PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Bimzelx Prior Authorization Policy
- Bimzelx® (bimekizumab-bkzx subcutaneous injection – UCB)

REVIEW DATE: 10/02/2024; selected revision 12/04/2024

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Bimzelx, an interleukin (IL)-17A and IL-17F blocker, is indicated for the following uses:[1]
- **Ankylosing spondylitis**, in adults with active disease.
- **Hidradentitis suppurativa**, in adults with moderate to severe disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.
- **Psoriatic arthritis**, in adults with active disease.
- **Plaque psoriasis**, in adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.

In the pivotal trial for non-radiographic axial spondyloarthritis, patients were required to have objective signs of inflammation, indicated by elevated C-reactive protein and/or sacroiliitis on magnetic resonance imaging.

Guidelines

Bimzelx is not addressed in available guidelines.
- **Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondylitis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[2] Following primary non-response to a tumor necrosis factor inhibitor (TNFi), either Cosentyx® (secukinumab subcutaneous injection) or Taltz® (ixekizumab subcutaneous injection) is recommended; however, if the patient is a

secondary non-responder, a second TNFi is recommended over switching out of the class. In patients with a contraindication to a TNFi, use of an IL blocker is recommended over traditional oral agents such as methotrexate or sulfasalazine.

- **Hidradenitis Suppurativa:** North American based hidradenitis suppurativa guidelines have not been updated to address Bimzlex.[3] Clinical management guidelines from the US and Canadian Hidradenitis Suppurativa Foundations (2019) note that for acute lesions of all stages, antiseptic washes, short-term oral steroids, and interlesional steroids are among the recommendations. Systemic antibiotics have been a mainstay of treatment. Adalimumab (level A strength of recommendation, level 1 evidence) is recommended to improve disease severity and quality of life in moderate to severe disease. German guidelines for hidradenitis suppurativa (2024) include recommendations for use of adalimumab and Cosentyx (both "shall be recommended") and Bimzelx ("should be recommended").[4] Off-label use of other biologics is also listed, but these generally have a lower level of recommendation ("may be considered").
- **Psoriatic Arthritis:** Guidelines from ACR (2019) recommend TNFis over other biologics for use in treatment-naïve patients with psoriatic arthritis and in those who were previously treated with an oral therapy.[5]
- **Plaque Psoriasis:** Guidelines for the treatment of psoriasis with biologics from the American Academy of Dermatologists and National Psoriasis Foundation (2019) list the approved biologics that may be used as monotherapy for adults with moderate to severe disease.[6]

Safety
There is a Warning/Precaution that Bimzelx may increase the risk of suicidal ideation and behavior (SIB).[1] Prescribers should weigh the potential risks and benefits before using Bimzelx in patients with a history of severe depression or SIB. Prescribers should also re-evaluate the risks and benefits of continuing treatment with Bimzelx if such events occur. In the pivotal trials, patients with moderately severe to severe depression, or a history of suicide attempt within the past 5 years were excluded.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Bimzelx. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Bimzelx as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Bimzelx to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Bimzelx® (bimekizumab-bkzx subcutaneous injection – UCB)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
      i. Patient is ≥ 18 years of age; AND

ii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
iii. The patient does **not** have moderately severe to severe depression; AND
iv. Within the past 5 years, the patient does **not** have a history of suicidal ideation or suicidal behavior; AND
v. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving Bimzelx. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
ii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
iii. The patient does **not** have moderately severe to severe depression; AND
iv. According to the prescriber, the patient does **not** have suicidal ideation or suicidal behavior; AND
v. Patient meets at least ONE of the following (a or b):
a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Bimzelx); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b) Compared with baseline (prior to initiating Bimzelx), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

2. Hidradenitis Suppurativa. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
i. Patient is ≥ 18 years of age; AND
ii. Patient has tried at least one other therapy; AND
Note: Examples include intralesional or oral corticosteroids (e.g., triamcinolone, prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), and isotretinoin.
iii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
iv. The patient does **not** have moderately severe to severe depression; AND
v. Within the past 5 years, the patient does **not** have a history of suicidal ideation or suicidal behavior; AND
vi. The medication is prescribed by or in consultation with a dermatologist.

B) Patient is Currently Receiving Bimzelx. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
i. Patient has been established on Bimzelx for at least 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with Bimzelx is reviewed under criterion A (Initial Therapy).
ii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND

iii. The patient does **not** have moderately severe to severe depression; AND
iv. According to the prescriber, the patient does **not** have suicidal ideation or suicidal behavior; AND
v. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Bimzelx); AND
Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index.**vi.** Compared with baseline (prior to initiating Bimzelx), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.

3. Non-Radiographic Axial Spondyloarthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):
A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
i. Patient is ≥ 18 years of age; AND
ii. Patient has objective signs of inflammation, defined as at least ONE of the following (a or b):
a) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
b) Sacroiliitis reported on magnetic resonance imaging; AND
iii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
iv. The patient does **not** have moderately severe to severe depression; AND
v. Within the past 5 years, the patient does **not** have a history of suicidal ideation or suicidal behavior; AND
vi. The medication is prescribed by or in consultation with a rheumatologist.
B) Patient is Currently Receiving Bimzelx. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
ii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
iii. The patient does **not** have moderately severe to severe depression; AND
iv. According to the prescriber, the patient does **not** have suicidal ideation or suicidal behavior; AND
v. Patient meets at least ONE of the following (a or b):
a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Bimzelx); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
b) Compared with baseline (prior to initiating Bimzelx), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

4. **Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient meets ONE of the following (a or b):
       - **a)** Patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
         Note: Examples include methotrexate, cyclosporine, or acitretin. A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for plaque psoriasis. A patient who has already tried a biologic for psoriasis is not required to "step back" and try a traditional systemic agent for psoriasis.
       - **b)** Patient has a contraindication to methotrexate, as determined by the prescriber; AND
     - **iii.** The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
     - **iv.** The patient does **not** have moderately severe to severe depression; AND
     - **v.** Within the past 5 years, the patient does **not** have a history of suicidal ideation or suicidal behavior; AND
     - **vi.** The medication is prescribed by or in consultation with a dermatologist.
   - **B)** Patient is Currently Receiving Bimzelx. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient has been established on therapy for at least 3 months; AND
       Note: A patient who has received < 3 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
     - **ii.** The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
     - **iii.** The patient does **not** have moderately severe to severe depression; AND
     - **iv.** According to the prescriber, the patient does **not** have suicidal ideation or suicidal behavior; AND
     - **v.** Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Bimzelx) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
     - **vi.** Compared with baseline (prior to receiving Bimzelx), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

5. **Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND
     - **iii.** The patient does **not** have moderately severe to severe depression; AND
     - **iv.** Within the past 5 years, the patient does **not** have a history of suicidal ideation or suicidal behavior; AND

v. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.

B) Patient is Currently Receiving Bimzelx. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).

ii. The prescriber attests that the patient has been assessed and evaluated for risks of suicidal ideation or behavior versus benefits of therapy; AND

iii. The patient does **not** have moderately severe to severe depression; AND

iv. According to the prescriber, the patient does **not** have suicidal ideation or suicidal behavior; AND

v. Patient meets at least ONE of the following (a or b):

a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Bimzelx); OR
Note: Examples of standardized measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

b) Compared with baseline (prior to initiating Bimzelx), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

- **Bimzelx® (bimekizumab-bkzx subcutaneous injection – UCB)**

is(are) considered experimental, investigational, or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use with other Biologics or with Targeted Synthetic Oral Small Molecule Drugs.** The requested medication should not be administered in combination with a biologic used for an inflammatory condition or with a targeted synthetic oral small molecule drug (see Appendix for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of controlled clinical trial data supporting additive efficacy.
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Bimzelx.

2. **Inflammatory Bowel Disease (i.e., Crohn's disease, ulcerative colitis).** Exacerbations of inflammatory bowel disease, in some cases serious, occurred in clinical trials involving patients treated with Bimzelx.[1]

REFERENCES

1. Bimzelx® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; November 2024.

2. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
3. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: a publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: topical, intralesional, and systemic medical management. *J Am Acad Dermatol*. 2019;81(1):91-101.
4. Zouboulis CC, Bechara FG, Fritz K, et al. S2k guideline for the treatment of hidradenitis suppurativa/acne inversa – short version. *Dtsch Dermatol Ges*. 2024;22(6):868-889.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the treatment of psoriatic arthritis. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.
6. 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(4):1029-1072.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/01/2023
Selected Revision	**Plaque Psoriasis:** For a patient currently taking Bimzelx, the timeframe for established on therapy was changed from 90 days to 3 months.	03/27/2024
Selected Revision	**Plaque Psoriasis:** In the Note, psoralen plus ultraviolet A light (PUVA) was removed from the examples of traditional systemic therapies. An additional Note was added that a 3-month trial of PUVA counts as a traditional systemic therapy. **Conditions Not Covered** **:** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).	09/11/2024
Early Annual Revision	**Ankylosing Spondylitis:** This condition and criteria for approval were added to the policy. **Non-Radiographic Axial Spondyloarthritis:** This condition and criteria for approval were added to the policy. **Plaque Psoriasis:** For initial approval and for a patient currently receiving Bimzelx, requirements were added that the prescriber attests the patient has been evaluated for the risks of suicidal ideation and behavior versus the benefits of therapy and that the patient does not have moderately severe to severe depression. For initial approval, a requirement was added that within the past 5 years, the patient does not have a history of suicidal ideation or suicidal behavior; for a patient currently receiving Bimzelx, a requirement was added that, according to the prescriber the patient does not have suicidal ideation or suicidal behavior. **Psoriatic Arthritis:** This condition and criteria for approval were added to the policy.	10/02/2024
Selected Revision	**Hidradenitis Suppurativa:** This newly approved condition was added to the policy.	12/04/2024

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, JIA, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	AS, HS, nr-axSpA, PsA, PsO
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC

		IV formulation: UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.