authorization may be required for ustekinumab products*
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed one of the following (a or b):
a. 320 mg at weeks 0, 4, 8, 12, and 16, then every 8 weeks;
b. Weight ≥ 120 kg: 320 mg at weeks 0, 4, 8, 12, and 16, then every 4 weeks.

Approval duration: 6 months

B. Psoriatic Arthritis (must meet all)**:**

1. Diagnosis of PsA;
2. Prescribed by or in consultation with a dermatologist or rheumatologist;
3. Age ≥ 18 years;
4. Failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d, *see Appendix D*):
a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
b. Otezla®;
c. One ustekinumab product (e.g. *Otulfi®, Pyzchiva® (branded), Steqeyma®, Yesintek™ are preferred*);
d. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
**Prior authorization may be required for adalimumab products, Otezla, ustekinumab products, and Xeljanz/Xeljanz XR*
5. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
6. Dose does not exceed one of the following (a or b):
a. PsA alone: 160 mg every 4 weeks;
b. PsA with coexistent PsO (i or ii):
- 320 mg at weeks 0, 4, 8, 12, and 16, then every 8 weeks;
- Weight ≥ 120 kg: 320 mg at weeks 0, 4, 8, 12, and 16, then every 4 weeks.

Approval duration: 6 months

C. Axial Spondylitis (must meet all)**:**

1. Diagnosis of AS or nr-axSpA;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for ≥ 4 weeks unless clinically significant adverse effects are experienced or all are contraindicated;

5. For AS, failure of ALL* of the following, each used for ≥ 3 consecutive months, unless clinically significant adverse effects are experienced or all are contraindicated (a and b, *see Appendix D*):
   a. One adalimumab product (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless the member has had a history of failure of two TNF blockers;
   b. If member has not responded or is intolerant to one or more TNF blockers, Xeljanz®/Xeljanz XR®, unless member has cardiovascular risk and benefits do not outweigh the risk of treatment;
   **Prior authorization may be required for adalimumab products and Xeljanz/Xeljanz XR*
6. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
7. Dose does not exceed 160 mg every 4 weeks.
   Approval duration: 6 months

D. Hidradenitis Suppurativa (must meet all)**:**
1. Diagnosis of HS;
2. Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist;
3. Age ≥ 18 years;
4. Documentation of Hurley stage II or stage III (*see Appendix D*);
5. Failure of one adalimumab product* (e.g., *Hadlima, Simlandi, Yusimry, adalimumab-aaty, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp are preferred*), unless member meets one of the following (a or b):
   a. History of failure of two TNF blockers;
   b. Contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for adalimumab products*
6. Failure of at least TWO of the following, each tried for ≥ 3 consecutive months from different therapeutic classes, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:
   a. Systemic antibiotic therapy (e.g., clindamycin, minocycline, doxycycline, rifampin);
   b. Oral retinoids (e.g., acitretin, isotretinoin);
   c. Hormonal treatment (e.g., estrogen-containing combined oral contraceptives, spironolactone);
7. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
8. Dose does not exceed 320 mg at weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks.
   Approval duration: 6 months

E. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or

b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

I. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Fidelis benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member meets one of the following (a or b):
   a. For HS: At least a 25% reduction in inflammatory nodules and abscesses;
   b. For all other indications: Member is responding positively to therapy;
3. Member does not have combination use with biological disease-modifying antirheumatic drugs or Janus kinase inhibitors (*see Section III: Diagnoses/Indications for which coverage is NOT authorized*);
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. PsA, AS, nr-axSpA: 160 mg every 4 weeks;
   b. PsO (with or without coexistent PsA) (i or ii):
      i. 320 mg every 8 weeks;
      ii. Weight ≥ 120 kg: 320 mg every 4 weeks;
   c. HS: 320 mg every 4 weeks.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

B. Combination use with biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Remicade® and its biosimilars, Simponi®], interleukin agents [e.g., Actemra® (IL-6RA) and its biosimilars, Arcalyst® (IL-1 blocker), Bimzelx® (IL-17A and F antagonist), Cosentyx® (IL-17A inhibitor), Ilaris® (IL-1 blocker), Ilumya™ (IL-23 inhibitor), Kevzara® (IL-6RA), Kineret® (IL-1RA), Omvoh™ (IL-23 antagonist), Siliq™ (IL-17RA), Skyrizi™ (IL-23 inhibitor), Spevigo® (IL-36 antagonist), Stelara® (IL-12/23 inhibitor) and its biosimilars, Taltz® (IL-17A inhibitor), Tremfya® (IL-23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Cibinqo™, Olumiant™, Rinvoq™, Xeljanz®/Xeljanz® XR,], anti-CD20 monoclonal antibodies [Rituxan® and its biosimilars], selective co-stimulation modulators [Orencia®], integrin receptor antagonists [Entyvio®], tyrosine kinase 2 inhibitors [Sotyktu™], and sphingosine 1-phosphate receptor modulator [Velsipity™] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AS: ankylosing spondylitis
BSA: body surface area
FDA: Food and Drug Administration
HS: hidradenitis suppurativa
MTX: methotrexate
nr-axSpA: non-radiographic axial spondyloarthritis
PsA: psoriatic arthritis
PsO: plaque psoriasis

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
acitretin (Soriatane®)	**PsO** 25 or 50 mg	50 mg/day
cyclosporine (Sandimmune®, Neoral®)	**PsO** 2.5 mg/kg/day PO divided BID	4 mg/kg/day
clindamycin (Cleocin®) + rifampin (Rifadin®)	**HS*** clindamycin 300 mg PO BID and rifampin 300 mg PO BID	clindamycin: 600 mg/day rifampin: 600 mg/day
doxycycline (Acticlate®)	**HS*** 50 – 100 mg PO BID	300 mg/day
Hormonal agents (e.g., estrogen-containing combined oral contraceptives, spironolactone)	**HS** varies	varies
isotretinoin (Absorica®, Amnesteem®, Claravis®, Myorisan®, Zenatane®)	**HS** varies	varies
methotrexate (Rheumatrex®)	**PsO** 10 – 25 mg/week PO or 2.5 mg PO Q12 hr for 3 doses/week	30 mg/week
minocycline (Minocin®)	**HS*** 50 – 100 mg PO BID	200 mg/day
Hadlima (adalimumab-bwwd), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), adalimumab-aaty (Yuflyma®), adalimumab-adaz (Hyrimoz®), adalimumab-fkjp (Hulio®), adalimumab-adbm (Cyltezo®)	**AS, PsA** 40 mg SC every other week **PsO** <u>Initial dose:</u> 80 mg SC <u>Maintenance dose:</u> 40 mg SC every other week starting one week after initial dose **HS** <u>Initial dose:</u> 160 mg SC on day 1, then 80 mg SC on Day 15 <u>Maintenance dose:</u> 40 mg SC every week or 80 mg SC every other week starting on Day 29	**AS, PsA, PsO:** 40 mg every other week **HS:** 40 mg/week
Otezla® (apremilast)	**PsA** <u>Initial dose:</u>	60 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Day 1: 10 mg PO QAM Day 2: 10 mg PO QAM and 10 mg PO QPM Day 3: 10 mg PO QAM and 20 mg PO QPM Day 4: 20 mg PO QAM and 20 mg PO QPM Day 5: 20 mg PO QAM and 30 mg PO QPM <u>Maintenance dose:</u> Day 6 and thereafter: 30 mg PO BID	
Otulfi® (ustekinumab-aauz), Pyzchiva® (ustekinumab-ttwe), Steqeyma® (ustekinumab-stba), Yesintek™ (ustekinumab-kfce)	**PsO** Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* Weight ≤ 100 kg: 45 mg Weight > 100 kg: 90 mg *Pediatrics (age 6 years to 17 years):* **Otulfi, Pyzchiva, Yesintek:** Weight < 60 kg: 0.75 mg/kg **Otulfi, Pyzchiva, Steqeyma, Yesintek:** Weight 60 to 100 kg: 45 mg Weight > 100 kg: 90 mg **PsA** Weight based dosing SC at weeks 0 and 4, followed by maintenance dose every 12 weeks *Adult:* 45 mg SC at weeks 0 and 4, followed by 45 mg every 12 weeks *Pediatrics (age 6 years to 17 years):* Weight based dosing SC at weeks 0 and 4, then every 12 weeks thereafter **Otulfi, Pyzchiva, Yesintek:**	PsO: 90 every 12 weeks PsA: 45 mg every 12 weeks

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Weight < 60 kg: 0.75 mg/kg **Otulfi, Pyzchiva, Steqeyma, Yesintek:** Weight ≥ 60 kg: 45 mg	
Taltz® (ixekizumab)	**AS, nr-axSpA, PsA** Initial dose: 160 mg (two 80 mg injections) SC at week 0 Maintenance dose: 80 mg SC every 4 weeks **PsO** Initial dose: 160 mg (two 80 mg injections) SC at Week 0, then 80 mg SC at Weeks 2, 4, 6, 8, 10, and 12 Maintenance dose: 80 mg SC every 4 weeks	80 mg every 4 weeks
Xeljanz® (tofacitinib)	**AS, PsA** 5 mg PO BID	10 mg/day
Xeljanz XR® (tofacitinib extended-release)	**AS, PsA** 11 mg PO QD	11 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- Definition of failure of MTX or DMARDs
  - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
  - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- TNF blockers:
  - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®, Zymfentra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

- HS:
  - HS is sometimes referred to as: "acne inversa, acne conglobata, apocrine acne, apocrinitis, Fox-den disease, hidradenitis axillaris, HS, pyodermia sinifica fistulans, Velpeau's disease, and Verneuil's disease."
  - In HS, Hurley stages are used to determine severity of disease. Hurley stage II indicates moderate disease, and is characterized by recurrent abscesses, with sinus tracts and scarring, presenting as single or multiple widely separated lesions. Hurley stage III indicates severe disease, and is characterized by diffuse or near-diffuse involvement presenting as multiple interconnected tracts and abscesses across an entire area.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PsO (with or without coexistent PsA)	320 mg (given as 2 SC injections of 160 mg each) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter For patients weighing ≥ 120 kg, consider a dosage of 320 mg every 4 weeks after Week 16.	320 mg/8 weeks (after loading doses) Weight ≥ 120 kg: 320 mg/4 weeks (after loading doses)
PsA	160 mg SC every 4 weeks	160 mg/4 weeks
AS	160 mg SC every 4 weeks	160 mg/4 weeks
nr-axSpA	160 mg SC every 4 weeks	160 mg/4 weeks
HS	320 mg SC at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter	320 mg/4 weeks (after loading doses)

V. Product Availability

- Single-dose prefilled syringes: 160 mg/mL, 320 mg/2 mL
- Single-dose prefilled autoinjectors: 160 mg/mL, 320 mg/2 mL

VI. References

1. Bimzelx Prescriber Information. Smyrna, GA: UCB, Inc; November 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761151s010lbl.pdf. Accessed February 28, 2025.
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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 Apr;80(4):1029-1072. doi: 10.1016/j.jaad.2018.11.057.
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9. Hendricks A, J, Hsiao J, L, Lowes M, A, Shi V, Y: A Comparison of International Management Guidelines for Hidradenitis Suppurativa. Dermatology 2021;237:81-96. doi: 10.1159/000503605.
10. Dagenet CB, Lee KH, Fragoso NM et al. Approach to the patient with hidradenitis suppurativa: Evaluating severity to guide therapy. *J Am Acad Dermatol*. 2024; 91:S22-6. Doi:10.1016/j.jaad.20024.09.007.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to- date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Reviews, Revisions, and Approvals	Date
Policy created	10/2025