

Effective: January 1, 2025

<b>Guideline Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
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**Applies to:**

**Commercial Products**

- Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988
- Tufts Health Plan Commercial products; Fax: 617-673-0988  
CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**Public Plans Products**

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

**Overview**

**Food and Drug Administration – Approved Indications**

**Bimzelx (bimekizumab-bkzx)** is a humanized interleukin-17A and F antagonist indicated for:

Disease State	
Ankylosing spondylitis	X
Hidradenitis suppurativa	X
Non-radiographic axial spondyloarthritis	X
Plaque psoriasis	X
Psoriatic arthritis	X

**Clinical Guideline Coverage Criteria**

The plan may authorize coverage of Bimzelx for Members when **ALL** of the following criteria are met:

**Ankylosing Spondylitis**

1. Documented diagnosis of ankylosing spondylitis
- AND**
2. Patient is at least 18 years of age
- AND**
3. Prescribed by or in consultation with a rheumatologist
- AND**
4. Documentation of **one (1)** of the following:
  - a. **Both** of the following:
    - i. One (1) of the following:
      1. Inadequate response or adverse reaction to one (1), or contraindication to all prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
      2. Previous treatment with a biologic agent indicated for the requested use
    - ii. Trial and failure with two (2), or contraindication to all of the following: Cimzia, Enbrel, Humira, Rinvoq, Simponi, Taltz, Xeljanz

- b. The patient is new to the plan and stable on Bimzelx and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

### Hidradenitis Suppurativa

- 1. Documented diagnosis of hidradenitis suppurativa  
**AND**
- 2. Patient is at least 18 years of age  
**AND**
- 3. Prescribed by or in consultation with a dermatologist  
**AND**
- 4. Documentation of **one (1)** of the following:
  - a. Both of the following:
    - i. Inadequate response to at least three (3) of the following conventional treatments
      - 1. Local hygiene and ordinary hygiene
      - 2. Weight reduction in patients who are obese
      - 3. Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate iv)
      - 4. Application of warm compresses with sodium chloride solution or Burow's solution
      - 5. Laser hair removal
      - 6. Cessation of cigarette smoking
      - 7. Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride
    - ii. Trial and failure with or contraindication to Humira
  - b. The patient is new to the plan and stable on Bimzelx and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

### Non-radiographic Axial Spondyloarthritis

- 1. Documented diagnosis of non-radiographic axial spondyloarthritis  
**AND**
- 2. Patient is at least 18 years of age  
**AND**
- 3. Prescribed by or in consultation with a rheumatologist  
**AND**
- 4. Documentation of **one (1)** of the following:
  - c. **Both** of the following:
    - i. One (1) of the following:
      - 1. Inadequate response or adverse reaction to one (1), or contraindication to all prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
      - 2. Previous treatment with a biologic agent indicated for the requested use
    - ii. Trial and failure with two (2), or contraindication to all of the following: Cimzia, Rinvoq, Taltz
  - d. The patient is new to the plan and stable on Bimzelx and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

### Plaque Psoriasis

- 1. Documented diagnosis of plaque psoriasis  
**AND**
- 2. Patient is at least 6 years of age  
**AND**
- 3. Prescribed by or in consultation with a dermatologist  
**AND**
- 4. Documentation of **one (1)** of the following:

- a. **Both** of the following:
  - i. One (1) of the following:
    - 1. Inadequate response to one (1), or contraindication to all of the following topical therapies: corticosteroids, vitamin D analogs, tazarotene, calcineurin inhibitors, anthralin, coal tar
    - 2. Previous treatment with a biologic agent indicated for the requested use
  - ii. Trial and failure with two (2), or contraindication to all of the following: Cimzia, Enbrel, Humira, Skyrizi, Stelara, Taltz, Tremfya
- b. The patient is new to the plan and stable on Bimzelx and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

## Psoriatic Arthritis

- 1. Documented diagnosis of psoriatic arthritis
- AND**
- 2. Patient is at least 18 years of age
- AND**
- 3. Prescribed by or consultation with a rheumatologist or dermatologist
- AND**
- 4. Documentation of **one (1)** of the following:
  - a. Trial and failure with two (2), or contraindication to all of the following: Cimzia, Enbrel, Humira, Simponi, Skyrizi, Stelara, Taltz, Tremfya, Rinvoq, Xeljanz
  - b. The patient is new to the plan and stable on Bimzelx and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

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## Limitations

- 1. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.

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## Codes

None

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## References

1. Bimzelx (bimekizumab-bkzx) [prescribing information]. Smyrna, GA: UCB, Inc.; November 2024.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2021;73(7):924-939
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;80:1029-72.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
5. 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.

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## Approval And Revision History

December 10, 2024: Reviewed by the Pharmacy & Therapeutics Committee.

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## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review,

consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.