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Subject: Bimekizumab-bkzx (Bimzelx®) Injection

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Dosage/ Administration | Position Statement | Billing/Coding | Reimbursement | Program Exceptions | Definitions

Related Guidelines | Other | References | Updates

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)

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 mainstays of treatment have been nonsteroidal anti-inflammatory drugs (NSAIDs) and exercise/physical therapy.

NSAIDs are used as first line therapy for patients with active AS, with continuous treatment with NSAIDs being preferred. In patients with stable disease, NSAIDs may be used on-demand to decrease the risk of adverse effects with long term use. No particular NSAID is recommended as a preferred option. Biologics should be used in patients who continue to have persistently high disease activity despite NSAIDs. Failure of standard treatment with NSAIDs can be defined as a lack of response (or intolerance) to at least 2 NSAIDs after at least a 4-week duration of therapy in total.

Tumor necrosis factor (TNF) inhibitors or interleukin (IL)-17 inhibitors are recommended as initial biologic therapy. Other present comorbidities (e.g., inflammatory bowel disease, psoriasis, uveitis) can help guide selection of the initial biologic agent/drug class. Patients who have an inadequate response to a TNF inhibitor or IL-17 inhibitor may switch to a biologic of the other drug class, or switch to a Janus kinase (JAK) inhibitor. Patients with secondary failure to a biologic (presence of antidrug antibodies) may switch to another biologic of the same or different mode of action.

Systemic glucocorticoids should generally not be used in the treatment of AS. Short-term glucocorticoid injections may be used in select patients with peripheral signs and symptoms. Conventional disease-modifying antirheumatic drugs (cDMARDs) (e.g., methotrexate, sulfasalazine, leflunomide) are not recommended as treatment due to their lack of efficacy. However, sulfasalazine may be considered in patients with peripheral arthritis.

Nonradiographic Axial Spondyloarthritis (nr-axSpA)

Nonradiographic axial spondyloarthritis (nr-axSpA) falls under the same spondyloarthritis family as ankylosing spondylitis (AS). Nr-axSpA is characterized by chronic back pain and features suggestive of spondyloarthritis (SpA), although advanced sacroiliac joint damage and spine ankylosis are absent. 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 mainstays of treatment have been NSAIDs and exercise/physical therapy.

NSAIDs are used as first line therapy for patients with active nr-axSpA, with continuous treatment with NSAIDs being preferred. In patients with stable disease, NSAIDs may be used on-demand to decrease the risk of adverse effects with long term use. No particular NSAID is recommended as a preferred option.(64) Biologics should be used in patients who continue to have persistently high disease activity despite NSAIDs. Failure of standard treatment with NSAIDs can be defined as a lack of response (or intolerance) to at least 2 NSAIDs after at least a 4-week duration of therapy in total.

Tumor necrosis factor (TNF) inhibitors or interleukin (IL)-17 inhibitors are recommended as initial biologic therapy. Other present comorbidities (e.g., inflammatory bowel disease, psoriasis, uveitis) can help guide selection of the initial biologic agent/drug class. Patients who have an inadequate response to a TNF inhibitor or IL-17 inhibitor may switch to a biologic of the other drug class, or switch to a Janus kinase (JAK) inhibitor. Patients with secondary failure to a biologic (presence of antidrug antibodies) may switch to another biologic of the same or different mode of action.

Systemic glucocorticoids should generally not be used in the treatment of nr-axSpA. Short-term glucocorticoid injections may be used in select patients with peripheral signs and symptoms. Conventional disease-modifying antirheumatic drugs (cDMARDs) (e.g., methotrexate, sulfasalazine, leflunomide) are not recommended as treatment due to their lack of efficacy. However, sulfasalazine may be considered in patients with peripheral arthritis.

Psoriatic Arthritis (PsA)

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis (PS), most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient due to one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and/or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Disease severity is based on the assessment of the level of disease activity at a given point in time, and the presence/absence of poor prognostic factors and long-term damage. Severe PsA is defined in the American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA and includes the presence of one or more of the following:

- Erosive disease
- Elevated markers of inflammation (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP]) attributable to PsA
- Long-term damage that interferes with function (e.g., joint deformities, vision loss)
- Highly active disease that causes a major impairment in quality of life, such as:
    - Active PsA at many sites including dactylitis and enthesitis
    - Function-limiting PsA at a few sites
- Rapidly progressive disease

Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis disorders, particularly spondyloarthritis and rheumatoid arthritis, and other management strategies of the cutaneous manifestations of psoriasis. Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and local glucocorticoid injections. Only patients with very mild peripheral disease may sufficiently benefit from NSAIDs as monotherapy, and instead patients are typically treated with disease-modifying antirheumatic drugs (DMARDs) and/or biologics. Efficacy of DMARD and biologic therapies should be assessed 3 months after initiation, and if adequate improvement is not seen then the treatment regimen should be updated or changed. The ACR-NPF guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and treatment recommendations for active disease are as follows:

- Treatment naïve patients:
    - First line options include oral small molecules (OSM), tumor necrosis factor (TNF) inhibitors, interleukin (IL)-17 inhibitors, and IL-12/23 inhibitors
        - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe PS, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitors
        - Biologics (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe PS

- Previous treatment with OSM and continued active disease:
    - Switch to a biologic (i.e., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor); recommended over switching to a different OSM
        - Biologic monotherapy is conditionally recommended over biologic plus MTX combination therapy
    - Switch to a different OSM (except apremilast) OR add on apremilast to current OSM therapy; recommended over adding another OSM
    - Add another OSM (except apremilast) to current OSM therapy; may consider for patients that have exhibited partial response to current OSM
    - Switch to apremilast monotherapy; may be considered instead of adding apremilast to current OSM therapy if the patient has intolerable side effects with the current OSM
- Previous treatment with a biologic and continued active disease:
    - Switch to another biologic (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) as monotherapy
    - Add MTX to the current biologic; may consider adding MTX in patients with a partial response to current biologic therapy

The European Alliance of Associations for Rheumatology (EULAR) guidelines for PsA (2023 update) also recommend a treat-to-target approach in therapy. MTX (preferred) or another conventional synthetic disease-modifying antirheumatic drug (csDMARD) (e.g., sulfasalazine, leflunomide) should be used for initial therapy. If the treatment target is not achieved with a csDMARD, a biologic should be initiated with preference of product being based on patient specific disease characteristics. Biologics include TNF inhibitors, IL-12/23 inhibitors, IL-17A inhibitors, IL-17A/F inhibitors, IL-23 inhibitors, and cytotoxic T-lymphocyte–associated antigen 4 (CTLA4) analogs. No order of preference of biologics is provided since none have demonstrated superiority for joint involvement, however, CTLA4 analogs are least preferred due to limited efficacy in clinical trials. The use of a Janus kinase (JAK) inhibitor (e.g., tofacitinib, upadacitinib) may be used after failure of a biologic or if biologics are not clinically appropriate for the patient. However, careful consideration should be applied prior to using a JAK inhibitor due to the increased risk of cardiovascular and malignancy events in older patients with RA and cardiovascular risk factors. A phosphodiesterase-4 (PDE4) inhibitor (i.e., apremilast) may be considered in patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a biologic nor a JAK inhibitor is appropriate. Patients with an inadequate response to a biologic or JAK inhibitor may switch to a different drug within the same class or switch to a different mode of action. Adding MTX to a biologic may increase drug survival by limiting the development of antidrug antibodies, especially for TNF inhibitors.

DERMATOLOGICAL DISORDERS

Psoriasis (PS)

Psoriasis (PS) is a chronic inflammatory skin and systemic disorder. It is a complex disease that affects the skin and joints and is associated with numerous comorbidities, including obesity and inflammatory bowel disease. Psoriasis vulgaris, or plaque psoriasis, is a cutaneous form that often presents with pink plaques with silvery scale on the scalp, elbows, knees, or presacral region, but any area of the skin may be involved. Plaque psoriasis is the most common form (affecting 90% of adults with psoriasis), but others include guttate, erythrodermic, pustular, inverse, nail, and psoriatic arthritis (PsA). PS is clinically diagnosed based on the presence of cutaneous and systemic symptoms, and treatment is similar for most forms but is guided by the body surface area (BSA) involved. The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as 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 causes serious

emotional consequences, occurs in select locations (e.g., hands, feet, scalp, face, or genital area), or when it causes intractable pruritus.

Topical therapies are most commonly used to treat mild to moderate PS, but they may be used in combination with phototherapy, systemic, or biologic therapies for the treatment of moderate to severe PS. Topical therapies alone can be sufficient for managing limited disease and also have fewer significant adverse effects compared to systemic treatment options. However, topical therapies may be inadequate to obtain and maintain skin clearance, and systemic therapies may be warranted. Conventional systemic agents are widely used as monotherapy or in combination with biologics for moderate to severe disease, and they are beneficial for widespread disease and ease of administration. Biologics are routinely used when one or more conventional agents fail to produce an adequate response but are considered first line in patients with severe PS or patients with concomitant severe PsA. The NPF medical board recommends a treat-to-target approach to therapy for psoriasis that includes the following:

- The preferred assessment instrument for determining treatment response is BSA
- The preferred time to perform initial evaluation of treatment response is after 3 months
- Target response after treatment initiation should be BSA less than or equal to 1% after 3 months
- Acceptable response is either a BSA less than or equal to 3% or a BSA improvement greater than or equal to 75% from baseline at 3 months after treatment initiation

Selection of treatment is based on several factors including benefit-risk assessment, clinical presentation, disease severity, and comorbidities. The AAD/NPF psoriasis treatment guidelines support the following treatment options:

- Topical therapies:
    - Topical corticosteroids (TCS)
    - Topical calcineurin inhibitors (TCIs), such as tacrolimus and pimecrolimus
    - Vitamin D analogues (e.g., calcipotriene and calcitriol)
    - Tazarotene (topical retinoid)
    - Coal tar preparations
    - Topical anthralin
- Psoralen plus ultraviolet light (PUVA) phototherapy
- Systemic non-biologic therapies:
    - Methotrexate (MTX)
    - Cyclosporine
    - Acitretin
    - Apremilast
- Biologic therapies:
    - Tumor necrosis factor (TNF)-α inhibitors (e.g., adalimumab, certolizumab, etanercept, infliximab)
    - Interleukin (IL)-17 inhibitors (e.g., brodalumab, ixekizumab, secukinumab)
    - IL-23 inhibitors (e.g., guselkumab, risankizumab, tildrakizumab)
    - IL-12/IL-23 Inhibitors (e.g., ustekinumab)

      *Note: Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics was published in 2019. No specific biologic drug/class is recommended as first-line for all patients with psoriasis, and instead choice of therapy should be individualized based on

patient specific factors. Additional biologic drugs have since received FDA approval for psoriasis that are not discussed.

Primary failure for biologics is defined as initial nonresponse to treatment. Primary failure to a tumor necrosis factor (TNF)-α inhibitor does not preclude successful response to a different TNF-α inhibitor, and failure of another biologic therapy does not preclude successful response to ustekinumab. All biologics may lose efficacy in a patient who initially responds favorably to the medication (secondary failure), and loss of efficacy may be attributed to the presence of antidrug antibodies. The concomitant use of MTX with a biologic may increase drug survival by limiting antibody formation.

For the treatment of PS in the pediatric patient population, topical corticosteroids are the mainstay option based on extensive clinical experience that supports efficacy. Topical calcineurin inhibitors are also a treatment option and may be preferred for psoriasis of the face, genitalia, and body folds. Vitamin D analogues are recommended as a treatment option for childhood plaque psoriasis and are considered safe, effective, and generally well tolerated. Other topical therapies that may be used for the treatment of pediatric psoriasis include tazarotene, anthralin, and coal tar. Phototherapy may be efficacious and well tolerated for pediatric patients with generalized psoriasis or localized psoriasis refractory to topical agents. Systemic non-biologic therapies, such as methotrexate, cyclosporine, and acitretin, are options for moderate to severe psoriasis. Biologic therapies (e.g., adalimumab, etanercept, infliximab, ustekinumab) have also shown efficacy in moderate to severe plaque psoriasis in this patient population.

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), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (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 duration of therapy **OR** b. The member has tried and had an inadequate response to **ONE** NSAID used in the treatment of AS after at least a 4-week duration of therapy **AND** an intolerance or hypersensitivity to **ONE** additional NSAID used in the treatment of AS **OR** c. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** d. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of AS **OR** e. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AS **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 **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR**

	c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the patient, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred AS products are:** • 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 duration of therapy **OR** b. The member has tried and had an inadequate response to **ONE** NSAID used in the treatment of AS after at least a 4-week duration of therapy **AND** an intolerance or hypersensitivity to **ONE** additional NSAID used in the treatment of AS **OR** c. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** d. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of nr-axSpA **OR** e. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA

	labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of nr-axSpA **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 **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR** c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) to at least **TWO** preferred products **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred nr-axSpA products are:** • 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** conventional agent used in the treatment of PsA **OR** c. The member has an FDA labeled contraindication to **ALL** 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, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, 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 (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA **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 **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR** c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred PsA products are:** • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept)

	• Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla/Otezla XR (apremilast) • Rinvoq/Rinvoq LQ (upadacitinib) • 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, calcipotriene, calcitriol, coal tar, cyclosporine, methotrexate, pimecrolimus, phototherapy [e.g., PUVA, UVB], 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, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, rapidly progressive) **OR** f. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) 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 **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR** c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred PS products are:** • Adalimumab-aaty • Adalimumab-adaz • Cosentyx (secukinumab) • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Otezla/Otezla XR (apremilast) • 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** systemic antibiotic therapy (i.e., oral tetracycline [doxycycline, minocycline, tetracycline]; clindamycin plus rifampin; clindamycin monotherapy) 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** systemic antibiotic therapy used in the treatment of HS **OR** c. The member has an FDA labeled contraindication to **ALL** systemic antibiotic therapies used in the treatment of HS **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) 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 **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR** c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products **OR** d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred HS products are:** • 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), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (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.

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10. Dogra S, Krishna V, Kanwar AJ. Efficacy and safety of systemic methotrexate in two fixed doses of 10 mg or 25 mg orally once weekly in adult patients with severe plaque-type psoriasis: a prospective, randomized, double-blind, dose-ranging study. Clin Exp Dermatol. 2012 Oct;37(7):729-34.
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12. Elmets CA, Lim HW, Stoff H, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. Epub 2019 July 25.
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/12/25.

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.
01/01/26	Review and revision to guideline consisting of updating the description, position statement and references. Bimzelx moved from a Step 3c agent (triple step) to a Step 3a agent (double step) for all FDA-approved indications.
07/01/26	Revision: Modified the prerequisite requirement that bypasses the conventional agent step to exclude sample use and include systemic targeted synthetic small molecule drugs as an option. Updated the HS prerequisites to only systemic antibiotic therapy. Added additional wording to the definition of severe active PsA. Removed Selarsdi as a preferred agent for PS and PsA.