

<b>Clinical Policy Title:</b>	Bimekizumab-bkzx
<b>Policy Number:</b>	RxA.812
<b>Drug(s) Applied:</b>	Bimzelx
<b>Original Policy Date:</b>	09/12/2024
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

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

1. Diagnosis of moderate to severe plaque psoriasis;
2. Member meets the following (a, b, and c):
  - a. Trial and failure of  $\geq 3$  months of at least one (1) conventional systemic therapy (methotrexate, cyclosporine, acitretin, phototherapy);
  - b. Trial and failure of at least two (2) of the following agents: adalimumab (Abrilada, Hadlima, adalimumab-aaty), Cimzia, Enbrel, Skyrizi, Stelara, or Tremfya;
  - c. Trial and failure of Taltz.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

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

1. Diagnosis of active Psoriatic arthritis;
2. Trial and failure of at least two (2) of the following agents: Enbrel, adalimumab (Abrilada, Hadlima, adalimumab-aaty), Cimzia, Rinvoq /LQ, Simponi, Skyrizi, Stelara, Taltz, Tremfya, Xeljanz/XR

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

#### C. Ankylosing spondylitis (must meet all):

1. Diagnosis of active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-AxSpA);
2. Trial and failure of at least two (2) of the following agents (a or b):
  - a. For AS: Cimzia, Enbrel, adalimumab (Abrilada, Hadlima, adalimumab-aaty), Rinvoq, Simponi, Xeljanz/XR, or Taltz.
  - b. For nr-AxSpA: Cimzia, Rinvoq, or Taltz

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

#### D. Hidradenitis Suppurativa (HS) (must meet all):

1. Diagnosis of moderate to severe HS;
2. Trial and failure of a least  $> 3$  months of systemic antibiotic therapy (e.g. clindamycin with rifampin, minocycline, doxycycline), unless contraindicated or clinically significant adverse effects are experienced;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

3. Trial and failure of one (1) of the following agents, unless contraindicated or clinically significant adverse effects are experienced: adalimumab (Abralada, Hadlima or adalimumab-aaty).

**Approval duration**

**All Lines of Business (except Medicare):** 12 months

**E. Continued Therapy Approval**

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria.

**Approval duration**

**All Lines of Business (except Medicare):** 12 months

**References**

1. Bimzelx. Package insert. UCB; 2024. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=26b88358-871f-4c80-9d80-b2fb16477f81&type=display#section-12.3>. Accessed December 3, 2024.
2. Camiña-Conforto G, Mateu-Arrom L, López-Ferrer A, Puig L. Bimekizumab in the Treatment of Plaque Psoriasis: Focus on Patient Selection and Perspectives. Patient Prefer Adherence. 2023. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10319282/>. Accessed December 3, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	09/12/2024	09/12/2024
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Updated adalimumab biosimilars.</li> <li>2. Updated to add new indications, Psoriatic Arthritis and Ankylosing Spondylitis.</li> <li>3. References were reviewed and updated.</li> </ol>	12/03/2024	12/05/2024
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Added new indication HS with t/f of alternatives</li> </ol>	1/29/2025	NA
Policy reviewed.	12/11/2025	12/11/2025