Blue Cross Blue Shield Blue Care Network of Michigan

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P&T Date: 12/12/2024

Bimzelx® (bimekizumab-bkzx)

HCPCS: J3590; C9399

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. Diagnosis of psoriasis
      i. Trial and failure, contraindication, or intolerance to one topical steroid
   c. Diagnosis of non-radiographic axial spondyloarthritis
   d. Diagnosis of ankylosing spondylitis
   e. Diagnosis of psoriatic arthritis
   f. Diagnosis of hidradenitis suppurativa
      i. Previous 3-month trial of oral antibiotics
   g. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic agents (DMARDs) for the same indication
   h. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

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Background Information:

- Bimzelx is an interleukin (IL)-17A and IL-17F inhibitor approved to treat:
    - Moderate to severe plaque psoriasis (PsO) in adults who are candidates for systemic therapy or phototherapy.
    - Adults with active psoriatic arthritis (PsA)
    - Adults with active non-radiographic axial spondyloarthritis (NRAS) with objective signs of inflammation
    - Adults with active ankylosing spondylitis (AS)
    - Adults with moderate to severe hidradenitis suppurativa (HS)
- Other drugs in this class (Cosentyx®, Taltz®, Siliq®) only target IL-17A.
- Psoriasis
    - PsO is a chronic, painful and life-altering immune-mediated disease which predominantly manifests with skin and joint involvement. Patients may also experience significant cardiovascular and psychological comorbidities. Approximately 2% of U.S. adults are affected by psoriasis (men and women equally), and it can occur at any age. Approximately 90% of psoriasis-affected patients have plaque psoriasis, which is characterized by well-defined round or oval plaques that vary in size and often coalesce. The severity of psoriasis is defined as: mild = less than 3% of body affected; moderate = 3-10% of body affected; and severe being more than 10% of the body affected.
    - Per the 2020 Joint American Academy of Dermatology - National Psoriasis Foundation (AAD-NPF) guidelines of care for the management and treatment of PsO with topical therapy and alternative medicine modalities for PsO severity measures: topical corticosteroids provide a high efficacy and good safety option for patients with localized disease. They are generally recommended as first-line therapy. Choice of steroid potency may depend on severity, location, patient preference, and patient age, while the duration of treatment may vary with steroid potency, location and severity of disease often ranging from 2-12 weeks. Therapeutic regimens may include 2-4 weeks with a topical steroid applied twice daily, followed by a maintenance regimen where topical steroids are alternated with a steroid-sparing topical agent. Treatment with topical steroids for over 12 weeks is recommended under careful supervision by a physician.
    - Per the 2019 Joint AAD-NPF Foundation guidelines of care for the management and treatment of PsO with phototherapy: phototherapy serves as a reasonable and effective treatment option for patients requiring more than topical medications and/or those wishing to avoid systemic medications or simply seeking an adjunct to a failing regimen. Guidelines also state that the majority of patients with mild-to-moderate disease have adequate disease control with topical therapies and phototherapy alone.
    - Per the 2020 Joint AAD-NPF guidelines of care for the management and treatment of PsO with systemic nonbiologic therapies: many oral medications, including methotrexate, cyclosporine, and acitretin, have been used for decades to treat psoriasis, each with its own benefits and risks. Most work by targeting the immune system, whereas others, such as acitretin, work predominantly by decreasing keratinocyte hyperproliferation, thus restoring the normal epidermal differentiation. Both methotrexate and cyclosporine are category A guideline recommendations for the treatment of moderate to severe PsO in adults and for severe, recalcitrant PsO, respectively. Studies examining the use of methotrexate and cyclosporine in PsO showed the primary efficacy endpoints met within 12-16 weeks. Acitretin is a category B guideline

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recommendation as monotherapy for plaque psoriasis, with full treatment response expected within 3-6 months.

- Per the 2019 Joint AAD-NPF guidelines of care for the management and treatment of PsO with biologics: biologic agents, as monotherapy or combined with other topical or systemic medications, have a high benefit-to-risk ratio. Tumor necrosis factor inhibitors (TNFi) and inhibitors of IL-12/IL-23, IL-23, and IL-17 have a category "A" recommendation as a monotherapy treatment option for adult patients with moderate-to-severe plaque PsO. Guidelines do not recommend one product over another and note the similar efficacy seen across biologics within the same class. Use of products with the lowest net cost therefore provide the greatest value.

- The guidelines have not been updated to include Bimzelx. Additionally, there are no published, robust studies to support the use of more than one biologic product or targeted DMARD in combination.

- Psoriatic Arthritis

  - PsA is a chronic inflammatory disease often associated with psoriasis. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches. These patches, called plaques, may appear anywhere on the body. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur.

  - Per the 2018 American College of Rheumatology (ACR)/National Psoriasis Foundation (NPF) guideline for the treatment of psoriatic arthritis:

    - All recommendations for treatment-naive patients with active PsA are conditional based on low- to very-low quality evidence.

    - In treatment-naïve patients, oral systemic medications (OSMs), such as methotrexate, sulfasalazine, cyclosporine, and leflunomide, may be used in patients without severe psoriatic arthritis and without severe psoriasis. OSMs have robust longitudinal safety and efficacy data in patients with PsA. Maximal response to OSMs are most commonly achieved within 3 months of therapy.

    - If PsA remains active despite OSM therapy, switching to a tumor necrosis factor inhibitor (TNFi), an IL-17 inhibitor (IL-17i), or an IL-12/23i is recommended over switching to a different OSM; switching to a TNFi biologic over an IL-17i or IL-12/23i biologic is conditionally recommended in this scenario based on moderate quality evidence. Additional treatment options include Orencia (abatacept) and Xeljanz (tofacitinib). The detailed recommendations for subsequent therapies can be found in the 2018 ACR/NPF guideline for the treatment of psoriatic arthritis

- Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

  - Axial spondyloarthritis, comprising AS and NRAS, is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.

  - The 2019 American College of Rheumatology recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with nonsteroidal anti-inflammatory drugs (NSAIDS),

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treatment with TNFi are recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient. Cosentyx® (secukinumab) or Taltz (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class. In the case of nonresponse (primary or secondary), the guidelines recommend against switching to treatment with a biosimilar since clinical response would not be expected to be different.

- Hidradenitis Suppurativa

    - Hidradenitis suppurativa (HS) also known as acne inversa, is a chronic, inflammatory, recurrent, debilitating skin disease of the hair follicle that usually presents after puberty with painful, deep-seated, inflamed lesions in the apocrine gland-bearing areas of the body, most commonly the axillae, inguinal and anogenital regions.

    - Per the 2019 North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations Part II: Topical, intralesional, and systemic medical management:

        - Systemic antibiotics have been a mainstay of HS treatment for decades, with many regimens reported. Tetracyclines are recommended in mild-to-moderate HS for a 12-week course or as long-term maintenance when appropriate. Clindamycin and rifampin in combination is effective as a second-line treatment for mild-to-moderate disease or as a first-line or adjunct treatment in severe disease. Moxifloxacin, metronidazole, and rifampin in combination are recommended as second- or third-line treatment in moderate-to-severe disease. Dapsone may be effective as maintenance therapy.

        - For moderate to severe disease (i.e., inflammatory lesions with skin tunnels or scarring; Hurley stage II or III disease) that is unresponsive to at least one oral antibiotic, biologic therapy may be indicated. Adalimumab was the first systemic biologic FDA approved for moderate to severe HS and is recommended by the 2019 guidelines to improve disease severity and quality of life in patients with moderate to severe HS. The guidelines have not been updated to include other biologics approved for HS, including bimekizumab and secukinumab.

References:

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3. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. J Am Acad Dermatol. 2020;S0190-9622(20)32288-X. doi:10.1016/j.jaad.2020.07.087
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6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2018; 0(0): 1-28. https://www.rheumatology.org/Portals/0/Files/PsA-Guideline-Early-View-Version.pdf
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<table>
<tr><td colspan="3">Policy History</td></tr>
<tr><td>#</td><td>Date</td><td>Change Description</td></tr>
<tr><td>1.3</td><td>Effective Date: 12/12/2024</td><td>Added criteria for the following new indications: psoriatic arthritis, non-radiographic axial spondyloarthritis, ankylosing spondylitis, and hidradenitis suppurativa</td></tr>
<tr><td>1.2</td><td>Effective Date: 10/03/2024</td><td>Added “for the same indication” to the not to be used in combination with other biologics or targeted DMARDs criteria</td></tr>
<tr><td>1.1</td><td>Effective Date: 02/12/2024</td><td>UM medical management system update for MAPPO and BCNA
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effective Date: 12/14/2023</td><td>New policy
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

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