LOUISIANA BLUE

bimekizumab-bkzx (Bimzelx®)

Policy # 00873
Original Effective Date: 04/08/2024
Current Effective Date: 02/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Plaque Psoriasis

Based on review of available data, the Company may consider bimekizumab-bkzx (Bimzelx®)‡ for the treatment of moderate to severe plaque psoriasis to be **eligible for coverage.****

Patient Selection Criteria

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

- Patient has a diagnosis of moderate to severe plaque psoriasis; AND
- Patient is 18 years of age or older; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has failed to respond to an adequate trial of one of the following treatment modalities unless there is clinical evidence or patient history that suggests the use of these treatments will be ineffective or cause an adverse reaction to the patient:
  - Ultraviolet B; OR
  - Psoralen positive Ultraviolet A; OR
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin); AND

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Patient has failed treatment with ONE of the following after at least TWO months of therapy with EACH product: adalimumab (Humira®, biosimilars)‡, etanercept (Enbrel®)‡, apremilast (Otezla®)‡, ustekinumab (Stelara®)‡, secukinumab (Cosentyx®)‡, guselkumab (Tremfya®)‡, risankizumab (Skyrizi®)‡, or deucravacitinib (Sotyktu™)‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR®)‡ or apremilast (Otezla); AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

Psoriatic Arthritis
Based on review of available data, the Company may consider bimekizumab-bkzx (Bimzelx) for the treatment of active psoriatic arthritis to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for bimekizumab-bkzx (Bimzelx) will be considered when the following criteria are met:

- Patient has a diagnosis of active psoriatic arthritis; AND
- Patient is 18 years of age or older; AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has failed treatment with ONE of the following after at least TWO months of therapy: etanercept (Enbrel), adalimumab (Humira, biosimilars), ustekinumab (Stelara), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), guselkumab (Tremfya), apremilast (Otezla), upadacitinib (Rinvoq™)‡, or risankizumab-rzaa (Skyrizi) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

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Non-Radiographic Axial Spondyloarthritis
Based on review of available data, the Company may consider bimekizumab-bkzx (Bimzelx) for the treatment of patients with non-radiographic axial spondyloarthritis to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for bimekizumab-bkzx (Bimzelx) will be considered when the following criteria are met:

- Patient has active non-radiographic axial spondyloarthritis as confirmed by the presence of sacroiliitis on magnetic resonance imaging (MRI); AND
- Patient is 18 years of age or older; AND
- Patient has failed at least TWO months of current continuous therapy with as least TWO different oral NSAIDs (at prescription strength dosages) unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient has failed treatment with ONE of the following after at least TWO months of therapy: certolizumab pegol (Cimzia®)‡, secukinumab (Cosentyx), or upadacitinib (Rinvoq) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

Ankylosing Spondylitis
Based on review of available data, the Company may consider bimekizumab-bkzx (Bimzelx) for the treatment of patients with active ankylosing spondylitis to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for bimekizumab-bkzx (Bimzelx) will be considered when the following criteria are met:

- Patient has a diagnosis of active ankylosing spondylitis; AND
- Patient is 18 years of age or older; AND
- Patient has failed treatment with non-steroidal anti-inflammatory drugs (NDAIDs) unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient; AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient has failed treatment with ONE of the following after at least TWO months of therapy: etanercept (Enbrel), adalimumab (Humira, biosimilars), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

Hidradenitis Suppurativa
Based on review of available data, the Company may consider bimekizumab-bkzx (Bimzelx) for the treatment of patients with hidradenitis suppurativa to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for bimekizumab-bkzx (Bimzelx) will be considered when the following criteria are met:

- Patient has moderate to severe hidradenitis suppurativa; AND
- Patient is 18 years of age or older; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has failed treatment with ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin) for hidradenitis suppurativa unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has failed treatment with ONE of the following after at least TWO months of therapy: adalimumab (Humira, biosimilars) or secukinumab (Cosentyx) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has a negative TB test (e.g., purified protein derivative [PPD], blood test) prior to treatment.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of bimekizumab-bkzx (Bimzelx) when any of the following criteria are not met to be **not medically necessary.****

- For plaque psoriasis:
  - Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
  - Patient has failed to respond to an adequate trial of one of the following treatment modalities:
    - Ultraviolet B; OR
    - Psoralen positive Ultraviolet A; OR
    - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin)
  - Patient has failed treatment with ONE of the following after at least TWO months of therapy with EACH product: adalimumab (i.e. Humira, biosimilars), etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara), secukinumab (Cosentyx), guselkumab (Tremfya), risankizumab (Skyrizi), or deucravacitinib (Sotyktu)
- For psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs
  - Patient has failed treatment with ONE of the following after at least TWO months of therapy: etanercept (Enbrel), adalimumab (Humira, biosimilars), ustekinumab (Stelara), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), guselkumab (Tremfya), apremilast (Otezla), upadacitinib (Rinvoq), or risankizumab-rzaa (Skyrizi)
- For non-radiographic axial spondyloarthritis:
  - Patient has failed at least TWO months of current continuous therapy with at least TWO different oral NSAIDs (at prescription strength dosages)
  - Patient has failed treatment with ONE of the following after at least TWO months of therapy: certolizumab pegol (Cimzia), secukinumab (Cosentyx), or upadacitinib (Rinvoq)
- For ankylosing spondylitis:
  - Patient has failed treatment with NSAIDs
  - Patient has failed treatment with ONE of the following after at least TWO months of therapy: etanercept (Enbrel), adalimumab (Humira, biosimilars), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq)
- For hidradenitis suppurativa:
  - Patient has failed treatment with ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin)
  - Patient has failed treatment with ONE of the following after at least TWO months of therapy: adalimumab (Humira, biosimilars) or secukinumab (Cosentyx)

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of bimekizumab-bkzx (Bimzelx) when the patient selection criteria are not met (with the exception of those denoted above as **not medically necessary****) to be **investigational.***

Background/Overview

Bimzelx is an interleukin-17A and 17F blocker indicated for the treatment adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, adults with active psoriatic arthritis, adults with non-radiographic axial spondyloarthritis with objective signs of inflammation, adults with active ankylosing spondylitis, and adults with moderate to severe hidradenitis suppurativa. Bimzelx is a humanized immunoglobulin (IgG) monoclonal antibody that inhibits the release of proinflammatory cytokines and chemokines by selectively binding to and neutralizing IL-17A, IL-17F and IL-17AF cytokines. Bimzelx is supplied as a 160 mg/mL single dose prefilled syringe or autoinjector. The recommended dosing for Bimzelx for plaque psoriasis is 320 mg (two 160 mg injections) administered subcutaneously (SC) at Weeks 0, 4, 8, 12, and 16 and then once every 8 weeks (Q8W) thereafter. For patients who weigh ≥ 120 kg, consider a dose of 320 mg once every 4 weeks (Q4W) after Week 16. The recommended dosing for psoriatic arthritis, non-radiographic axial spondyloarthritis, and ankylosing spondylitis is 160 mg administered subcutaneously every for weeks. For hidradenitis suppurativa, 320 mg of Bimzelx is to be administered by subcutaneous injection at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16, and then every 4 weeks thereafter.

Plaque Psoriasis

Psoriasis is a common skin condition caused by an increase in production of skin cells and characterized by frequent episodes of redness, itching and thick, dry silvery scales on the skin. It is most commonly seen on the trunk, elbows, knees, scalp, or lower back. Plaques can also occur on thinner and more sensitive skin, such as body folds and facial and genital regions, which may be more difficult to treat. This condition can appear suddenly or gradually and may affect people of any age. The average age of onset is 33 years. The severity of disease is classified by disease location, the amount of the body affected by the psoriasis, and impact on quality of life. Mild to moderate psoriasis can be managed with topical treatments. Typical treatments for severe cases of plaque psoriasis include ultraviolet therapy or systemic therapies such as methotrexate or cyclosporine. Systemic therapy can also be used for localized disease involving areas such as scalp, palms and soles, and genitals, or psoriasis unresponsive to topical therapy. Newer biologic therapies are also approved for the treatment of plaque psoriasis.

Psoriatic Arthritis
Psoriatic arthritis is an arthritis that is often associated with psoriasis of the skin. Typically, first line treatments such as traditional DMARDs are used to treat this condition. An example of a traditional DMARD would include methotrexate.

Non-Radiographic Axial Spondyloarthritis
Axial spondyloarthritis is an inflammatory arthritis of the spine. It often presents as chronic back pain, typically before the age of 45 and is often associated with one or more articular features (e.g., synovitis, enthesitis, and dactylitis) and/or non-articular features (e.g., uveitis, psoriasis, and inflammatory bowel diseases). Patients with this condition are classified as having one of two types of axial spondyloarthritis: either radiographic or non-radiographic. As supported by the name, the non-radiographic variety isn't evident on plain radiography and instead the diagnosis is supported by evidence of active inflammation of the sacroiliac joints via magnetic resonance imaging (MRI). Traditional pharmacologic therapy for the treatment of non-radiographic axial spondyloarthritis includes oral NSAIDs. Approximately 70-80% of patients with this condition report substantial relief with NSAID therapy. The effect of an NSAID is typically seen within two to four weeks and multiple NSAIDs need to be tried as patient response to a particular NSAID isn't predictable. Currently, Cimzia is the only TNF inhibitor product that is approved for non-radiographic axial spondyloarthritis. Taltz and Cosentyx, both interleukin blockers, are also approved for this indication. Rinvoq, a Janus kinase inhibitor, has this indication as well. If a response to two NSAIDs has not proven beneficial, a tumor necrosis factor (TNF) alpha inhibitor, such as Cimzia, or an interleukin blocker, such as Taltz or Cosentyx, would be the next treatment option. Rinvoq is typically used after failure of a TNF inhibitor.

Ankylosing Spondylitis
Ankylosing spondylitis is a chronic inflammatory disease that affects the joints between the vertebrae of the spine and the joints between the spine and the pelvis. It eventually causes the affected vertebrae to fuse or grow together. NSAIDs, such as aspirin, are used to reduce inflammation and pain associated with the condition. Corticosteroid therapy or medications to suppress the immune system may be prescribed to control various symptoms.

Hidradenitis Suppurativa
Hidradenitis suppurativa is an inflammatory skin condition, also known as acne inversa. Hidradenitis suppurativa is a chronic, suppurative process involving the skin and subcutaneous tissues. The initial presentation of the disease typically includes recurrent, painful, and inflamed nodules. The pathogenesis of hidradenitis suppurativa is somewhat unknown, but it is thought that follicular occlusion, follicular rupture, and an associated immune response appear to be important events in the clinical manifestations of this disease. Hidradenitis suppurativa typically occurs on intertriginous skin. The most common site is usually the axilla. Non-intertriginous skin can be affected as well. In

addition to Cosentyx and Humira, Bimzelx is the only other treatment to be approved by the Food and Drug Administration for the treatment of moderate to severe hidradenitis suppurativa. Other agents typically used for the treatment of hidradenitis suppurativa include systemic antibiotics, intralesional or oral corticosteroids, or isotretinoin products.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Bimzelx is approved for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. In November of 2024, Bimzelx gained FDA approval for four additional indications which include the treatment of adults with active psoriatic arthritis, adults with non-radiographic axial spondyloarthritis with objective signs of inflammation, adults with active ankylosing spondylitis, and adults with moderate to severe hidradenitis suppurativa.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Plaque Psoriasis

The efficacy of Bimzelx was evaluated in three Phase III, randomized, double-blind, multicenter, pivotal studies and one non-pivotal study in adults with plaque psoriasis. Each study assessed induction therapy at Week 16 and maintenance therapy using Q4W or Q8W dosing. Three of the studies used another biologic as an active comparator (BE-VIVID vs. Stelara [ustekinumab SC injection], BE-SURE vs. adalimumab SC injection [Humira, biosimilars], and BE-RADIANT vs. Cosentyx [secukinumab SC injection]). Primary endpoints of the trials included the proportion of patients reporting 90% or greater improvement in the Psoriasis Area and Severity Index score from baseline (PASI 90) and Investigator's Global Assessment (IGA) score of 0 or 1 (indicating clear or almost clear skin). The pivotal trials included: BE-VIVID, BE-SURE, and BE-READY. The results of the BE-VIVID trial, which included 567 patients, found a higher proportion of patients on Bimzelx achieved a PASI 90 at Week 16 (85% vs. 50% with Stelara and 5% with placebo; $P < 0.0001$ for Bimzelx vs. both comparisons). IGA response was also more common at Week 16 with Bimzelx (84% vs. 53% with Stelara and 5% with placebo; $P < 0.0001$ for Bimzelx vs. both comparisons). A total of 478 patients were enrolled in the BE-SURE trial which demonstrated superiority of Bimzelx at Week 16 and Week 24. A higher proportion of patients on Bimzelx achieved a PASI 90 at Week 16 (86% vs. 47% with adalimumab; $P < 0.001$ for noninferiority and superiority). IGA 0/1 was also more common at Week 16 with Bimzelx (85% vs. 57% with adalimumab; $P < 0.001$ for noninferiority and superiority). At Week 56, PASI 90 response was achieved in a similar proportion of patients taking maintenance dosing with Bimzelx Q4W (85%)

and Q8W (83%). PASI 90/100 was achieved at Week 56 in 82%/67% of patients who switched from adalimumab to Bimzelx at Week 24. The results of the BE-READY trial, which included 435 patients randomized to treatment with Bimzelx or placebo, showed the PASI 90 response at Week 16 was higher with Bimzelx (91%) compared with placebo (1%) [$P < 0.001$]. IGA 0/1 was also more common at Week 16 with Bimzelx (93% vs. 1% with placebo; $P < 0.001$).

Psoriatic Arthritis
The safety and efficacy of Bimzelx were assessed in 1,112 subjects in two multicenter, randomized, double-blind, placebo-controlled studies (Trial PsA-1 and Trial PsA-2) in subjects 18 years and older with active psoriatic arthritis (PsA). The PsA-1 study evaluated 852 biologic-naïve subjects, who were treated with either Bimzelx 160 mg every 4 weeks up to Week 52, adalimumab 40 mg every 2 weeks up to Week 52 (active reference arm), or placebo. Subjects receiving placebo were switched to Bimzelx every 4 weeks at Week 16 to Week 52. The PsA-2 study evaluated 400 anti-TNFα experienced subjects (inadequate response or intolerance to treatment), who were treated with Bimzelx 160 mg every 4 weeks or placebo up to Week 16. For both studies, the primary endpoint was the proportion of subjects who achieved an America College of Rheumatology (ACR) 50 response at Week 16. In both studies, treatment with Bimzelx resulted in significant improvement in disease activity, as measured by ACR, compared to placebo at Week 16. Responses in Trial PsA-2 (anti-TNF experienced) were similar to Trial PsA-1. In Trial PsA-1, 43.9% of subjects achieved the primary endpoint of ACR 50 response at Week 16, compared to 10% of subjects treated with placebo. In Trial PsA-2, 43.4% of subjects achieved the primary endpoint of ACR 50 response at Week 16, compared to 6.8% of subjects treated with placebo.

Non-Radiographic Axial Spondyloarthritis
The efficacy and safety were assessed in 254 patients in one randomized, double-blind, placebo-controlled study (Trial nr-axSpA-1) in adult subjects 18 years of age and older with active non-radiographic axial spondyloarthritis. Subjects had to have objective signs of inflammation with elevated C-reactive protein (CRP) level and/or evidence of sacroiliitis on Magnet Resonance Imaging (MRI). Subjects met ASAS classification criteria for axial spondyloarthritis and have active disease as defined by BASDAI greater than or equal to 4, spinal pain of greater than or equal to 4 (0-10 numeric rating scale [NRS]), and no definitive radiographic evidence of structural damage in the sacroiliac joints. Subjects were randomized to receive Bimzelx 160 mg or placebo every 4 weeks up to the completion of Week 16 assessments. Starting at Week 16, all subjects received Bimzelx every 4 weeks up to Week 52. The primary endpoint was at least 40% improvement in Assessment of Spondyloarthritis International Society (ASAS 40) at Week 16. In Trial nr-axSpA-1, treatment with Bimzelx resulted in significant improvements in the measure of disease activity compared to placebo at Week 16. In Trial nr-axSpA-1, 47.7% of subjects treated with Bimzelx achieved an ASAS 40 response compared to 21.4% or subjects treated with placebo.

Ankylosing Spondylitis
The efficacy and safety were assessed in 332 patients in one randomized, double-blind, placebo-controlled study (Trial AS-1) in adult subjects 18 years of age and older with active ankylosing spondylitis. Subjects had to have documented radiologic evidence (x-ray) fulfilling the Modified New York criteria for AS. Subjects had active disease as defined by BASDAI ≥ 4 and spinal pain ≥ 4 on a 0 to 10 numeric rating scale (NRS) (from BASDAI Item 2). Subjects also had a history of inadequate response to 2 different non-steroidal anti-inflammatory drugs (NSAIDs), or intolerance or contraindication to NSAIDs. Subjects were randomized 2:1 to receive Bimzelx 160 mg or placebo every 4 weeks up to the completion of Week 16 assessments. Starting at Week 16, all subjects received Bimzelx every 4 weeks up to Week 52. The primary endpoint was at least 40% improvement in Assessment of Spondyloarthritis International Society (ASAS 40) at Week 16. In Trial AS-1, treatment with Bimzelx resulted in significant improvements in the measure of disease activity compared to placebo at Week 16. In Trial AS-1 44.8% of subjects treated with Bimzelx achieved the primary endpoint of an ASAS 40 response compared to 22.5% of those being treated with placebo.

Hidradenitis Suppurativa
The safety and efficacy of Bimzelx were assessed in two Phase 3 multicenter, randomized, double blind, placebo-controlled trials (Trial HS-1 and Trial HS-2) in 1,014 adult subjects with moderate to severe HS of at least 6 months with Hurley Stage II or Hurley Stage III disease, and with ≥ 5 inflammatory lesions [i.e., number of abscesses plus number of inflammatory nodules (AN count)], and a history of inadequate response to a course of systemic antibiotics for the treatment of HS. Subjects received Bimzelx 320 mg every 2 weeks (Q2W) for 48 weeks, or BIMZELX 320 mg every 4 weeks (Q4W) up to Week 48, or Bimzelx 320 mg Q2W to Week 16, followed by 320 mg Q4W up to Week 48, or placebo. At Week 16, subjects receiving placebo were switched to Bimzelx 320 mg Q2W to Week 48. The primary efficacy endpoint in both trials was the Hidradenitis Suppurativa Clinical Response 50 (HiSCR50) at Week 16, defined by at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess or draining tunnel count relative to baseline. In Trial HS-1 48% of subjects receiving Bimzelx achieved HiSCR50 compared to 29% of subjects receiving placebo. In Trial HS-2, 52% of subjects receiving Bimzelx achieved HiSCR50 compared to 32% of subjects receiving placebo.

References

1. Bimzelx [package insert]. UCB, Inc. Smyrna, Georgia. November 2024.
2. Bimzelx Drug Evaluation. Express Scripts. October 25, 2023.

Policy History

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03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. New policy.

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01/02/2025 Medical Policy Committee review
01/08/2025 Medical Policy Implementation Committee approval. Added new indications, psoriatic arthritis, non-radiographic spondyloarthritis, ankylosing spondylitis, and hidradenitis suppurativa, to policy with criteria. Updated relevant sections.
Next Scheduled Review Date: 01/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.