09-J2000-30

Original Effective Date: 03/15/15

Reviewed: 11/13/24

Revised: 01/01/25

Subject: Secukinumab (Cosentyx®) Injection and Infusion

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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, with the additional use of disease-modifying antirheumatic drugs (DMARDs) in patients with peripheral arthritis. The American College of Rheumatology (ACR), Spondylitis Association of America (SAA), and Spondyloarthritis Research and Treatment Network (SPARTAN) recommend the following pharmacological treatment for AS:

- Stable AS: First line therapy with on demand NSAIDs; there is also a conditional recommendation for continuation of TNF inhibitor as monotherapy
- Active AS:
    - First line therapy with continuous NSAIDs with physical therapy
    - TNF inhibitor recommended for patients with active AS despite an adequate trial with NSAIDs
        - Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response
    - Recommendations for nonresponse to TNF therapy (all conditional):
        - Primary nonresponse: switch to secukinumab or ixekizumab over another TNF
        - Secondary nonresponse: switch to another TNF over a non-TNF biologic
        - Recommend against addition of sulfasalazine or MTX
        - Recommend against switching to a biosimilar of the failed TNF
    - TNF-inhibitors are conditionally recommended over secukinumab or ixekizumab
    - Secukinumab or ixekizumab are conditionally recommended over DMARDs in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
    - DMARDs (i.e., methotrexate [MTX], sulfasalazine) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
    - Methotrexate is not recommended as add on therapy to TNF inhibitors in stable and active AS
    - If patient has concomitant inflammatory bowel disease (IBD) or recurrent uveitis, TNF-inhibitors are recommended over other biologics

- Glucocorticoids are not recommended

Nonradiographic Axial Spondyloarthritis (nr-axSpA)

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

- Stable SpA: conditional recommendation for on-demand treatment with NSAIDs
- Active SpA:
  - First line therapy with continuous NSAIDs with physical therapy
  - TNF inhibitor conditionally recommended for patients with active SpA despite an adequate trial with NSAIDs
    - Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response
  - TNF-inhibitors are conditionally recommended over secukinumab or ixekizumab
  - Secukinumab or ixekizumab are conditionally recommended over DMARDs in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
  - Recommendations for nonresponse to TNF therapy (all conditional):
    - Primary nonresponse: switch to secukinumab or ixekizumab over another TNF
    - Secondary nonresponse: switch to another TNF over a non-TNF biologic
    - Recommend against addition of sulfasalazine or MTX
    - Recommend against switching to a biosimilar of the failed TNF
  - DMARDs (i.e., methotrexate, sulfasalazine) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
  - Methotrexate is not recommended as add on therapy to TNF inhibitors in stable and active AS
  - If patient has concomitant inflammatory bowel disease or recurrent uveitis, TNF-inhibitors are recommended over other biologics
  - Glucocorticoids are not recommended

Enthesitis Related Arthritis

Juvenile idiopathic arthritis (JIA) is a group of heterogenous forms of arthritis characterized by onset before 16 years of age, involving one or more joints, and lasting 6 weeks or more. Enthesitis related arthritis (ERA) is one form of JIA in which patients have predominately enthesitis, enthesitis and arthritis, juvenile ankylosing spondylitis, or inflammatory bowel disease associated arthropathy. The International

League Against Rheumatism as arthritis and enthesitis that lasts at least 6 weeks in a child less than 16 years OR arthritis or enthesitis with two of the following features: sacroiliac tenderness or inflammatory spinal pain, HLA-B27 positivity, onset of arthritis in a male patient older than 6 years, and family history of HLA-B27 associated disease. 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.

The ACR 2019 guidelines recommend the following treatment approach for ERA:

- NSAIDs are strongly recommended over no treatment in children and adolescents
- TNF inhibitors are conditionally recommended over methotrexate or sulfasalazine in children and adolescents with active enthesitis despite treatment with NSAIDs
- First line therapy with continuous NSAIDs and physical therapy for adult patients
- DMARDs (i.e., methotrexate [MTX], sulfasalazine) are only conditionally recommended in patients that have failed NSAIDs and have contraindications to TNF-inhibitors
    - Lack of response (or intolerance) to at least 2 different NSAIDs over 1 month or incomplete response to at least 2 different NSAIDs over 2 months would be an adequate NSAID trial to judge response

Psoriatic Arthritis (PsA)

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

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

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

- Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient and health care provider to be due to PsA based on the presence of one of the following:
    - Actively inflamed joints
    - Dactylitis
    - Enthesitis
    - Axial disease
    - Active skin and/or nail involvement
    - Extraarticular manifestations such as uveitis or inflammatory bowel disease
- Disease severity includes level of disease activity at a given time point and the presence/absence of poor prognostic factors and long-term damage

- Severe PsA disease includes the presence of 1 or more of the following:
  - Erosive disease
  - Elevated markers of inflammation (ESR, CRP) attributable to PsA
  - Long-term damage that interferes with function (i.e., joint deformities)
  - Highly active disease that causes a major impairment in quality of life
  - Active PsA at many sites including dactylitis, enthesitis
  - Function limiting PsA at a few sites
  - Rapidly progressive disease
- Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, local glucocorticoid injections
- Treatment recommendations for active disease:
  - Treatment naïve patients first line options include oral small molecules (OSM), TNF biologics, IL-17 inhibitor, and IL-12/23 inhibitor
    - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe psoriasis, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitor
    - Biologics (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe psoriasis
  - Previous treatment with OSM and continued active disease:
    - Switch to a different OSM (except apremilast) in patients without severe PsA or severe PS, contraindications to TNF biologics, prefers oral therapy OR add on apremilast to current OSM therapy
    - May add another OSM (except apremilast) to current OSM therapy for patients that have exhibited partial response to current OSM in patients without severe PsA or severe PS, contraindications to TNF biologics, or prefers oral therapy
    - Biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) monotherapy
  - Previous treatment with a biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor) and continued active disease:
    - Switch to another biologic (i.e., TNF biologic, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) monotherapy or add MTX to the current TNF biologic

DERMATOLOGICAL DISORDERS

Psoriasis (PS)

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

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

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

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

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

- Mild to moderate disease (less than 5% of BSA):
  - Topical corticosteroids (strength of recommendation A)
  - Off-label use of 0.1% tacrolimus for psoriasis involving the face as well as inverse psoriasis (strength of recommendation B)
  - Long-term use (up to 52 weeks) of topical vitamin D analogs including calcipotriene, calcitriol, tacalcitol, and maxacalcitol (strength of recommendation A)
  - Use of calcipotriene foam and calcipotriene plus betamethasone dipropionate gel for the treatment of mild to moderate scalp psoriasis (strength of recommendation A)
  - Use of tacalcitol ointment or calcipotriene combined with hydrocortisone for facial psoriasis (strength of recommendation B)
  - Vitamin D analogs in combination with topical corticosteroids (strength of recommendation A)
  - Topical tazarotene alone or in combination with narrowband ultraviolet B (NB-UVB) (strength of recommendation B), or topical corticosteroids (strength of recommendation A)
  - Topical salicylic acid alone or in combination with topical corticosteroids (strength of recommendation B)
  - Coal tar preparations (strength of evidence A)

- Moderate to severe disease without PsA (5% or more of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
    - Methotrexate (adults) (strength of evidence A)
    - Methotrexate is less effective than TNF-inhibitors (strength of evidence B)
    - Combination therapy with methotrexate and NB-UVB (adult patients) (strength of evidence B)
    - Cyclosporine for patients with severe, recalcitrant (strength of recommendation A), erythrodermic, generalized pustular, and/or palmoplantar psoriasis (strength of recommendation B)
    - Acitretin as monotherapy or in combination with psoralen plus ultraviolet light (PUVA) or broad band ultraviolet light (BB-UVA [strength of evidence B])
    - If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
    - Apremilast (strength of recommendation A)
    - TNF-α inhibiters monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence B) or in combination with acitretin (strength of evidence C)
    - TNF-α inhibitors should be considered as a preferred treatment option for patients with concomitant PsA
    - Infliximab (strength of evidence A)
    - IL-12/IL-23 Inhibitors monotherapy (strength of evidence A) or in combination with topical corticosteroids with or without a vitamin D analogue (strength of evidence C) or in combination with acitretin or methotrexate (strength of evidence B)
    - IL-12/IL-23 inhibitors in combination with apremilast or cyclosporine (strength of evidence C)
    - IL-17 inhibitors monotherapy (strength of evidence A)
    - IL-23 inhibitors monotherapy for moderate to severe plaque psoriasis or as monotherapy for generalized pustular psoriasis (strength of evidence B)

*Strength of recommendation and descriptions

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

Biologics are routinely used when one or more traditional systemic agents fail to produce adequate response, but are considered first line in patients with moderate to severe psoriasis with concomitant severe PsA. Primary failure is defined as initial nonresponse to treatment. Primary failure to a TNF-α

inhibitor does not preclude successful response to a different TNF-α inhibitor. Failure of another biologic therapy does not preclude successful response to ustekinumab.

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

- The preferred assessment instrument for determining disease severity is BSA
- Target response after treatment initiation should be BSA ≤1% after 3 months
- Acceptable response is either a BSA ≤3% or a BSA improvement ≥75% from baseline at 3 months after treatment initiation

Hidradenitis Suppurativa (HS)

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

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

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

POSITION STATEMENT:

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 (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
5. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed:
        - 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** of the conventional agents used in the treatment of PsA **OR** 3. The member has an FDA labeled contraindication to **ALL** of the 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], 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 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, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** 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], rapidly progressive) **OR** 6. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS
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 trial **OR** 2. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** 3. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of AS **OR** 4. 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 trial **OR** 2. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of nr-axSpA

	OR 3. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of nr-axSpA **OR** 4. 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)	**EITHER** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to TWO different NSAIDs used in the treatment of ERA after at least a 4-week total trial **OR** b. The member has an intolerance or hypersensitivity to TWO different NSAIDs used in the treatment of ERA **OR** c. The member has an FDA-labeled contraindication to **ALL** NSAIDs used in the treatment of ERA **OR** 2. 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 (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", "c", "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 (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **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** of the conventional agents used in the treatment of PsA **OR** c. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of PsA **OR** d. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities], rapidly progressive) **OR** e. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** f. The member's medication history indicates use of another biologic immunomodulator agent **OR** Otezla that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to 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 agents 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 trial **OR** b. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** c. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of AS **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AS 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to 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 agents 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 trial **OR** b. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of nr-axSpA **OR** c. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of nr-axSpA **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of nr-axSpA 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to 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 agents 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 (upadacitinib), Opzelura (ruxolitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (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.

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

REFERENCES:

1. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. J Am Acad Dermatol. 2017 Feb;76(2):290-298.
2. Alhusayen R, Shear NH. Pharmacologic interventions for hidradenitis suppurativa: what does the evidence say? Am J Clin Dermatol. 2012 Oct 1;13(5):283-91.
3. Alikhan A, Sayed C, Alavi A, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management. J Am Acad Dermatol. 2019 Jul;81(1):91-101. Epub 2019 Mar 11.

4. Blauvelt A, Prinz JC, Gottlieb AB, et al. Secukinumab administration by pre-filled syringe: efficacy, safety and usability results from a randomized controlled trial in psoriasis (FEATURE). Br J Dermatol 2015;172(2):484-93.
5. Blauvelt A, Reich K, Tsai TF, et al. Secukinumab is superior to ustekinumab in clearing skin of subjects with moderate-to-severe plaque psoriasis up to 1 year: Results from the CLEAR study. J Am Acad Dermatol. 2017 Jan;76(1):60-69. e9.
6. Blok JL, van Hattem S, Jonkman MF, et al. Systemic therapy with immunosuppressive agents and retinoids in hidradenitis suppurativa: a systematic review. Br J Dermatol. 2013;168(2):243.
7. Braun J, Baraliakos X, Deodhar A, et al.; MEASURE 1 study group. Effect of secukinumab on clinical and radiographic outcomes in ankylosing spondylitis: 2-year results from the randomised phase III MEASURE 1 study. Ann Rheum Dis. 2017 Jun;76(6):1070-1077.
8. Canadian Psoriasis Guidelines Addendum Committee. 2016 Addendum to the Canadian Guidelines for the Management of Plaque Psoriasis 2009. J Cutan Med Surg. 2016 Sep;20(5):375-431.
9. Clinical Pharmacology powered by ClinicalKey [Internet]. Tampa, FL: Elsevier.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed 10/29/24.
10. Coates LC, Kavanaugh A, Mease PJ et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis: Treatment Recommendations for Psoriatic Arthritis 2015. Arthritis Rheumatol 2016; 68:1060–71.
11. Cosentyx (secukinumab) injection [package insert]. Novartis Pharmaceuticals Corporation. East Hanover, NJ. October 2024.
12. Dogra S, Jain A, Kanwar AJ. Efficacy and safety of acitretin in three fixed doses of 25, 35 and 50 mg in adult patients with severe plaque type psoriasis: a randomized, double blind, parallel group, dose ranging study. J Eur Acad Dermatol Venereol. 2013 Mar;27(3): e305-11.
13. Dogra S, Krishna V, Kanwar AJ. Efficacy and safety of systemic methotrexate in two fixed doses of 10 mg or 25 mg orally once weekly in adult patients with severe plaque-type psoriasis: a prospective, randomized, double-blind, dose-ranging study. Clin Exp Dermatol. 2012 Oct;37(7):729-34.
14. Elmets CA, Leonardi CL, Davis DM, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities. J Am Acad Dermatol. 2019 Apr;80(4):1073-1113. Epub 2019 Feb 13.
15. Elmets CA, Lim HW, Stoff H, et al. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. Epub 2019 July 25.
16. FDA Orphan Drug Designations and Approvals [Internet]. Washington, D.C. [cited 2024 Oct 29]. Available from: http://www.accessdata.fda.gov/scripts/opdlisting/oopd/.
17. Gener G, Canoui-Poitrine F, Revuz JE, et al. Combination therapy with clindamycin and rifampicin for hidradenitis suppurativa: a series of 116 consecutive patients. Dermatology. 2009;219(2):148-54.
18. Gossec L, Kerschbaumer A, Ferreira RJO, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2023 update. Ann Rheum Dis. 2024 May 15;83(6):706-719.
19. Griffiths CEM, Armstrong AW, Gudjonsson JE, Barker JNWN. Psoriasis. Lancet. 2021;397(10281): 1301-1315.
20. Ingram JR, Woo PN, Chua SL, et al. Interventions for hidradenitis suppurativa. Cochrane Database Syst Rev. 2015 Oct 7;(10):CD010081.
21. Jemec GB. Clinical practice. Hidradenitis suppurativa. N Engl J Med. 2012 Jan;366(2):158-64.

22. Kalb RE, Strober B, Weinstein G, Lebwohl M. Methotrexate and psoriasis: 2009 National Psoriasis Foundation Consensus Conference. J Am Acad Dermatol 2009; 60:824-37.

23. Kavanaugh A, Mease PJ, Reimold AM, et al.; FUTURE-1 Study Group. Secukinumab for Long-Term Treatment of Psoriatic Arthritis: A Two-Year Followup from a Phase III, Randomized, Double-Blind Placebo-Controlled Study. Arthritis Care Res (Hoboken). 2017 Mar;69(3):347-355.

24. Kimball AB, Jemec GBE, Alavi A, et al. Secukinumab in moderate-to-severe hidradenitis suppurativa (SUNSHINE and SUNRISE): week 16 and week 52 results of two identical, multicentre, randomised, placebo-controlled, double-blind phase 3 trials. Lancet. 2023;401(10378):747-761.

25. Krause ML, Amin A, and Makol A. Use of DMARDs and biologics during pregnancy and lactation in rheumatoid arthritis: what the rheumatologist needs to know. Ther Adv Musculoskelet Dis. 2014 Oct; 6(5): 169–184.

26. Langley RG, Elewski BE, Lebwohl M, et al. Secukinumab in plaque psoriasis – results of two phase 3 trials. N Engl J Med 2014; 371: 326-38.

27. Menter A, Korman, NJ, Elmets, CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. J Am Acad Dermatol 2011; 65:137-74.

28. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol. 2009 Sep;61(3):451-85.

29. Menter A, Strober BE, Kaplan DH et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019 Apr;80(4):1029-1072. Epub 2019 Feb 13.

30. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 10/29/24.

31. Paul C, Lacour JP, Tedremets L, et al. Efficacy, safety and usability of secukinumab administered by autoinjector/pen in psoriasis: a randomized, controlled trial (JUNCTURE). J Eur Acad Dermatol Venereol. 2014 Sep 22.

32. Rambhatla PV, Lim HW, Hamzavi I. A systematic review of treatments for hidradenitis suppurativa. Arch Dermatol. 2012 Apr;148(4):439-46.

33. Rahimi R, Nikfar S, Rezaie A, et al. Pregnancy outcome in women with inflammatory bowel disease following exposure to 5-aminosalicylic acid drugs: a meta-analysis. Reprod. Toxicol; 2008:25,271–275.

34. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis. 2022 Oct 19: ard-2022-223297. Epub ahead of print.

35. Sbidian E, Chaimani A, Garcia-Doval, et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. Cochrane Database Syst Rev. 2021 Apr 19;4(4):CD011535. Update in: Cochrane Database Syst Rev. 2022 May 23;5:CD011535.

36. Sieper J, Deodhar A, Marzo-Ortega H, et al.; MEASURE 2 Study Group. Secukinumab efficacy in anti-TNF-naive and anti-TNF-experienced subjects with active ankylosing spondylitis: results from the MEASURE 2 Study. Ann Rheum Dis. 2017 Mar;76(3):571-592.

37. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019 Jan;71(1):5-32. Epub 2018 Nov 30.

38. Smith CH, Jabbar-Lopez JK, Yiu ZZ, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. Br J Dermatol 2017; 177: 628-136.
39. van der Zee HH, Boer J, Prens EP, et al. The effect of combined treatment with oral clindamycin and oral rifampicin in patients with hidradenitis suppurativa. Dermatology. 2009;219(2):143-7. Epub 2009 Jul 08.
40. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1285-1299. Epub 2019 Aug 21.
41. Weiss PF. Diagnosis and treatment of enthesitis-related arthritis. Adolescent health, medicine and therapeutics, 2012(3), 67–74.

COMMITTEE APPROVAL:

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

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.