Drug Coverage Policy

Effective Date.....03/01/2024
Coverage Policy Number.....IP0603
Policy Title.....Bimzelx

Inflammatory Conditions – Bimzelx

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

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

Bimzelx is considered medically necessary when the following criteria are met:

1. **Plaque Psoriasis.** Individual meets **ALL** of the following criteria:
    A. Age 18 years or older
    B. Body Surface Area (BSA) of greater than 5% OR BSA less than 5% and there is and there is involvement of the scalp, face, the palms and soles (i.e., palmoplantar disease), or genitals
    C. Documentation of **ONE** of the following:
        i. Failure to **ONE** of the following, unless contraindicated or intolerant:

a. Topical therapy (for example, topical corticosteroids, topical vitamin D analogs, Tazorac)
b. Systemic therapy (for example, methotrexate, cyclosporine, Soriatane)
c. Phototherapy

ii. Already tried a biologic or targeted synthetic DMARD (tsDMARD) for Plaque Psoriasis

D. Medication is prescribed by, or in consultation with, a dermatologist
E. Preferred product criteria is met for the products listed in the below table(s)

Employer Plans:

Product	Criteria
Bimzelx (bimekizumab-bkzx)	**<u>Standard/Performance/Legacy Drug List Plans</u>** Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, or **Humira**) [requires prior authorization] B. **Enbrel** [requires prior authorization] C. **Otezla** [requires prior authorization] D. **Skyrizi SC** [requires prior authorization] E. **Stelara SC** [requires prior authorization] F. **Taltz** [requires prior authorization] G. **Tremfya** [requires prior authorization] **<u>Value/Advantage/Cigna Total Savings Drug List Plans</u>** Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/ Cyltezo**, **Hadlima,** or **Humira**) [requires prior authorization] B. **Enbrel** [requires prior authorization] C. **Otezla** [requires prior authorization] D. **Skyrizi SC** [requires prior authorization] E. **Stelara SC** [requires prior authorization] F. **Taltz** [requires prior authorization] G. **Tremfya** [requires prior authorization]

Individual and Family Plans:

Product	Criteria
Bimzelx (bimekizumab-bkzx)	Documentation of failure, contraindication, or intolerance to **TWO** of the following: A. **Adalimumab Product** (**adalimumab-adaz/Hyrimoz** [manufactured by Sandoz/Novartis], **adalimumab – adbm/Cyltezo**, **Hadlima**, or **Humira**) [requires prior authorization] B. **Cimzia** [requires prior authorization] C. **Cosentyx subcutaneous injection** [requires prior authorization]

Product	Criteria
	D. **Enbrel** [requires prior authorization] E. **Otezla** [requires prior authorization] F. **Skyrizi SC** [requires prior authorization] G. **Stelara SC** [requires prior authorization] H. **Tremfya** [requires prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of Bimzelx (bimekizumab-bkzx) is considered medically necessary for Plaque Psoriasis when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Bimzelx should not be administered in combination with a biologic used for an inflammatory condition (see Appendix for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMRADs has a potential for a higher rate of adverse effects and lacks controlled trial data in support of additive efficacy.

   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]

Background

OVERVIEW
Overview
Bimzelx, an interleukin (IL)-17A and IL-17F blocker, is indicated for treatment of adults with moderate to severe **plaque psoriasis** who are candidates for systemic therapy or phototherapy.[1]

Guidelines
Bimzelx is not addressed in available guidelines. 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.[3]

References

1. Bimzelx® subcutaneous injection [prescribing information]. Smyrna, GA: UCB; October 2023.
2. 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.

Revision Details

Type of Revision	Summary of Changes	Date
New		03/1/2024

The policy effective date is in force until updated or retired.

Appendix

	Mechanism of Action	Examples of Inflammatory 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, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, 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
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA, PMR
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

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-17RA	PsO
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A and IL-17F	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
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
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion, vedolizimab SC injection)	Integrin receptor antagonist	SC formulation: UC
		IV formulation: CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Sotyktu™ (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). 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; PMR – Polymyalgia rheumatic; ^ 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; TYK2 – Tyrosine kinase 2.