09-J4000-70

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Reviewed: 02/14/24

Revised: 07/01/24

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.

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%).

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

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 self-administered products with prerequisites for certain indications are as follows:

Table 1

Disease State	Step 1	Step 2 (Directed	Step 3a (Directed to	Step 3b (Directed to	Step 3c (Directed to

	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors	to ONE step 1 agent)	TWO step 1 agents)	TWO agents from step 1 and/or step 2)	THREE step 1 agents)
Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SQ: Cosentyx, Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, Cosentyx	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Hadlima, Humira	Oral: Rinvoq, Rinvoq LQ, Xeljanz	SQ: Actemra (Hadlima, or Humira is a required Step 1 agent)	N/A	SQ: Orencia	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Psoriatic Arthritis (PsA)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Rinvoq LQ, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Rheumatoid Arthritis (RA)	SQ: Enbrel, Hadlima, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Hadlima, or Humira is a required Step 1 agents)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Dermatological Disorders						
Hidradenitis Suppurativa (HS)	SQ: Cosentyx, Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Psoriasis (PS)	SQ: Cosentyx, Enbrel, Hadlima, Humira, Skyrizi, Stelara, Tremfya	N/A	Oral: Sotyktu	SQ: Cimzia	N/A	SQ: Abrilada**, Amjevita**, **Bimzelx**,

	Oral: Otezla					Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Siliq, Simlandi**, Taltz, Yuflyma**, Yusimry**
Inflammatory Bowel Disease						
Crohn's Disease (CD)	SQ: Hadlima, Humira, Skyrizi, Stelara	Oral: Rinvoq	N/A	SQ: Cimzia (Hadlima, or Humira are required Step 1 agents)	SQ: Entyvio	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yusimry**, Zymfentra
Ulcerative Colitis (UC)	SQ: Hadlima, Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Hadlima or Humira is a required Step 1 agents)	N/A	SQ: Entyvio Oral: Zeposia (Hadlima, Humira, Rinvoq, Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Omvoh, Simlandi**, Yuflyma**, Yusimry**, Zymfentra Oral: Velsipity
Other						
Uveitis	SQ: Hadlima, Humira	N/A	N/A	N/A	N/A	SQ: Abrilada**, Amjevita**, Cyltezo**, Hulio**, Hyrimoz**, Idacio**, Simlandi**, Yuflyma**, Yusimry**
Indications Without Prerequisite Biologic Immunomodulators						
Alopecia Areata (AA) Atopic Dermatitis (AD) Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Juvenile Psoriatic Arthritis (JPsA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID)	N/A	N/A	N/A	N/A	N/A	N/A

Polymyalgia Rheumatica (PMR) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)						

Note: Hadlima and Humira are required Step 1 agents

Note: For Xeljanz products (Xeljanz and Xeljanz XR) and Rinvoq products (Rinvoq and Rinvoq LQ), a trial of either or both dosage forms collectively counts as **ONE** product

Note: Branded generic available for Cyltezo, Hulio, Hyrimoz, Idacio, Simlandi and Yuflyma are included as a target at the same step level in this program

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 2, 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
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist for 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), 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", or "c"):
    a. The dosage does not exceed:

- 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

b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) 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

c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval duration: 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]

Table 2

Diagnosis	Criteria
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: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Skyrizi (risankizumab) • Stelara (ustekinumab) • Tremfya (guselkumab) **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: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast)

	• Skyrizi (risankizumab) • Stelara (ustekinumab) • Tremfya (guselkumab) **OR** c. The member has an FDA labeled contraindication to **ALL** of the following: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Skyrizi (risankizumab) • Stelara (ustekinumab) • Tremfya (guselkumab) **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: • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla (apremilast) • Skyrizi (risankizumab) • Stelara (ustekinumab) • Tremfya (guselkumab)
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., dermatologist for 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), 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", or "c"):
    a. The dosage does not exceed 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
    b. The requested quantity (dose) exceeds the program quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e. DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) 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
    c. The requested quantity (dose) exceeds the program quantity limit and exceeds the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required).

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 moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

- The recommended dosage is 320 mg (given as 2 subcutaneous injections of 160 mg each) at Weeks 0, 4, 8, 12, and 16, then every 8 weeks thereafter. For patients weighing ≥120 kg, consider a dosage of 320 mg every 4 weeks after Week 16. 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.
- 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.
- 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

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**.**

DEFINITIONS:

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.

RELATED GUIDELINES:

Adalimumab Products, 09-J0000-46
Apremilast (Otezla) Tablet, 09-J2000-19
Certolizumab pegol (Cimzia), 09-J0000-77
Deucravacitinib (Sotyktu), 09-J4000-37
Etanercept (Enbrel), 09-J0000-38
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:

Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab

Kevzara (sarilumab)
Kineret (anakinra)
Nucala (mepolizumab)
Omvoh (mirikizumab-mrkz)
Orencia (abatacept)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi Aria (golimumab)
Skyrizi (risankizumab-rzaa)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence ((tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tyruko (natalizumab-sztn)
Tysabri (natalizumab)
Wezlana (ustekinumab-auub)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zymfentra (infliximab-dyyb)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 02/14/24.

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.