HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Bimzelx (bimekizumab-bkzx)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Bimzelx, initially approved by the FDA in 2023, is an interleukin-17 A and F antagonist indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy, adults with active psoriatic arthritis (PsA), adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation and adults with active ankylosing spondylitis. IL-17A and IL-17F are naturally occurring cytokines that are involved in normal inflammatory and immune responses. Bimzelx inhibits the release of proinflammatory cytokines and chemokines.

Bimzelx (bimekizumab-bkzx) will be considered for coverage when the following criteria are met:

Plaque Psoriasis (PsO)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a diagnosis of moderate to severe plaque psoriasis characterized by 3% or more of body surface area (BSA) or disease affecting sensitive areas (e.g., hands, feet, face, genitals, etc.); AND
4. Member has tried and failed to respond to treatment with at least one of the following:
   a) At least 12 weeks of photochemotherapy (i.e., psoralen plus ultraviolet A therapy);
   b) At least 12 weeks of phototherapy (i.e., UVB light therapy, Excimer laser treatments);
   c) At least a 4-week trial with topical antipsoriatic agents (i.e., anthralin, calcipotriene, coal tar, corticosteroids, tazarotene, tacrolimus, pimecrolimus);
   d) At least a 12-week trial of a systemic non-biologic DMARD (i.e., cyclosporine, methotrexate, acitretin); AND
5. Member has tried and failed at least two preferred biologic DMARDs; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** Administer 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing ≥ 120 kg, consider a dosage of 320 mg every 4 weeks after Week 16. Quantity Limit: 2 mL per 28 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease such as BSA improvement or decrease in pain, itching or scaling, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

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Psoriatic Arthritis (PsA)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist or dermatologist; AND
3. Member has a diagnosis of active PsA; AND
4. Member has met a 4-week trial of an NSAID taken at maximally tolerated doses **AND** a 3-month trial of a non-biologic DMARD agent (e.g., methotrexate, sulfasalazine, cyclosporine, etc.) unless **ONE** of the following situations is met:
   a) Non-biologic DMARD is **NOT** required for:
      i) Concomitant axial disease (i.e., involving sacroiliac joint and spine) or enthesitis; OR
   b) NSAID and non-biologic DMARD are **NOT** required for:
      i) Severe PsA (defined as having at least one of the following: erosive disease, active PsA at many sites including dactylitis or enthesitis, elevated levels of ESR or CRP, joint deformities, or major impairment in quality of life); AND
5. Member has tried and failed at least two preferred biologic DMARDs; AND
6. Member has had a negative tuberculosis test within the past 12 months.
7. **Dosage allowed/Quantity limit:** Administer 160 mg by subcutaneous injection every 4 weeks. Quantity limit: 1 syringe or autoinjector per 28 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased joint swelling and pain, improved skin appearance, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Ankylosing Spondylitis (AS) or Non-radiographic Axial Spondyloarthritis (nr-axSpA)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a rheumatologist; AND
3. Member has a documented diagnosis of active AS, axSpA, or nr-axSpA; AND
4. Member shows **ONE** of the following signs or symptoms of inflammation:
   a) Elevated serum C-reactive protein (CRP);
   b) Sacroiliitis on magnetic resonance imaging (MRI); AND
5. Member has had a trial and failure of **TWO** NSAIDs for 14 days each, taken at the maximum recommended dosages; AND
6. Member has tried and failed at least two preferred biologic DMARDs; AND
7. Member has had a negative tuberculosis test within the past 12 months.
8. **Dosage allowed/Quantity limit:** Administer 160 mg by subcutaneous injection every 4 weeks. Quantity limit: 1 syringe or autoinjector per 28 days.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:
1. Chart notes have been provided showing improvement of signs and symptoms of disease such as decreased morning stiffness, tenderness or inflammatory back pain, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Hidradenitis Suppurativa (HS)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a dermatologist; AND
3. Member has a documented diagnosis of moderate to severe HS with Hurley stage II or III disease; AND
4. Member has been counseled on weight loss if they are overweight or obese; AND
5. Member is a non-smoker or has been counseled on smoking cessation and advised to quit; AND
6. Member has tried and failed at least one of the following:
    a. Topical clindamycin x 12 weeks and an oral tetracycline x 12 weeks (sequential or concomitant)
    b. Oral clindamycin plus rifampicin x 8-12 weeks; AND
7. Member has tried and failed at least two preferred biologic DMARDs; AND
8. Member has had a negative tuberculosis test within the past 12 months.
9. **Dosage allowed/Quantity limit**: 320 mg by subcutaneous injection at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, then every 4 weeks thereafter.
   QL: 4 mL/28 days for 16 weeks, then 2 mL/28 days for maintenance

If all the above requirements are met, the medication will be approved for 6 months.

For reauthorization:
1. Chart notes must include documentation of a positive clinical response such as reduced count of total abscesses and inflammatory nodules or reduction of skin pain.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Bimzelx (bimekizumab-bkzx) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/02/2023	New policy for Bimzelx created.
10/10/2024	Converted double trial of topicals + systemic therapy to a single trial with both topical and systemic options for PsO
10/14/2024	Added PsA, AS and nr-axSpA indications.
11/12/2024	Added trial of two preferred biologic DMARDs
11/22/2024	Added criteria for HS indication. Removed “as 2 separate injections” from PSO dosing.
12/4/2024	Added trial of two preferred biologic DMARDs to HS criteria

References:

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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(4):1029-1072.
4. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. *J Am Acad Dermatol.* 2019;81(3):775-804
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10. Akgul O, Ozgocmen S. Classification criteria for spondyloarthropathies. World J Orthop. 2011;2(12):107-115. doi:10.5312/wjo.v2.i12.07.

Effective date: 01/01/2025
Revised date: 12/04/2024

MI-EXC-P-3321474

Appendix Preferred Biologic Products	
Approved for Rheumatoid Arthritis	• Actemra (requires step through preferred adalimumab product) • Adalimumab-adaz, adalimumab-fkjp • Enbrel • Hadlima • Humira • Cimzia • Rinvoq
Approved for Juvenile Idiopathic Arthritis	• Actemra (requires step through preferred adalimumab product) • Adalimumab-adaz, adalimumab-fkjp • Enbrel • Hadlima • Humira • Cimzia
Approved for Ankylosing Spondylitis	• Adalimumab-adaz, adalimumab-fkjp • Cosentyx • Enbrel • Hadlima • Humira

	• Rinvoq • Cimzia
Approved for Non-radiographic Axial Spondyloarthritis	• Cimzia • Cosentyx • Rinvoq
Approved for Atopic Dermatitis	• Rinvoq
Approved for Psoriatic Arthritis	• Adalimumab-adaz, adalimumab-fkjp • Cosentyx • Enbrel • Hadlima • Humira • Otezla • Skyrizi • Stelara • Tremfya • Cimzia
Approved for Plaque Psoriasis	• Adalimumab-adaz, adalimumab-fkjp • Cosentyx • Enbrel • Hadlima • Humira • Otezla • Skyrizi • Stelara • Tremfya • Cimzia
Approved for Crohn's Disease	• Adalimumab-adaz, adalimumab-fkjp • Hadlima • Humira • Stelara • Rinvoq • Skyrizi • Cimzia
Approved for Ulcerative Colitis	• Adalimumab-adaz, adalimumab-fkjp • Hadlima • Humira • Stelara • Rinvoq • Skyrizi


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