

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Bimzelx Prior Authorization Policy

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

REVIEW DATE: 11/01/2023

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

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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Bimzelx is recommended in those who meet the following criteria:

FDA-Approved Indication

1. Plaque Psoriasis. Approve for the duration noted if the patient meets ONE of the following criteria (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following criteria (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following conditions (a or b):

a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR

Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). 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 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 criteria (i, ii, and iii):
 - i. Patient has been established on therapy for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy is reviewed under criterion A (Initial Therapy).
 - ii. 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
 - iii. Compared with baseline (prior to receiving Bimzelx), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Bimzelx is not recommended in the following situations:

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 DMARDs has a potential for a higher rate of adverse effects and lacks controlled trial data in support of 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
3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|--------------------|-------------|
| New Policy | -- | 11/01/2023 |

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, vedolizumab 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.