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Subject: Secukinumab (Cosentyx®) Injection and Infusion

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DESCRIPTION:

Secukinumab (Cosentyx) for subcutaneous (SC) administration was approved by the U.S. Food and Drug Administration (FDA) in January 2015 for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. In January 2016 the FDA approved two additional indications, the treatment of adult patients with active psoriatic arthritis and the treatment of adult patients with active ankylosing spondylitis. In June 2020, the FDA approved the additional indication of treatment of adult patients with active non-radiographic axial spondyloarthritis (nraxSpA) with objective signs of inflammation. In May 2021, the moderate to severe plaque psoriasis indication was expanded to include pediatric patients 6 years of age and older. In December 2021, the indication of active psoriatic arthritis was expanded to include pediatric patients 2 years of age or older. Also in December 2021, the FDA approved the additional indication of active enthesitis-related arthritis (ERA) in patients 4 years of age and older. In October 2023, an intravenous (IV) formulation of secukinumab was approved by the FDA for adult patients with active psoriatic arthritis (PsA), active ankylosing spondylitis (AS), or active non-radiographic axial spondyloarthritis (nr-axSpA). It is the first and only treatment (as of November 2023) approved in an IV formulation that specifically targets interleukin-17A (IL-17A), and it is the only non-tumor necrosis factor (TNF) IV option available for these three indications. At the approved dose of 1.75mg/kg IV every four weeks (given over 30 minutes), with or without a loading dose, the level of drug in the blood was found to be within the range of the estimated steady-state concentrations as Cosentyx 150 mg and 300 mg when administered subcutaneously. Also in October 2023, the FDA approved a new indication for Cosentyx SC for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS). It is the first IL-17A blocker approved for HS. Secukinumab is a human IgG1 monoclonal antibody that selectively binds to

the interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. It was the first-in-class biologic agent to target IL-17. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines.

RHEUMATOID DISORDERS

Ankylosing spondylitis (AS)

Ankylosing spondylitis (AS) is a form of chronic inflammatory arthritis characterized by sacroiliitis, 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.

Enthesitis Related Arthritis

Enthesitis related arthritis (ERA) is a form of juvenile idiopathic arthritis (JIA) with an onset at less than 16 years of age. ERA typically presents initially with musculoskeletal pain, followed by signs of inflammation typical of peripheral arthritis. Enthesitis is a distinct feature of ERA and is defined as inflammation of an enthesis, which is a site where a tendon, ligament, or joint capsule attaches to bone. ERA is the pediatric counterpart of adult nonradiographic axial spondyloarthritis (nr-axSpA).

The American College of Rheumatology (ACR)/Arthritis Foundation guidelines (2019) recommend the following approach to treatment of children and adolescents with JIA and active enthesitis:

- Treatment with non-steroidal anti-inflammatory drugs (NSAIDs) is strongly recommended as first-line therapy
- If the disease remains active despite treatment with NSAIDs, a tumor necrosis factor (TNF)-inhibitor is conditionally recommended over methotrexate or sulfasalazine
- Bridging therapy with a limited course of oral glucocorticoids (less than 3 months) during initiation or escalation of therapy is conditionally recommended

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. The interleukin (IL)-17 inhibitor secukinumab is approved by the Food and Drug Administration (FDA) for the treatment of ERA and has been shown to be effective in increasing the time to disease relapse. Studies have shown that the synovial fluid of children with ERA present high levels of IL-17.

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:

Site of Care: If intravenous secukinumab (Cosentyx) is administered in a hospital-affiliated outpatient setting, additional requirements may apply depending on the member's benefit. Refer to 09-J3000-46: Site of Care Policy for Select Specialty Medications.

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. This statement does not apply to the intravenous (IV) formulation of secukinumab.

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

SUBCUTANEOUS COSENTYX (PHARMACY BENEFIT)

Initiation of subcutaneous secukinumab (Cosentyx) 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 subcutaneous secukinumab (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with subcutaneous secukinumab (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. Subcutaneous secukinumab 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 subcutaneous secukinumab
            II. The prescriber has provided information in support of using subcutaneous secukinumab 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, ERA, 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 subcutaneous secukinumab
4. Member will **NOT** be using subcutaneous secukinumab 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:
        - Loading dose:
            - Adult PS, PS with PsA, and HS - 300 mg at weeks 0, 1, 2, 3, and 4
            - ERA, pediatric PsA, and pediatric PS - 75 mg (if less than 50 kg) or 150 mg (if 50 kg or greater) at weeks 0, 1, 2, 3, and 4
            - Other indications – no loading dose
        - Maintenance dose (**ANY** of the following):
            - 75 mg every 4 weeks (28 days) [pediatric members less than 50 kg (110 lbs.)]
                - QL: 75 mg/0.5 mL syringe - 1 syringe/28 days
            - 150 mg every 4 weeks (28 days) [adults and pediatric members 50 kg (110 lbs.) or greater]
                - QL: 150 mg/mL pen - 1 pen/28 days
                - QL: 150 mg/mL syringe - 1 syringe/28 days
            - 300 mg every 4 weeks (28 days), **AND ONE** of the following [adult dosing]:
                i. The member has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis, **OR** hidradenitis suppurativa (HS)

                OR

                ii. The member has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis **AND** has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy
                    - QL: 300 mg/2 mL UnoReady pen - 1 pen/28 days
                    - QL: 300 mg/2 mL syringe - 1 syringe/28 days
                    - QL: 300 mg/2 mL (2 x 150 mg/mL) pen - 2 150 mg pens (in one carton)/28 days
                    - QL: 300 mg/2 mL (2 x 150 mg/mL) syringe - 2 150 mg syringes (in one carton)/28 days

- 300 mg every 2 weeks (14 days), AND BOTH of the following [adult dosing]:
    i. The member has a diagnosis of hidradenitis suppurativa (HS)

    AND

    ii. The member has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy

    - QL: 300 mg/2 mL UnoReady pen - 1 pen/14 days
    - QL: 300 mg/2 mL syringe - 1 syringe/14 days
    - QL: 300 mg/2 mL (2 x 150 mg/mL) pen – 2 150 mg pens (in one carton)/14 days
    - QL: 300 mg/2 mL (2 x 150 mg/mL) syringe - 2 150 mg syringes (in one carton)/14 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*:

- ERA, HS, pediatric PsA (<18 years of age), PS and PS with PsA - Loading dose (doses on week 0, 1, 2, 3, and 4) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- Other indications – 12 months

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

Table 1

Diagnosis	Criteria
Active psoriatic arthritis (PsA)	**ONE** of the following: 1. 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** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PsA **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PsA **OR** 4. 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], rapidly progressive)

	OR 5. 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** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla/Otezla XR that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA
Moderate to severe plaque psoriasis (PS)	**ONE** of the following: 1. 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** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PS **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PS **OR** 4. 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** 5. 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], rapidly progressive) **OR** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla/Otezla XR that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS

Active ankylosing spondylitis (AS)	**ONE** of the following: 1. 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** 2. 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** 3. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** 4. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of AS **OR** 5. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AS
Active non-radiographic axial spondyloarthritis (nr-axSpA)	**ONE** of the following: 1. 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** 2. The member has tried and had an inadequate response to **ONE** NSAID used in the treatment of nr-axSpA after at least a 4-week duration of therapy **AND** an intolerance or hypersensitivity to **ONE** additional NSAID used in the treatment of nr-axSpA OR 3. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of nr-axSpA **OR** 4. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of nr-axSpA **OR**

	5. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of nr-axSpA
Active enthesitis-related arthritis (ERA)	**ONE** of the following: 1. The member has tried and had an inadequate response to **TWO** different NSAIDs used in the treatment of ERA after at least a 4-week TOTAL duration of therapy **OR** 2. The member has tried and had an inadequate response to **ONE** NSAID used in the treatment of ERA after at least a 4-week duration of therapy **AND** an intolerance or hypersensitivity to **ONE** additional NSAID used in the treatment of ERA **OR** 3. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of ERA **OR** 4. The member has an FDA-labeled contraindication to **ALL** NSAIDs used in the treatment of ERA **OR** 5. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of ERA
Moderate to severe hidradenitis suppurative (HS)	ONE of the following: a. The member has tried and had an inadequate response to ONE conventional agent (i.e., oral tetracyclines [doxycycline, minocycline, tetracycline]; oral contraceptives [females only]; metformin [females only]; finasteride [females only]; spironolactone [females only]; intralesional corticosteroids [triamcinolone]; clindamycin in combination with rifampin; combination of rifampin, moxifloxacin, and metronidazole; cyclosporine, oral retinoids) used in the treatment of HS after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of HS **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of HS

	OR d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of HS
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 subcutaneous secukinumab (Cosentyx) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for subcutaneous secukinumab 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 subcutaneous secukinumab therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for AS, ERA, 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 subcutaneous secukinumab
5. Member will **NOT** be using secukinumab 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", "d", "e", "f", or "g"):
    a. The dosage does not exceed 75 mg every 4 weeks (28 days) for pediatric members less than 50 kg (110 lbs.)
        - QL: 75 mg/0.5 mL syringe - 1 syringe/28 days
    b. The dosage does not exceed 150 mg every 4 weeks (28 days) for adults and pediatric members 50 kg (110 lbs.) or greater
        - QL: 150 mg/mL pen - 1 pen/28 days
        - QL: 150 mg/mL syringe - 1 syringe/28 days
    c. The dosage does not exceed 300 mg every 4 weeks (28 days), **AND ONE** of the following (adult dosing only):
        i. The member has a diagnosis of moderate to severe plaque psoriasis with or without coexistent active psoriatic arthritis, **OR** hidradenitis suppurativa (HS)

        OR

ii. The member has a diagnosis of active psoriatic arthritis or active ankylosing spondylitis **AND** has tried and had an inadequate response to Cosentyx 150 mg every 4 weeks after at least a 3-month duration of therapy

- QL: 300 mg/2 mL UnoReady pen - 1 pen/28 days
- QL: 300 mg/2 mL syringe - 1 syringe/28 days
- QL: 300 mg/2 mL (2 x 150 mg/mL) pen – 2 150 mg pens (in one carton)/28 days
- QL: 300 mg/2 mL (2 x 150 mg/mL) syringe - 2 150 mg syringes (in one carton)/28 days

d. The dosage does not exceed 300 mg every 2 weeks (14 days), AND BOTH of the following (adult dosing only]:

i. The member has a diagnosis of hidradenitis suppurativa (HS)

AND

ii. The member has tried and had an inadequate response to Cosentyx 300 mg every 4 weeks after at least a 3-month duration of therapy

- QL: 300 mg/2 mL UnoReady pen - 1 pen/14 days
- QL: 300 mg/2 mL syringe - 1 syringe/14 days
- QL: 300 mg/2 mL (2 x 150 mg/mL) pen – 2 150 mg pens (in one carton)/14 days
- QL: 300 mg/2 mL (2 x 150 mg/mL) syringe - 2 150 mg syringes (in one carton)/14 days

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

iii. 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

iv. **ALL** of the following (“1”, “2”, and “3”):

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

5. 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)

6. **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)

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

   iii. 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

   iv. 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)

g. 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"):

   iii. 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

   iv. 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

INTRAVENOUS COSENTYX (MEDICAL BENEFIT)

Initiation of intravenous (IV) secukinumab (Cosentyx) **meets the definition of medical necessity** when **ALL** of the following are met ("1" and "6"):

1. Intravenous secukinumab will be used for the treatment of an indication listed in Table 2 and **ALL** of the indication-specific and maximum-allowable dose criteria are met
2. **EITHER** of the following if the member has an FDA-approved indication ("a" or "b")
   a. The member's age is within FDA labeling for the requested indication for intravenous secukinumab
   b. The prescriber has provided information in support of using intravenous secukinumab for the member's age for the requested indication
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for AS, nr-axSpA, PsA) or has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to IV secukinumab
5. Member will **NOT** be using IV secukinumab 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. **EITHER** of the following ("a" or "b"):

a. The dosage does not exceed 1.75 mg/kg (maximum of 300 mg) once every 4 weeks*

b. The dose is supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a for the requested indication, **OR** 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

*__NOTE__: Loading doses are **NOT** approvable.

Table 2

Diagnosis	Criteria
Active psoriatic arthritis (PsA)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 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], rapidly progressive) **OR** e. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** f. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla/Otezla XR 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 a self-administered or provider-administered tumor necrosis factor (TNF) inhibitor after at least a 3-month duration of therapy [examples of provider-administered TNF inhibitors include IV infliximab products (Avsola, Inflectra, Remicade), certolizumab pegol (Cimzia), and IV golimumab (Simponi Aria)] **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor **OR** c. The member has an FDA labeled contraindication to **ALL** TNF inhibitors for PsA **OR** d. The prescriber has provided information indicating why **ALL** TNF inhibitors are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication
Active ankylosing spondylitis (AS)	**BOTH** of the following ("1" and "2"): 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 indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AS **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 a self-administered or provider-administered tumor necrosis factor (TNF) inhibitor after at least a 3-month duration of therapy [examples of provider-administered TNF inhibitors include IV infliximab products (Avsola, Inflectra, Remicade), certolizumab pegol (Cimzia), and IV golimumab (Simponi Aria)] **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor **OR** c. The member has an FDA labeled contraindication to **ALL** TNF inhibitors for AS **OR** d. The prescriber has provided information indicating why **ALL** TNF inhibitors are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication
Active non-radiographic axial spondyloarthritis (nr-axSpA)	**BOTH** of the following ("1" and "2"): 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 nr-axSpA after at least a 4-week duration of therapy **AND** an intolerance or hypersensitivity to **ONE** additional NSAID used in the treatment of nr-axSpA **OR**

	c. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of nr-axSpA **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 indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of nr-axSpA **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 a self-administered or provider-administered tumor necrosis factor (TNF) inhibitor after at least a 3-month duration of therapy [examples of provider-administered TNF inhibitors include IV infliximab products (Avsola, Inflectra, Remicade), certolizumab pegol (Cimzia), and IV golimumab (Simponi Aria)] **OR** b. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to therapy with a TNF inhibitor **OR** c. The member has an FDA labeled contraindication to **ALL** TNF inhibitors for nr-axSpA **OR** d. The prescriber has provided information indicating why **ALL** TNF inhibitors are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication
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 intravenous (IV) secukinumab (Cosentyx) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for IV secukinumab has been previously approved by Florida Blue or another health plan in the past 2 years for the treatment of a condition in Table 2, **OR** the member previously met **ALL** indication-specific initiation criteria
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for AS, nr-axSpA, PsA) or has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to IV secukinumab
4. Member has had clinical benefit with IV secukinumab therapy
5. Member will **NOT** be using IV secukinumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), 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. **EITHER** of the following ("a" or "b"):
    a. The dosage does not exceed 1.75 mg/kg (maximum of 300 mg) every 4 weeks
    b. The dose is supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a for the requested indication, **OR** the prescriber has provided information in support of therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

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

FDA-approved

- Moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy (SC only)
    - Adults (18 years of age and older):
        - 300 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks
        - For some patients, a dose of 150 mg may be acceptable
    - Pediatric patients (6 years of age and older):
        - Less than 50 kg - 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks
        - 50 kg or greater - 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks
- Active psoriatic arthritis in patients 2 years of age and older (SC and IV)
    - For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis for SC administration, use the dosing and administration recommendations for plaque psoriasis.

- May be administered with or without methotrexate
- Subcutaneous dosing (2 years of age and older):
  - Adults (18 years of age and older):
    - With a loading dosage: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
    - Without a loading dosage: 150 mg every 4 weeks
    - If a patient continues to have active psoriatic arthritis, consider a dosage of 300 mg
  - Pediatric patients (2 years of age and older):
    - For patients 15 kg to <50 kg: 75 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
    - For patients weighing ≥50 kg: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
- Intravenous dosing (adults 18 years of age and older only):
  - With a loading dosage: 6 mg/kg loading dose given at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter (maintenance dosage).
  - Without a loading dosage: 1.75 mg/kg every 4 weeks
  - Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose
  - Administer as an IV infusion over a period of 30 minutes

- Adult patients with active ankylosing spondylitis (SC and IV)
  - May be administered with or without a loading dosage
  - Subcutaneous dosing:
    - With a loading dosage: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
    - Without a loading dosage: 150 mg every 4 weeks
    - If a patient continues to have active ankylosing spondylitis, consider a dosage of 300 mg every 4 weeks.
  - Intravenous dosing:
    - With a loading dosage: 6 mg/kg loading dose given at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter (maintenance dosage).
    - Without a loading dosage: 1.75 mg/kg every 4 weeks
    - Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose
    - Administer as an IV infusion over a period of 30 minutes
- Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation (SC and IV)
  - May be administered with or without a loading dosage
  - Subcutaneous dosing:
    - With a loading dosage: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter

        - Without a loading dosage: 150 mg every 4 weeks
    - Intravenous dosing:
        - With a loading dosage: 6 mg/kg loading dose given at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter (maintenance dosage).
        - Without a loading dosage: 1.75 mg/kg every 4 weeks
        - Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose
        - Administer as an IV infusion over a period of 30 minutes
- Active enthesitis-related arthritis (ERA) in patients 4 years of age and older (SC only)
    - For patients weighing ≥15 kg and <50 kg
        - 75 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks
    - For patients weighing ≥50 kg
        - 150 mg by subcutaneous injection at weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks
- Adult patients with moderate to severe hidradenitis suppurativa (HS) (SC only)
    - 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3 and 4 and every 4 weeks thereafter.
    - If a patient does not adequately respond, consider increasing the dosage to 300 mg every 2 weeks. Each 300 mg dosage is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.

Dose Adjustments

Refer to prescribing information.

Drug Availability

- For subcutaneous use:
    - Carton of one 300 mg/2 mL (300 mg dose) single-dose UnoReady pen
    - Carton of one 300 mg/2 mL (150 mg/mL) single-dose prefilled syringe
    - Carton of two 150 mg/mL (300 mg dose) single-dose Sensoready pens
    - Carton of one 150 mg/mL single-dose Sensoready pen
    - Carton of two 150 mg/mL (300 mg dose) single-dose prefilled syringes
    - Carton of one 150 mg/mL single-dose prefilled syringe
    - Carton of one 75 mg/0.5 mL single-dose prefilled syringe
- For intravenous use:
    - Carton of one 125 mg/5 mL (25 mg/mL) solution in a single-dose vial for dilution prior to IV infusion

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Serious hypersensitivity reaction to secukinumab or to any of the excipients

Precautions/Warnings

- **Infections**: Serious infections have occurred. Caution should be exercised when considering use in patients with a chronic infection or a history of recurrent infection. If a serious infection develops, discontinue until the infection resolves.
- **Hypersensitivity Reactions**: If an anaphylactic reaction or other serious allergic reaction occurs, discontinue Cosentyx immediately and initiate appropriate therapy.
- **Tuberculosis (TB):** Prior to initiating treatment, evaluate for TB. Monitored closely for signs and symptoms of active TB during and after treatment.
- **Inflammatory Bowel Disease**: Exacerbations observed in clinical trials. Caution should be exercised when prescribing to patients with inflammatory bowel disease.
- **Hypersensitivity Reactions**: Anaphylaxis and cases of urticaria have occurred.
- **Eczematous Eruptions**: Cases of severe eczematous eruptions, including atopic dermatitis-like eruptions, dyshidrotic eczema, and erythroderma, were reported in patients receiving secukinumab; some cases resulted in hospitalization.
- **Risk of Hypersensitivity in Latex-sensitive Individuals**: The removable cap of the Cosentyx Sensoready pen and the Cosentyx prefilled syringe contains natural rubber latex which may cause an allergic reaction in latex-sensitive individuals.
- **Vaccinations:** Live vaccines should not be given with secukinumab. Non-live vaccinations during treatment may not elicit an immune response sufficient to prevent disease.

BILLING/CODING INFORMATION:

HCPCS Coding

J3247	Injection, secukinumab, intravenous, 1 mg
J3590	Unclassified biologics [for SC formulation only]

ICD-10 Diagnosis Codes That Support Medical Necessity for J3590 (SC only, NDCs 00078-1070-68, 00078-1070-97, 00078-0639-41, 00078-0639-68, 00078-0639-98, 00078-0639-97, 00078-1056-97)

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
M08.80	Other juvenile arthritis, unspecified site
M45.0 – M45.9	Ankylosing spondylitis
M45.A0 – M45.AB	Non-radiographic axial spondyloarthritis
M46.81 – M46.89	Other specified inflammatory spondylopathies

ICD-10 Diagnosis Codes That Support Medical Necessity for J3247 (IV only, NCD 00078-1168-61)

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
M45.0 – M45.9	Ankylosing spondylitis
M45.A0 – M45.AB	Non-radiographic axial spondyloarthritis

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 the last guideline review date.

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).

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:

Abatacept (Orencia), 09-J0000-67
Abrocitinib (Cibinqo), 09-J4000-27
Adalimumab (Humira), 09-J0000-46
Apremilast (Otezla) Tablet, 09-J2000-19
Brodalumab (Siliq) Injection, 09-J2000-74
Certolizumab Pegol (Cimzi®), 09-J0000-77
Etanercept (Enbrel), 09-J0000-38
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Guselkumab (Tremfya), 09-J2000-87
Infliximab Products [infliximab (Remicade), infliximab-dyyb (Inflectra), and infliximab-abda (Renflexis)], 09-J0000-39
Ixekizumab (Taltz), 09-J2000-62
Psoralens with Ultraviolet A (PUVA), 09-10000-16
Risankizumab (Skyrizi), 09-J3000-45
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 3: Conventional Synthetic DMARDs

Generic Name	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:

03/15/15	New Medical Coverage Guideline.
04/15/15	Revision to guideline; updated HCPCS coding.
06/15/15	Revision to guideline; updated position statement.
09/15/15	Review and revision to guideline; consisting of updating position statement, precautions, and references.
11/01/15	Revision: ICD-9 Codes deleted.
03/15/16	Revision to guidelines consisting of description, position statement, dosage/administration, billing/coding, definitions, and references resulting from two new FDA-approved indications.
09/15/16	Review and revision to guideline consisting of updating position statement, precautions, billing/coding, related guidelines, and references.
10/15/17	Review and revision to guideline consisting of updating description, position statement, dosage/administration, coding/billing, definitions, related guidelines, and references.
01/01/18	Revision to guideline consisting of updating the preferred self-administered biologic products according to indication for use. Secukinumab (Cosentyx) was added as a preferred product for axial spondyloarthritis, plaque psoriasis, and psoriatic arthritis.
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 and references.
10/15/19	Review and revision to guideline consisting of updating the description, position statement, related guidelines, billing/coding, and references.
01/01/20	Revision to guideline consisting of updating the position statement “Note” due to changes in preferred products.
07/01/20	Revision to guideline consisting of updating the description and position statement.
01/01/21	Review and revision to guideline consisting of updating the description, position statement, related guidelines, billing/coding, and references.
03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.
07/15/21	Revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, other section, and references.
10/01/21	Revision: Addition of new ICD-10 code range M45.A0 – M45.AB.
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, billing/coding, other section, and references.
05/15/22	Revision to guideline consisting of updating the 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, position statement, dosage/administration, precautions, billing/coding, definitions, other section, and references. Added IV Cosentyx to guideline. IV formulation will be covered for its FDA-approved indications (PsA, AS, and nr-axSpA). Similar to subcutaneous Cosentyx, IV loading doses are not permitted for these indications. IV Cosentyx is included in the Site of Care Program. Position statement divided into one section for "SUBCUTANEOUS COSENTYX (PHARMACY BENEFIT)" and one section for "INTRAVENOUS COSENTYX (MEDICAL BENEFIT)" as criteria are different. Update to IDC-10 codes. Cosentyx SC is now indicated for adults with moderate to severe hidradenitis suppurativa (HS). It is a step 1a agent. New dosing allowance up to 300 every 2 weeks for HS. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
04/01/24	Revision: Added HCPCS code C9166.
05/15/24	Revision to guideline consisting of updating the position statement. Added a step requirement through a TNF inhibitor for all indications for initiation of IV Cosentyx.
07/01/24	Revision to guideline consisting of updating the description section, position statement, related guidelines, and other section. 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. Added HCPCS code J3247 and deleted code C9166.
10/01/24	Updates to Table 1.
01/01/25	Review and revision to guideline consisting of updating the description, position statement, other section, and references. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. Clarified that the age requirement that exists for subcutaneous Cosentyx also applies to intravenous Cosentyx. New drugs added to the list of drugs that are not permitted for use in combination.
01/01/26	Review and revision to guideline consisting of updating the description, position statement and references.