

## PHARMACY POLICY STATEMENT

### North Carolina Marketplace

|                     |                                   |
|---------------------|-----------------------------------|
| <b>DRUG NAME</b>    | <b>Bimzelx (bimekizumab-bkzx)</b> |
| <b>BENEFIT TYPE</b> | Pharmacy                          |
| <b>STATUS</b>       | 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  $\geq 120$  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.***

## 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.**

**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   |

References:

1. Bimzelx [prescribing information]. Smyrna, GA: UCB Inc.; 2024.
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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
5. 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 Jan;71(1):5-32.
6. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021 [published correction appears in *Nat Rev Rheumatol*. 2022 Dec;18(12):734. doi: 10.1038/s41584-022-00861-w]. *Nat Rev Rheumatol*. 2022;18(8):465-479. doi:10.1038/s41584-022-00798-0
7. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. *Ann Rheum Dis*. 2024;83(6):706-719. Published 2024 May 15. doi:10.1136/ard-2024-225531
8. 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 Oct;71(10):1599-1613. doi: 10.1002/art.41042. Epub 2019 Aug 22.
9. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. *Ann Rheum Dis*. 2023;82(1):19-34. doi:10.1136/ard-2022-223296
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: 10/14/2024

## Appendix Preferred Biologic Products

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|---|--|
| Approved for Rheumatoid Arthritis                     | <ul style="list-style-type: none"> <li>• Actemra (requires step through preferred adalimumab product)</li> <li>• Adalimumab-adaz, adalimumab-fkjp</li> <li>• Enbrel</li> <li>• Hadlima</li> <li>• Humira</li> <li>• Cimzia</li> <li>• Rinvoq</li> </ul>      |
| Approved for Juvenile Idiopathic Arthritis            | <ul style="list-style-type: none"> <li>• Actemra (requires step through preferred adalimumab product)</li> <li>• Adalimumab-adaz, adalimumab-fkjp</li> <li>• Enbrel</li> <li>• Hadlima</li> <li>• Humira</li> <li>• Cimzia</li> </ul>                        |
| Approved for Ankylosing Spondylitis                   | <ul style="list-style-type: none"> <li>• Adalimumab-adaz, adalimumab-fkjp</li> <li>• Cosentyx</li> <li>• Enbrel</li> <li>• Hadlima</li> <li>• Humira</li> <li>• Rinvoq</li> <li>• Cimzia</li> </ul>  |
| Approved for Non-radiographic Axial Spondyloarthritis | <ul style="list-style-type: none"> <li>• Cimzia</li> <li>• Cosentyx</li> <li>• Rinvoq</li> </ul>   |
| Approved for Atopic Dermatitis                        | <ul style="list-style-type: none"> <li>• Rinvoq</li> </ul>   |
| Approved for Psoriatic Arthritis                      | <ul style="list-style-type: none"> <li>• Adalimumab-adaz, adalimumab-fkjp</li> <li>• Cosentyx</li> <li>• Enbrel</li> <li>• Hadlima</li> <li>• Humira</li> <li>• Otezla</li> <li>• Skyrizi</li> <li>• Stelara</li> <li>• Tremfya</li> <li>• Cimzia</li> </ul> |
| Approved for Plaque Psoriasis                         | <ul style="list-style-type: none"> <li>• Adalimumab-adaz, adalimumab-fkjp</li> <li>• Cosentyx</li> <li>• Enbrel</li> <li>• Hadlima</li> <li>• Humira</li> <li>• Otezla</li> <li>• Skyrizi</li> <li>• Stelara</li> </ul>                                      |

|                                 |   |
|---------------------------------|---|
|                                 | <ul style="list-style-type: none"> <li>• Tremfya</li> <li>• Cimzia</li> </ul>   |
| Approved for Crohn's Disease    | <ul style="list-style-type: none"> <li>• Adalimumab-adaz, adalimumab-fkjp</li> <li>• Hadlima</li> <li>• Humira</li> <li>• Stelara</li> <li>• Rinvoq</li> <li>• Skyrizi</li> <li>• Cimzia</li> </ul> |
| Approved for Ulcerative Colitis | <ul style="list-style-type: none"> <li>• Adalimumab-adaz, adalimumab-fkjp</li> <li>• Hadlima</li> <li>• Humira</li> <li>• Stelara</li> <li>• Rinvoq</li> <li>• Skyrizi</li> </ul>                   |