09-J4000-70

Original Effective Date: 04/01/24

Reviewed: 11/13/24

Revised: 07/01/25

Subject: Bimekizumab-bkzx (Bimzelx®) Injection

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DESCRIPTION:

Bimekizumab (Bimzelx) is an injectable humanized monoclonal IgG1/kappa antibody with two identical antigen binding regions that selectively bind to human interleukin 17A (IL-17A), IL-17F, and IL-17AF cytokines. This blocks their interactions with the IL-17 receptor complex which inhibits the release of pro-inflammatory cytokines and chemokines. Bimekizumab was approved by the US Food and Drug Administration (FDA) in October 2023 for "the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy". Bimekizumab is the fourth biologic agent that targets the IL-17 pathway to be approved by the FDA for treatment of psoriasis. Secukinumab (Cosentyx), approved in January 2015, was the first followed by ixekizumab (Taltz), approved in March 2016, and then brodalumab (Siliq) approved in February 2017. Of note, bimekizumab is the first FDA-approved agent that specifically targets both IL-17A and IL-17F. In September 2024, the FDA approved three new indications for bimekizumab which include the treatment of adults with (1) active psoriatic arthritis (PsA), (2) active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, and (3) active ankylosing spondylitis (AS). Unlike plaque psoriasis, the dosages for these indications do not require loading doses. In November 2024, the FDA approved an additional indication of treatment of adults with moderate to severe hidradenitis suppurativa (HS). Treatment of HS requires loading doses and maintenance dosing that is more frequent than for the other indications.

Bimekizumab vs. placebo was evaluated in patients with moderate to severe plaque psoriasis over 56 weeks in the randomized BE READY trial (n=435). Patients were randomized 4:1 to receive bimekizumab 320 mg SQ (n=349) or placebo (n=86) every 4 weeks for 16 weeks. If PASI90 was achieved, patients were randomized 1:1:1 to receive bimekizumab 320 mg every 4 weeks or bimekizumab 320 mg every 8 weeks (n=206), or placebo (treatment withdrawal; n=105). At week 16, significantly more patients receiving bimekizumab vs. placebo achieved 90% or greater improvement from baseline in Psoriasis Area and

Severity Index (PASI90) (91% vs 1%) and achieved an Investigator's Global Assessment (IGA) score of 0 or 1 (93% vs 1%).

Bimekizumab vs. adalimumab was evaluated in patients with moderate to severe plaque psoriasis in a randomized non-inferiority BE SURE trial (n=478). Patients were randomized 1:1:1 to receive bimekizumab 320 mg SQ every 4 weeks for 56 weeks (n=158), bimekizumab 320 mg every 4 weeks for 16 weeks and then every 8 weeks for weeks 16 to 56 (n=161), or adalimumab 80 mg at baseline followed by 40 mg 1 week later and then every 2 weeks thereafter until week 24 (then switched to bimekizumab 320 mg every 4 weeks until week 56; n=159). Bimekizumab was non-inferior and superior to adalimumab with regards to achieving PASI90 at week 16 (86.2% vs. 47.2%) and achieved an IGA score of 0 or 1 at week 16 (85.3% vs. 57.2%).

Bimekizumab vs. ustekinumab was evaluated in patients with moderate to severe plaque psoriasis over 52 weeks in the randomized BE VIVID trial (n=567). Patients were randomized 4:2:1 to receive bimekizumab 320 mg SQ every 4 weeks (n=321), ustekinumab 45 mg or 90 mg (determined by patient weight) at weeks 0 and 4 and then every 12 weeks (n=163), or placebo (n=83). After the first 16 weeks, patients receiving placebo were switched to bimekizumab to complete the remaining 36 weeks of the study. More patients receiving bimekizumab therapy achieved a PASI90 at week 16 compared with ustekinumab (85% vs. 50%) and compared with placebo (85% vs. 5%). More patients receiving bimekizumab therapy achieved an IGA score of 0 or 1 at week 16 compared with ustekinumab (84% vs. 53%) and compared with placebo (84% vs. 5%).

RHEUMATOID DISORDERS

Ankylosing spondylitis (AS)

Ankylosing spondylitis (AS) is a form of chronic inflammatory arthritis characterized by sacroiliiitis, enthesitis, and a marked propensity for sacroiliac joint and spinal fusion. AS is distinguished by universal involvement with sacroiliac joint inflammation or fusion and more prevalent spinal ankylosis. Goals of treatment for AS are to reduce symptoms, maintain spinal flexibility and normal posture, reduce functional limitations, maintain work ability, and decrease disease complications. The mainstay of treatment has been NSAIDs and exercise, with the additional use of DMARDs in patients with peripheral arthritis. The American College of Rheumatology (ACR), Spondylitis Association of America (SAA), and Spondyloarthritis Research and Treatment Network (SPARTAN) recommend the following pharmacological treatment for AS:

- Stable AS: First line therapy with on demand NSAIDs; there is also a conditional recommendation for continuation of TNF inhibitor as monotherapy
- Active AS:
    - First line therapy with continuous NSAIDs and physical therapy
    - TNF inhibitor recommended for patients with active AS despite an adequate trial with NSAIDs
        - Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response

- Recommendations for nonresponse to TNF therapy (all conditional):
  - Primary nonresponse: switch to secukinumab or ixekizumab over another TNF
  - Secondary nonresponse: switch to another TNF over a non-TNF biologic
  - Recommend against addition of sulfasalazine or MTX
  - Recommend against switching to a biosimilar of the failed TNF
- TNF-inhibitors are conditionally recommended over secukinumab or ixekizumab
- Secukinumab or ixekizumab are conditionally recommended over DMARDs in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
- DMARDs (i.e., methotrexate [MTX], sulfasalazine, leflunomide, pamidronate, thalidomide, apremilast) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
- Methotrexate is not recommended as add on therapy to TNF inhibitors in stable and active AS
- If patient has concomitant inflammatory bowel disease (IBD) or recurrent uveitis, TNF-inhibitors are recommended over other biologics
- Glucocorticoids are not recommended

Nonradiographic Axial Spondyloarthritis (nr-axSpA)

Nonradiographic axial spondyloarthritis (nr-axSpA) falls under the same spondyloarthritis family as ankylosing spondylitis (AS). Nr-axSpA includes patients with chronic back pain and features suggestive of spondyloarthritis (SpA), but do not meet the classification of AS. The goals of treatment are to reduce symptoms, maintain spinal flexibility and normal posture, reduce functional limitations, maintain work ability, and decrease disease complications. The mainstay of treatment has been NSAIDs and exercise, with the additional use of DMARDs in patients with peripheral arthritis. The American College of Rheumatology (ACR), Spondylitis Association of America (SAA), and Spondyloarthritis Research and Treatment Network (SPARTAN) recommendation for nr-axSpA are the same as AS:

- Stable SpA: conditional recommendation for on-demand treatment with NSAIDs
- Active SpA:
  - First line therapy with continuous NSAIDs and physical therapy
  - TNF inhibitor conditionally recommended for patients with active SpA despite an adequate trial with NSAIDs
    - Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response
  - TNF-inhibitors are conditionally recommended over secukinumab or ixekizumab
  - Secukinumab or ixekizumab are conditionally recommended over DMARDs in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
  - Recommendations for nonresponse to TNF therapy (all conditional):
    - Primary nonresponse: switch to secukinumab or ixekizumab over another TNF

        - Secondary nonresponse: switch to another TNF over a non-TNF biologic
        - Recommend against addition of sulfasalazine or MTX
        - Recommend against switching to a biosimilar of the failed TNF
    - DMARDs (i.e., methotrexate, sulfasalazine, leflunomide, pamidronate, thalidomide, apremilast) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
    - Methotrexate is not recommended as add on therapy to TNF inhibitors in stable and active AS
    - If patient has concomitant inflammatory bowel disease or recurrent uveitis, TNF-inhibitors are recommended over other biologics
    - Glucocorticoids are not recommended

Psoriatic Arthritis (PsA)

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis, most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis, particularly spondyloarthritis and RA, and other management strategies of the cutaneous manifestations of psoriasis.

The American Academy of Dermatology (AAD) recommends initiating MTX in most patients with moderate to severe PsA. After 12 to 16 weeks of MTX therapy with appropriate dose escalation, the AAD recommends adding or switching to a TNF inhibitor if there is minimal improvement on MTX monotherapy.

The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and the following:

- Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient and health care provider to be due to PsA based on the presence of one of the following:
    - Actively inflamed joints
    - Dactylitis
    - Enthesitis
    - Axial disease
    - Active skin and/or nail involvement
    - Extraarticular manifestations such as uveitis or inflammatory bowel disease
- Disease severity includes level of disease activity at a given time point and the presence/absence of poor prognostic factors and long-term damage
- Severe PsA disease includes the presence of 1 or more of the following:
    - Erosive disease
    - Elevated markers of inflammation (ESR, CRP) attributable to PsA
    - Long-term damage that interferes with function (i.e., joint deformities)

- Highly active disease that causes a major impairment in quality of life
- Active PsA at many sites including dactylitis, enthesitis
- Function limiting PsA at a few sites
- Rapidly progressive disease

- Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, local glucocorticoid injections
- Treatment recommendations for active disease:
  - Treatment naïve patients first line options include oral small molecules (OSM), TNF biologics, IL-17 inhibitor, and IL-12/23 inhibitor
    - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe psoriasis, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitor
    - Biologics (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe psoriasis
  - Previous treatment with OSM and continued active disease:
    - Switch to a different OSM (except apremilast) in patients without severe PsA or severe PS, contraindications to TNF biologics, prefers oral therapy OR add on apremilast to current OSM therapy
    - May add another OSM (except apremilast) to current OSM therapy for patients that have exhibited partial response to current OSM in patients without severe PsA or severe PS, contraindications to TNF biologics, or prefers oral therapy
    - Biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) monotherapy
  - Previous treatment with a biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) and continued active disease:
    - Switch to another biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) monotherapy or add MTX to the current TNF biologic

DERMATOLOGICAL DISORDERS

Psoriasis (PS)

Psoriasis (PS) is a chronic inflammatory skin condition that is often associated with systemic manifestations, especially arthritis. Diagnosis is usually clinical, based on the presence of typical erythematous scaly patches, papules, and plaques that are often pruritic and sometimes painful.

Treatment goals for psoriasis include improvement of skin, nail, and joint lesions plus enhanced quality of life.

The American Academy of Family Physicians (AAFP) categorizes psoriasis severity into mild to moderate (less than 5% of body surface area [BSA]) and moderate to severe (5% or more of BSA). The AAFP psoriasis treatment guidelines recommend basing treatment on disease severity:

- Mild to moderate (less than 5% of BSA and sparing the genitals, hands, feet, and face):
  - Candidate for intermittent therapy: topical corticosteroids, vitamin D analogs (calcipotriene and calcitriol), or tazarotene (Tazorac)
  - Candidate for continuous therapy: calcineurin inhibitors (tacrolimus and pimecrolimus)
- Severe (5% or more of BSA or involving the genitals, hands, feet, and face):
  - Less than 20% of BSA affected: vitamin D analogs (calcipotriene and calcitriol) with or without phototherapy. These agents have a slower onset of action but a longer disease-free interval than topical corticosteroids
  - 20% or more of BSA affected: systemic therapy with MTX, cyclosporine, acitretin, or biologics. Biologics are recommended for those with concomitant PsA
- Less commonly used topical therapies include non-medicated moisturizers, salicylic acid, coal tar, and anthralin

The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as limited or mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it occurs in select locations (e.g., hands, feet, scalp, face, or genital area) or when it causes intractable pruritus. The AAD psoriasis treatment guidelines recommend the following*:

- Mild to moderate disease (less than 5% of BSA):
  - Topical corticosteroids strength of recommendation A
  - Off-label use of 0.1% tacrolimus for psoriasis involving the face as well as inverse psoriasis strength of evidence B
  - Long-term use (up to 52 weeks) of topical vitamin D analogs including calcipotriene, calcitriol, tacalcitol, and maxacalcitol strength of recommendation A
  - Use of calcipotriene foam and calcipotriene plus betamethasone dipropionate gel for the treatment of mild to moderate scalp psoriasis level of recommendation A
  - Use of taclicitiol ointment or calcipotriene combined with hydrocortisone for facial psoriasis strength of recommendation B
  - Vitamin D analogs in combination with topical corticosteroids strength of recommendation A
  - Topical tazarotene alone or in combination with narrowband ultraviolet B (NB-UVB) strength of recommendation B, or topical corticosteroids strength of recommendation A
  - Topical salicylic acid alone or in combination with topical corticosteroids strength of recommendation B
  - Coal tar preparations strength of evidence A
- Moderate to severe disease without PsA (5% or more of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
  - Methotrexate (adults) strength of evidence A
  - Methotrexate is less effective than TNF-inhibitors strength of evidence B
  - Combination therapy with methotrexate and NB-UVB (adult patients) strength of evidence B

- Cyclosporine for patients with severe, recalcitrant strength of recommendation A , erythrodermic, generalized pustular, and/or palmoplantar psoriasis strength of recommendation B
- Acitretin as monotherapy or in combination with psoralen plus ultraviolet light (PUVA) or broad band ultraviolet light (BB-UVA strength of evidence B
- If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
- Apremilast strength of recommendation A
- TNF-α inhibiters monotherapy strength of evidence A or in combination with topical corticosteroids with or without a vitamin D analogue strength of evidence B or in combination with acitretin strength of evidence C
- TNF-α inhibitors should be considered as a preferred treatment option for patients concomitant PsA
- Infliximab strength of evidence A
- IL-12/IL-23 Inhibitors monotherapy strength of evidence A or in combination with topical corticosteroids with or without a vitamin D analogue strength of evidence C or in combination with acitretin or methotrexate strength of evidence B
- IL-12/IL-23 inhibitors in combination with apremilast or cyclosporine strength of evidence C
- IL-17 inhibitors monotherapy strength of evidence A
- IL-23 inhibitors monotherapy for moderate to severe plaque psoriasis or as monotherapy for generalized pustular psoriasis strength of evidence B

* Strength of recommendation and descriptions

Strength of recommendation	Description
A	Recommendation based on consistent and good-quality patient-oriented evidence
B	Recommendation based on inconsistent or limited-quantity patient-oriented evidence
C	Recommendation based on consensus, opinion, case studies, or disease-oriented evidence

Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA. Primary failure is defined as initial nonresponse to treatment. Primary failure to a TNF-α inhibitor does not preclude successful response to a different TNF-α inhibitor. Failure of another biologic therapy does not preclude successful response to ustekinumab.

The National Psoriasis Foundation (NPF) medical board recommend a treat-to-target approach to therapy for psoriasis that include the following:

- The preferred assessment instrument for determining disease severity is BSA

- Target response after treatment initiation should be BSA ≤1% after 3 months
- Acceptable response is either a BSA ≤3% or a BSA improvement ≥75% from baseline at 3 months after treatment initiation

Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic inflammatory disease causing painful, nodules to form in the folds of the skin and often secrete puss and blood. HS can be described as mild (single or few lesions in one area of the skin, Hurley Stage I), moderate (repeated cycles of enlarged lesions that break open and occur in more than one area of the skin, Hurley Stage II), and severe (widespread lesions, scarring, and chronic pain; Hurley Stage III).

Pharmacological treatment for mild HS includes topical clindamycin, oral tetracyclines, hormonal treatment, retinoids, intralesional corticosteroid injections (i.e., triamcinolone), and deroofing. Oral tetracyclines are recommended for mild to moderate HS for at least a 12 week course or as long-term maintenance. Combination clindamycin and rifampin is effective second-line therapy for mild to moderate HS, or as first-line or adjunct therapy for severe HS. Combination rifampin, moxifloxacin, and metronidazole are recommended as second or third-line therapy for moderate to severe disease. Dapsone may be effective for a minority of patients with mild to moderate HS as long-term maintenance therapy. Oral retinoids, such as acitretin and isotretinoin, have also been used for mild HS as second or third-line therapy. Hormonal therapy may be considered in female patients for mild to moderate disease as monotherapy, or as adjunct therapy for severe disease. such as hormonal contraceptives, metformin, finasteride, and spironolactone.

Treatment recommendations for moderate to severe and refractory HS include immunosuppressants (e.g., cyclosporine and low dose systemic corticosteroids) and biologic agents. The TNF-inhibitors that are recommended are adalimumab, at doses within FDA labeling, and infliximab, but optimal doses have not been established. Anakinra and ustekinumab may be effective but require dose ranging studies to determine optimal doses for management.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

NOTE: The list of self-administered products with prerequisites for certain indications can be found at Preferred Agents and Drug List.

Initiation of bimekizumab (Bimzelx) meets the definition of medical necessity when **ALL** of the following are met ("1" to "5"):

1. **ONE** of the following ("a", "b", or "c"):

a. The member has been treated with bimekizumab (starting on samples is not approvable) within the past 90 days

b. The prescriber states the member has been treated with bimekizumab (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed

c. **BOTH** of the following ('i" and "ii"):

i. Bimekizumab will be used for the treatment of an indication listed in Table 1, and **ALL** of the indication-specific criteria are met

ii. **EITHER** of the following if the member has an FDA-approved indication ("I" or "II")

I. The member's age is within FDA labeling for the requested indication for bimekizumab

II. The prescriber has provided information in support of using bimekizumab for the member's age for the requested indication

2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for AS, nr-axSpA, PsA; dermatologist for HS, PS) or the prescriber has consulted with a specialist in the area of the member's diagnosis

3. Member does **NOT** have any FDA labeled contraindications to bimekizumab

4. Member will **NOT** be using bimekizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]

5. **ANY** of the following ("a", "b", "c", or "d"):

a. The dosage does not exceed the following based on the indication for use:

i. AS, nr-axSpA, PsA without coexisting PS - 160 mg SQ every 4 weeks

- QL: 160 mg/mL autoinjector/pen - 1 autoinjectors/pens (1 mL)/28 days
- QL: 160 mg/mL syringe - 1 syringes (1 mL)/28 days

ii. Psoriasis (PS) or PsA with coexisting PS:

- Loading dose - 320 mg SQ at weeks 0, 4, 8, 12, and 16
- Maintenance dose - 320 mg SQ every 8 weeks, starting 8 weeks after week 16 (i.e., on week 24):
  - QL: 160 mg/mL autoinjector/pen - 2 autoinjectors/pens (2 mL)/56 days
  - QL: 160 mg/mL syringe - 2 syringes (2 mL)/56 days
  - QL: 320 mg/2 mL autoinjector/pen - 1 autoinjector/pen (2 mL)/56 days
  - QL: 320 mg/2 mL syringe - 1 syringe (2 mL)/56 days

iii. Hidradenitis suppurativa (HS):

- Loading dose - 320 mg SQ at weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16 (i.e., every 2 weeks for the first 16 weeks)
- Maintenance dose - 320 mg SQ every 4 weeks, starting 4 weeks after week 16 (i.e., on week 20):
    - QL: 160 mg/mL autoinjector/pen - 4 autoinjectors/pens (4 mL)/56 days
    - QL: 160 mg/mL syringe - 4 syringes (4 mL)/56 days
    - QL: 320 mg/2 mL autoinjector/pen - 2 autoinjector2/pen2 (4 mL)/56 days
    - QL: 320 mg/2 mL syringe - 2 syringes (4 mL)/56 days

b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication, AND the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. **ALL** of the following ("1", "2", and "3"):

      1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication

      2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)

      3. **EITHER** of the following ("a" or "b"):

         a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

         b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

   ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

   i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration:

- PS or PsA with coexisting PS - Loading dose (doses on week 0, 4, 8, 12, and 16) for 16 weeks, then maintenance dose for 36 additional weeks [52 weeks for total duration of approval]
- AS, nr-axSpA, PsA without coexisting PS and other indications – 12 months*

*__NOTE__: For the diagnoses of AS, nr-axSpA, and PsA (without PS), loading doses are **NOT** approvable.

Table 1

Diagnosis	Criteria
Active ankylosing spondylitis (AS)	**BOTH** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to **TWO** different NSAIDs used in the treatment of AS after at least a 4-week total trial **OR** b. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** c. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of AS **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AS 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** of the following preferred products after at least a 3-month trial per product:

	• Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib) **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **THREE** of the following: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib)

	• Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib) **OR** d. **ALL** of the following are not clinically appropriate for the patient, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib)
Active non-radiographic axial spondyloarthritis (nr-axSpA)	**BOTH** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to **TWO** different NSAIDs used in the treatment of nr-axSpA after at least a 4-week total trial **OR** b. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** c. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of nr-axSpA **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of nr-axSpA 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation):

	a. The member has tried and had an inadequate response to at least **THREE** of the following preferred products after at least a 3-month trial per product: • Cimzia (certolizumab pegol) • Cosentyx (secukinumab) • Rinvoq (upadacitinib) **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) to at least **THREE** of the following: • Cimzia (certolizumab pegol) • Cosentyx (secukinumab) • Rinvoq (upadacitinib) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Cimzia (certolizumab pegol) • Cosentyx (secukinumab) • Rinvoq (upadacitinib) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Cimzia (certolizumab pegol) • Cosentyx (secukinumab) • Rinvoq (upadacitinib)
Active psoriatic arthritis (PsA)	**BOTH** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR**

	b. The member has an intolerance or hypersensitivity to **ONE** of the conventional agents used in the treatment of PsA **OR** c. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of PsA **OR** d. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** e. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** f. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** of the following preferred products after at least a 3-month trial per product: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa)

	• Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce) **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **THREE** of the following: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd)

	• Humira (adalimumab) • Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab-rzaa) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Xeljanz/Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce)
Moderate to severe plaque psoriasis (PS)	**BOTH** of the following:

	1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PS **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PS **OR** d. The member has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** e. The member has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** f. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** of the following preferred products after at least a 3-month trial per product: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab)

	• Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Sotyktu (deucravacitinib) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Yesintek (ustekinumab-kfce) **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **THREE** of the following preferred products: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Sotyktu (deucravacitinib) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Yesintek (ustekinumab-kfce) **OR**

	c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Sotyktu (deucravacitinib) • Stelara (ustekinumab) • Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Yesintek (ustekinumab-kfce) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Selarsdi (ustekinumab-aekn) • Simlandi (adalimumab-ryvk) • Skyrizi (risankizumab) • Sotyktu (deucravacitinib) • Stelara (ustekinumab)

	• Steqeyma (ustekinumab-stba) • Tremfya (guselkumab) • Yesintek (ustekinumab-kfce)
Moderate to severe hidradenitis suppurative (HS)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of HS **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of HS **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of HS **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** of the following preferred products after at least a 3-month trial per product: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Hadlima (adalimumab-bwwd) • Humira (adalimumab)

	• Simlandi (adalimumab-ryvk) **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **THREE** of the following preferred products: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk) **OR** d. **ALL** of the following are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried agents for the requested indication: • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of bimekizumab (Bimzelx) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for bimekizumab has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with bimekizumab therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for AS, nr-axSpA, PsA; dermatologist for HS, PS) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to bimekizumab
5. Member will **NOT** be using bimekizumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed the following based on the indication for use:
        - AS, nr-axSpA, and PsA without coexisting PS - 160 mg SQ every 4 weeks
            - QL: 160 mg/mL autoinjector/pen - 1 autoinjectors/pens (1 mL)/28 days
            - QL: 160 mg/mL syringe - 1 syringes (1 mL)/28 days
        - PS or PsA with coexisting PS - 320 mg SQ every 8 weeks (56 days)
            - QL: 160 mg/mL autoinjector/pen - 2 autoinjectors/pens (2 mL)/56 days
            - QL: 160 mg/mL syringe - 2 syringes (2 mL)/56 days
            - QL: 320 mg/2 mL autoinjector/pen - 1 autoinjector/pen (2 mL)/56 days
            - QL: 320 mg/2 mL syringe - 1 syringe (2 mL)/56 days
        - HS - 320 mg SQ every 4 weeks (28 days)
            - QL: 160 mg/mL autoinjector/pen - 4 autoinjectors/pens (4 mL)/56 days
            - QL: 160 mg/mL syringe - 4 syringes (4 mL)/56 days
            - QL: 320 mg/2 mL autoinjector/pen - 2 autoinjector2/pen2 (4 mL)/56 days
            - QL: 320 mg/2 mL syringe - 2 syringes (4 mL)/56 days
    b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
        i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. **ALL** of the following ("1", "2", and "3"):

1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
3. **EITHER** of the following ("a" or "b"):
   a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
   b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Indicated for the treatment of (1) moderate to severe plaque psoriasis (PS) in adult patients who are candidates for systemic therapy or phototherapy, (2) adults with active psoriatic arthritis (PsA), (3) adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation, (4) adults with active ankylosing spondylitis, and (5) adults with moderate to severe hidradenitis suppurativa (HS).
- The recommended dosage for PS is 320 mg 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.
- The recommended dosage for AS, nr-axSpA, PsA is 160 mg every 4 weeks. For PsA patients with coexisting moderate to severe PS, use the dosage and administration for PS.
- The recommended dosage for HS is 320 mg at Weeks 0, 2, 4, 6, 8, 10, 12, 14, and 16 (i.e., every 2 weeks for the first 16 weeks), then every 4 weeks thereafter.
- Before injecting, remove the carton from the refrigerator and allow to reach room temperature (30 to 45 minutes) without removing the prefilled syringes or autoinjectors from the carton to protect from light.
- Bimzelx is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject after training in subcutaneous injection technique. For each dose, inject two separate 160 mg single-dose prefilled syringes or autoinjectors subcutaneously at different anatomic locations (such as thighs, abdomen or back of upper arm).

Dose Adjustments

- No specific guidelines for dosage adjustments for renal or hepatic impairment are available. It appears that no dosage adjustments are needed.

Drug Availability

- Autoinjector:
    - Carton of two 160 mg/mL single-dose autoinjectors. Each prefilled autoinjector is fixed with a 27 gauge ½ inch needle.
    - Carton of one 160 mg/mL single-dose autoinjector. The prefilled autoinjector is fixed with a 27 gauge ½ inch needle.
    - Carton of one 320 mg/2 mL (160 mg/mL) single-dose autoinjector fixed with a 27 gauge ½ inch needle.
- Prefilled Syringe:
    - Carton of two 160 mg/mL single-dose prefilled syringes. Each prefilled syringe is fixed with a 27 gauge ½ inch needle with needle guard.
    - Carton of one 160 mg/mL single dose prefilled syringe. The prefilled syringe is fixed with a 27 gauge ½ inch needle with a needle guard.
    - Carton of one 320 mg/2 mL (160 mg/mL) single-dose prefilled syringe with a 27 gauge ½ inch needle.
- Store cartons refrigerated between 2°C to 8°C (36°F to 46°F). Keep the product in the original carton to protect it from light until the time of use. Do not freeze. Do not shake. Do not use beyond

expiration date. Bimzelx does not contain a preservative; discard any unused portion. Not made with natural rubber latex.

- When necessary, prefilled syringes or autoinjectors may be stored at room temperature up to 25°C (77°F) in the original carton for a single period of up to 30 days. Once Bimzelx prefilled syringes or autoinjectors have been stored at room temperature, do not place back in refrigerator. Write the date removed from the refrigerator in the space provided on the carton and discard if not used within a 30-day period.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- None

Precautions/Warnings

- **Suicidal Ideation and Behavior (SI/B**): May increase risk of SI/B. Advise patients, their caregivers, and families to monitor for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise them to promptly seek medical attention or call the National Suicide and Crisis Lifeline at 988. Carefully weigh risks and benefits of treatment with Bimzelx in patients with a history of severe depression and/or suicidal ideation or behavior.
- **Infections**: May increase risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, do not administer Bimzelx until the infection resolves.
- **Tuberculosis (TB)**: Avoid use in patients with active TB. Initiate treatment of latent TB prior to Bimzelx treatment.
- **Liver Biochemical Abnormalities**: Elevated serum transaminases were reported in clinical trials. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline and according to routine patient management. Permanently discontinue use of Bimzelx in patients with causally - associated combined elevations of transaminases and bilirubin.
- **Inflammatory Bowel Disease (IBD)**: Cases of IBD were reported in clinical trials with IL-17 inhibitors, including Bimzelx. Avoid use of Bimzelx in patients with active IBD. Monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

BILLING/CODING INFORMATION

HCPCS Coding

J3590	Unclassified biologics

ICD-10 Diagnosis Codes That Support Medical Necessity

L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
L73.2	Hidradenitis suppurativa
M45.0 – M45.9	Ankylosing spondylitis
M45.A0 – M45.AB	Non-radiographic axial spondyloarthritis
M46.81 – M46.89	Other specified inflammatory spondylopathies

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation**.**

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Hidradenitis suppurativa (HS) (a.k.a., acne inversa): 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. HS may have a large impact on quality of life, often causing depression, impaired sexual health, and embarrassment. Squamous cell carcinoma may arise from chronic (10-30 years of evolution) lesions. The main goals of treatment are to prevent the formation of new lesion, treat new lesions, and eliminate existing nodules and sinus tract to limit or prevent scar formation.

Plaque psoriasis: It is the most common form of psoriasis. It affects 80 to 90% of people with psoriasis. Plaque psoriasis typically appears as raised areas of inflamed skin covered with silvery white scaly skin. These areas are called plaques.

Psoriatic arthritis (PsA): joint inflammation that occurs in about 5% to 10% of people with psoriasis (a common skin disorder). It is a severe form of arthritis accompanied by inflammation, psoriasis of the skin or nails, and a negative test for rheumatoid factor. Enthesitis refers to inflammation of entheses, the site where ligaments or tendons insert into the bones. It is a distinctive feature of PsA and does not occur with other forms of arthritis. Common locations for enthesitis include the bottoms of the feet, the Achilles' tendons, and the places where ligaments attach to the ribs, spine, and pelvis.

RELATED GUIDELINES:

Adalimumab Products, 09-J0000-46
Apremilast (Otezla) Tablet, 09-J2000-19
Brodalumab (Siliq), 09-J4000-70
Certolizumab pegol (Cimzia), 09-J0000-77
Deucravacitinib (Sotyktu), 09-J4000-37
Etanercept (Enbrel), 09-J0000-38
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Guselkumab (Tremfya), 09-J2000-87
Infliximab Products, 09-J0000-39
Ixekizumab (Taltz), 09-J2000-62
Psoralens with Ultraviolet A (PUVA), 09-10000-16
Risankizumab (Skyrizi), 09-J3000-45
Secukinumab (Cosentyx), 09-J2000-30
Tildrakizumab-asmn (Ilumya), 09-J3000-04
Ustekinumab (Stelara), 09-J1000-16

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

REFERENCES:

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2. Bimzelx (bimekizumab injection, solution) [prescribing information]. UCB, Inc.; Smyrna, GA. September 2024.
3. Blauvelt A, Papp KA, Merola JF, et al. Bimekizumab for patients with moderate to severe plaque psoriasis: 60-week results from BE ABLE 2, a randomized, double-blinded, placebo-controlled, phase 2b extension study. J Am Acad Dermatol. 2020 Nov;83(5):1367-1374.
4. Blok JL, van Hattem S, Jonkman MF, et al. Systemic therapy with immunosuppressive agents and retinoids in hidradenitis suppurativa: a systematic review. Br J Dermatol. 2013;168(2):243.
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6. Clinical Pharmacology powered by ClinicalKey [Internet]. Tampa, FL: Elsevier.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed 10/29/24.
7. Coates LC, Kavanaugh A, Mease PJ et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis: Treatment Recommendations for Psoriatic Arthritis 2015. Arthritis Rheumatol 2016; 68:1060–71.
8. Dogra S, Jain A, Kanwar AJ. Efficacy and safety of acitretin in three fixed doses of 25, 35 and 50 mg in adult patients with severe plaque type psoriasis: a randomized, double blind, parallel group, dose ranging study. J Eur Acad Dermatol Venereol. 2012; 27:305-311.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/13/24.

GUIDELINE UPDATE INFORMATION:

04/01/24	New Medical Coverage Guideline.
07/01/24	Revision to guideline consisting of updating the position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
10/01/24	Revision to guideline consisting of updating the position statement. Updates to Table 1. Simlandi added among the required prerequisite agents.
11/15/24	Revision to guideline consisting of updating the description section, position statement, dosage/administration, billing/coding, related guidelines, other section, and references based on the new FDA-approved indications for AS, nr-axSpA, PsA. Bimzelx is a step 3c agent for these uses.
01/01/25	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for AS, PsA, and PS. Sotyktu added among the prerequisite therapies for PS. New FDA-approved indication for HS. Bimzelx is a step 3c agent for HS. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/25	Revision: Added Selarsdi, Steqeyma and Yesintek among the preferred agents for PS and PsA.