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Subject: Apremilast (Otezla, Otezla XR) Tablet

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DESCRIPTION:

Apremilast (Otezla) was approved by the US Food and Drug Administration (FDA) for the treatment of adults with active psoriatic arthritis (PsA) in March 2014 and then moderate-to-severe plaque psoriasis in September 2014. In July 2019, the indications were expanded to include the treatment of adult patients with oral ulcers associated with Behçet's Disease. The treatment of Behçet's disease was a previously granted orphan drug designation by the FDA in 2013. Apremilast, as sponsored by the innovator drug company, also was granted orphan drug designation by the FDA for the treatment of pediatric patients with ulcerative colitis in 2018. In December 2021, the plaque psoriasis indication was expanded to include mild-to-moderate disease, with the revised indication now worded as "for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy". In April 2024, the FDA approved an additional indication for pediatric patients of "treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy". In July 2025, the FDA approved an expansion of the active PsA indication to include pediatric patients 6 of age and older and weighing at least 20 kg. In August 2025, an extended-release (ER) formulation of apremilast (Otezla XR) was approved by the FDA for the same indications as Otezla. The minimum weight for Otezla XR in pediatric patients is 50 kg (110 lbs). Apremilast exerts its therapeutic activity through inhibition of phosphodiesterase-4 (PDE-4). PDE-4 inhibition promotes intracellular accumulation of cyclic adenosine monophosphate; this accumulation results in a downregulation of inflammatory responses and ultimately reduces inflammation. The National Comprehensive Cancer Network (NCCN) guidelines on the Management of Immune Checkpoint Inhibitor -Related-Toxicities include apremilast (2A recommendation) as a consideration for the management of immunotherapy-related toxicities that include the following: (1) moderate (10 to 30% body surface area [BSA]) psoriasis and psoriasiform diseases if not responsive to high-potency topical corticosteroids, severe (>30% BSA) psoriasis and

psoriasiform diseases, and (3) moderate to severe inflammatory arthritis that has symptoms suggestive of psoriatic arthritis or spondyloarthropathies.

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.

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.

Behcet's Disease (BD)

BD is a chronic systemic inflammatory disease, defined as a variable vessel vasculitis, characterized by mucocutaneous lesions and involves numerous organ systems (e.g., mucocutaneous, musculoskeletal, ocular, vascular, neurologic, and gastrointestinal). BD has a relapsing-remitting course of disease and usually begins in the second or third decade of life. Recurring oral ulcers are seen in over 95% of patients and are typically the first clinical manifestation of the disease, usually preceding the diagnosis by an average of 6 to 7 years. No disease specific laboratory, histopathologic, or genetic findings exist to diagnose a patient with BD, and instead the diagnosis is mainly based on clinical presentation and findings. The International Study Group (ISG) criteria for the diagnosis of BD should be considered when diagnosing people with suspected BD. It is the most widely used diagnosis criteria and has been shown

to have 95% sensitivity and 98% specificity. In order to meet ISG criteria, a patient must have recurrent oral ulceration, with at least three occurrences during a 12-month period.

The goal of treatment in patients with BD is to suppress inflammatory exacerbations and recurrences to prevent irreversible organ damage. Disease manifestations may improve over time in many patients. Ocular, vascular, neurological, and gastrointestinal involvement may be associated with a poor prognosis. Treatment needs to be individualized based on the type and severity of organ involvement, and a multidisciplinary approach is necessary for optimal care. Skin, mucosa, and joint involvement can impair a patient's quality of life but typically does not cause permanent damage. However, if scarring occurs due to chronic oral ulceration, vigorous treatment is needed to prevent oropharyngeal narrowing.

For the treatment of an acute exacerbation of oral ulcers, a topical corticosteroid (i.e., triamcinolone acetonide oral paste) should be used as it may help with the rapid healing of the lesions. A topical corticosteroid may also be used as adjunctive therapy with a systemic immunosuppressant in patients with more severe disease. If topical corticosteroid therapy alone is inadequate to control the disease, colchicine should be used to treat mucocutaneous lesions. Colchicine should be tried first for the prevention of recurrent mucocutaneous lesions due to its safety and tolerability. If lesions continue to recur despite colchicine, immunomodulatory or immunosuppressive agents, such as azathioprine or apremilast, can be used.

Efficacy

The efficacy of Otezla for the treatment of oral ulcers associated with BD was established in a multicenter, randomized, placebo-controlled trial (NCT02307513). Patients were required to have a diagnosis of BD according to International Study Group criteria and have active oral ulcers at the time of enrollment and randomization. Patients had to have at least 3 occurrences of oral ulcers within the previous 12 months despite previous treatment with at least one non-biologic therapy (e.g., topical corticosteroids, colchicine, immunosuppressants). All subjects had a history of recurrent oral ulcers that were currently active. Otezla had a greater reduction in the number of oral ulcers and patient reported ulcer pain when compared to placebo.

POSITION STATEMENT:

Comparative Effectiveness

The Food and Drug Administration 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 apremilast (Otezla) or apremilast extended release (Otezla XR) **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 the requested apremilast product (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with the requested apremilast product (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. The requested apremilast product 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 the requested apremilast product
            II. The prescriber has provided information in support of using the requested apremilast product for the member's age for the requested indication
2. **ONE** of the following ("a" or "b"):
    a. The member has a diagnosis of mild severity plaque psoriasis
    b. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist, rheumatologist) or has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to the requested apremilast product
4. Member will **NOT** be using the requested apremilast product 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), 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 the following based on weight and age:
        i. Otezla:
            - Adults (18 years and older) and children weighing 50 kg (110 lbs) or more
                - Titration dose: Day 1: 10 mg in the morning, Day 2: 10 mg in morning and 10 mg in evening, Day 3: 10 mg in morning and 20 mg in evening, Day 4: 20 mg in morning and 20 mg in evening, Day 5: 20 mg in morning and 30 mg in evening, Day 6 and beyond: 30 mg twice daily
                    - 10 mg, 20 mg & 30 mg tablet starter pack (4 week) - 1 starter pack (55 tablets)/180 days

                    Maintenance dose – 30 mg twice daily

                    - QL: 30 mg tablets - 60 tablets/30 days (2 tablets/day)
            - Children (less than 18 years) and weighing less than 50 kg (110 lbs)

- Titration dose: Day 1: 10 mg in the morning, Day 2: 10 mg in morning and 10 mg in evening, Day 3: 10 mg in morning and 20 mg in evening, Day 4: 20 mg in morning and 20 mg in evening, Day 5: 20 mg in morning and 20 mg in evening, Day 6 and beyond: 20 mg twice daily
  - 10 mg & 20 mg tablet starter pack (4 week) - 1 starter pack (55 tablets)/180 days
- Maintenance dose - 20 mg twice daily
  - QL: 20 mg tablets - 60 tablets/30 days (2 tablets/day)

ii. Otezla XR:

- Adults (18 years and older) and children weighing 50 kg (110 lbs) or more
  - Titration dose: Day 1: 10 mg in the morning, Day 2: 10 mg in morning and 10 mg in evening, Day 3: 10 mg in morning and 20 mg in evening, Day 4: 20 mg in morning and 20 mg in evening, Day 5: 20 mg in morning and 20 mg in evening, Day 6 and beyond: 75 mg ER tablet once daily
    - 10 mg, 20 mg, & 30 mg tablet and 75 mg ER tablet starter pack (4 week) - 1 starter pack (41 tablets)/180 days
  - Maintenance dose - 75 mg once daily
    - QL: 75 mg ER tablets - 30 tablets/30 days (1 tablet/day)

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

Table 1

Diagnosis	Criteria
Active psoriatic arthritis (PsA)	**BOTH** of the following: 1. If the member is a pediatric patient (6 to 17 years of age), then **ONE** of the following ("a" or "b"): a. The requested agent is Otezla, **AND** member weighs at least 20 kg (44 lbs)

	OR b. The requested agent is Otezla XR, **AND** member weighs at least 50 kg (110 lbs) **AND** 2. **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's medication history indicates use of a biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA
Plaque psoriasis (PS)	**BOTH** of the following: 1. If the member is a pediatric patient (6 to 17 years of age), then **BOTH** of the following ("i" and "ii"): i. The member has moderate to severe plaque psoriasis **AND** ii. **ONE** of the following: • The requested agent is Otezla, **AND** member weighs at least 20 kg (44 lbs) **OR** • The requested agent is Otezla XR, **AND** member weighs at least 50 kg (110 lbs) **AND** 2. **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, 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's medication history indicates use of a biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS
Behcet's disease (BD)	**ALL** of the following: 1. The member has active oral ulcers associated with BD **AND** 2. The member has had at least 3 occurrences of oral ulcers in the last 12 months **AND** 3. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of BD **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of BD **OR** d. The member's medication history indicates use of a biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of BD.

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 apremilast (Otezla) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for the requested apremilast product 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 the requested apremilast product
3. **ONE** of the following ("a" or "b"):
    a. The member has a diagnosis of mild severity plaque psoriasis
    b. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist, rheumatologist) or has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to the requested apremilast product
5. Member will **NOT** be using the requested apremilast product 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)]; 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 the following based on weight and age:
        i. Otezla:
            - Adults (18 years and older) and children weighing 50 kg (110 lbs) or more – 30 mg twice daily
                - QL: 30 mg tablets – 60 tablets/30 days (2 tablets/day)
            - Children (less than 18 years) and weighing less than 50 kg (110 lbs) - 20 mg twice daily
                - QL: 20 mg tablets – 60 tablets/30 days (2 tablets/day)
        ii. Otezla XR:
            - Adults (18 years and older) and children weighing 50 kg (110 lbs) or more – 75 mg once daily
                - QL: 75 mg ER tablets – 30 tablets/30 days (1 tablets/day)
    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** there is 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

Apremilast (Otezla) is indicated for (1) the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 20 kg with active psoriatic arthritis, (2) the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy, (3) the treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, and (4) the treatment of adult patients with oral ulcers associated with Behçet's Disease.

Apremilast extended release (Otezla XR) is indicated for (1) the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 50 kg with active psoriatic arthritis, (2) the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy, (3) the treatment of pediatric patients 6 years of age and older and weighing at least 50 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, and (4) the treatment of adult patients with oral ulcers associated with Behçet's Disease.

To reduce the risk of gastrointestinal symptoms, the following titration schedule is recommended. Otezla XR should only be started after the initial 5-day titration with Otezla.

Adults:

- Day 1: 10 mg in the morning
- Day 2: 10 mg in morning and 10 mg in evening
- Day 3: 10 mg in morning and 20 mg in evening
- Day 4: 20 mg in morning and 20 mg in evening
- Day 5: 20 mg in morning and 30 mg in evening
- Day 6 and after: 30 mg twice daily (Otezla) or 75 mg once daily (Otezla XR)

Pediatric patients (6 years and older) with PsA or PS:

- 50 kg or more – same schedule as adults
- 20 kg to less than 50 kg (for Otezla only):

- Day 1: 10 mg in the morning
- Day 2: 10 mg in morning and 10 mg in evening
- Day 3: 10 mg in morning and 20 mg in evening
- Day 4: 20 mg in morning and 20 mg in evening
- Day 5: 20 mg in morning and 20 mg in evening
- Day 6 and after: 20 mg twice daily

Patients treated with Otezla 30 mg twice daily may be switched to Otezla XR 75 mg once daily the day following the last dose of Otezla 30 mg. Patients treated with Otezla XR 75 mg once daily may be switched to Otezla 30 mg twice daily the day following the last dose of Otezla XR 75 mg

Dose Adjustments

Adults – For Otezla, reduce the dose to 30 mg once daily for persons with severe renal impairment (i.e., creatinine clearance less than 30 ml/min). For initial dose titration, titrate using only the morning schedule and skip evening doses. Otezla XR is NOT recommended for adult patients with severe renal impairment; the appropriate dosage for these patients has not been determined. No dose adjustment is necessary in patients with hepatic impairment.

Pediatric patients (6 years and older) with PsA or PS - Refer to the product labeling.

Product Availability

Apremilast (Otezla) is supplied as 10-, 20-, and 30-mg tablets.

- Configurations for 30 mg BID Dosage
  - 28-day treatment initiation pack (55513-0369-55) - 55-tablet blister pack including tablets for titration and maintenance dosage: 4 tablets (10 mg each), 4 tablets (20 mg each), and 47 tablets (30 mg each)
  - 60-count bottle of 30 mg tablets (55513-0137-60)
- Configurations for 20 mg BID Dosage
  - 28-day treatment initiation pack (55513-0508-55) - 55-tablet blister pack including tablets for titration and maintenance dosage: 4 tablets (10 mg each) and 51 tablets (20 mg each)
  - 60-count bottle of 20 mg tablets (55513-0497-60)

Apremilast ER (Otezla XR) is supplied as 75 mg extended-release (ER) tablets.

- 28-day treatment initiation pack (55513-0516-41) - 41-tablet blister titration pack including tablets for titration and maintenance dosage
  - Otezla - 4 tablets (10 mg each), 4 tablets (20 mg each), and 19 tablets (30 mg each)
  - Otezla XR - 14 ER tablets (75 mg each)
- 30-count bottle of 75 mg ER tablets (55513-0519-30)

PRECAUTIONS:

Boxed Warning

- None

Contraindication

- Known hypersensitivity to apremilast or any excipients in the formulation

Precautions/Warnings

- **Hypersensitivity**: Hypersensitivity reactions, including cases of angioedema and anaphylaxis, have been reported during post marketing surveillance. Avoid the use in patients with known hypersensitivity to apremilast/apremilast ER or to any of the excipients in the formulation. If signs or symptoms of serious hypersensitivity reactions develop during treatment, discontinue apremilast/apremilast ER and institute appropriate therapy.
- **Diarrhea, Nausea, and Vomiting**: There have been postmarketing reports of severe diarrhea, nausea, and vomiting associated with the use of apremilast. Most events occurred within the first few weeks of treatment. Monitor patients who are more susceptible to complications of diarrhea or vomiting. Patients who reduced dosage or discontinued treatment generally improved quickly. Consider dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting.
- **Depression**: Advise patients, their caregivers, and families to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes and if such changes occur to contact their healthcare provider. Carefully weigh risks and benefits of treatment with apremilast/apremilast ER in persons with a history of depression and/or suicidal thoughts or behavior.
- **Weight Decrease**: Monitor weight regularly. If unexplained or clinically significant weight loss occurs, evaluate weight loss and consider discontinuation of apremilast/apremilast ER.
- **Drug Interactions**: Use with strong cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended because loss of efficacy may occur.

BILLING/CODING INFORMATION:

HCPCS Coding

J8499	Prescription drug, oral, non-chemotherapeutic, NOS

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
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy

M35.2	Behçet's disease
T45.AX5A	Adverse effect of immune checkpoint inhibitors and immunostimulant drugs, initial encounter
T45.AX5D	Adverse effect of immune checkpoint inhibitors and immunostimulant drugs, subsequent encounter
T45.AX5S	Adverse effect of immune checkpoint inhibitors and immunostimulant drugs, sequela

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 Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

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.

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:

DMARDs: An acronym for disease-modifying antirheumatic drugs. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., baricitinib, tofacitinib, apremilast), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD (boDMARD).

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: 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:

Abatacept (Orencia), 09-J0000-67
Adalimumab Products, 09-J0000-46
Bimekizumab (Bimzelx), 09-J4000-70
Brodalumab (Siliq) Injection, 09-J2000-74
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.

Table 2: Conventional Synthetic DMARDs

DMARD Generic Name	DMARD Brand Name
Auranofin (oral gold)	Ridaura
Azathioprine	Imuran
Cyclosporine	Neoral, Sandimmune
Hydroxychloroquine	Plaquenil
Leflunomide	Arava
Methotrexate	Rheumatrex, Trexall
Sulfasalazine	Azulfidine, Azulfidine EN-Tabs

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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:

09/15/14	New Medical Coverage Guideline.
12/15/14	Revision to guideline.
04/15/15	Revision of guideline; consisting of position statement to exclude combination therapy.
09/15/15	Review and revision of guidelines; consisting of updating description section, position statement, dosage/administration, billing/coding, related guidelines, definitions, and references.
11/01/15	Revision: ICD-9 Codes deleted.
09/15/16	Review and revision of guidelines consisting of updating description section, position statement, billing/coding, related guidelines, and references.
02/01/17	Revision to guideline consisting of removing the two preferred agent prerequisite requirement.
10/15/17	Review and revision to guideline consisting of updating description, position statement, dosage/administration, definitions, related guidelines, and references.
07/01/18	Revision to guideline consisting of updating the position statement.
10/15/18	Review and revision to guideline consisting of updating the position statement, billing/coding, and references.
10/15/19	Review and revision to guideline consisting of updating description, position statement, dosage/administration, related guidelines, and references.
07/01/20	Revision to guideline consisting of updating the description, position statement, billing/coding, related guidelines, and definitions.
01/01/21	Review and revision to guideline consisting of updating the position statement and references.
03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.
11/15/21	Revision to guideline consisting of updating the position statement.
01/01/22	Review and revision to guideline consisting of updating the position statement, other section, and references.
02/15/22	Update to Table 1 in Position Statement.
03/15/22	Revision to guidelines consisting of updating the description, position statement, dosage/administration, precautions, other section, and references.
05/15/22	Update to Table 1 in Position Statement.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Update to Table 1 in Position Statement.
01/01/23	Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination.
04/15/23	Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.

07/01/23	Revision to guideline consisting of updating the position statement and other section. Amjevita and Hadlima added as Step 1a agents. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
01/01/24	Review and revision to guideline consisting of updating the description section (NCCN info), position statement, other section, billing/coding, and references. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/24	Revision to guideline consisting of updating the description, position statement, related guidelines, other section, and references. Updates to the positioning of agents in Table 1. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
10/01/24	Updates to Table 1.
11/15/24	Revision to guideline consisting of updating the description, position statement, billing/coding, other section, and references based the new FDA approved indication for the treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. A new 60-count bottle of 20 mg tablets was released to support the 20 mg BID maintenance dosing in patients 20 to 50 kg.
01/01/25	Review and revision to guideline consisting of updating the position statement, other section, and references. Removed specialist requirement for the diagnosis of mild severity plaque psoriasis. For PS indication, divided criteria requirement for adults and pediatrics. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. New drugs were added to the list of drugs that are not permitted for use in combination.
09/15/25	Revision to guideline consisting of updating the description, position statement, dosage/administration, billing/coding, and references based the expanded FDA approved indication for the treatment of pediatric patients 6 years of age and older and weighing at least 20 kg with active PsA.
01/01/26	Review and revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, and references. New extended-release formulation of apremilast (Otezla XR) added to the guideline. The minimum weight for Otezla XR in pediatric patient is 50 kg (110 lbs).