09-J2000-30

Original Effective Date: 03/15/15

Reviewed: 11/09/22

Revised: 01/01/23

Subject: Secukinumab (Cosentyx®) Injection

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DESCRIPTION:

Secukinumab (Cosentyx) 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. 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 (great than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when is 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:

- Limited disease (less than 5% of BSA):
    - Topical corticosteroids are first line as either monotherapy or in conjunction with non-steroidal topical agents
    - Vitamin D analogs, calcipotriene, calcipotriol, and calcitriol, are other first line agents and are often used in combination with topical corticosteroids
    - Tazarotene is a corticosteroid sparing agent and can be used in combination with topical corticosteroids to produce a synergistic effect and longer durations of treatment benefit and remission
    - Phototherapy is another first line option for limited disease, and allows for selective targeting of localized lesions and resistant areas such as the scalp and skin folds, leaving surrounding, non-lesional skin unaffected
    - Calcineurin inhibitors (tacrolimus and pimecrolimus) may also be considered first line for intertriginous, inverse, face, and genital psoriasis
    - Systemic agents are considered second line and only for short term use
- Moderate to severe disease without PsA (more than 5% of BSA or psoriasis in vulnerable areas [e.g., face, genitals, hands, and feet] that adversely affects quality of life):
    - UV-therapy is considered first line as monotherapy or in combination with acitretin or MTX
    - If UV-therapy is unavailable, first line therapies include MTX, cyclosporine, acitretin, and biologics
    - Second line systemic agents include leflunomide, sulfasalazine, and tacrolimus
- 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

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

- The preferred assessment instrument for determining disease severity is BSA

- Target response after treatment initiation should be BSA ≤1% after 3 months
- Acceptable response is either a BSA ≤3% or a BSA improvement ≥75% from baseline at 3 months after treatment initiation

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

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

Table 1

Disease State	Step 1		Step 2 (Directed to ONE step 1 agent)	Step 3a (Directed to TWO step 1 agents)	Step 3b (Directed to TWO agents from step 1 and/or step 2)	Step 3c (Directed to THREE step 1 agents)
	Step 1a	Step 1b (Directed to ONE TNF inhibitor) NOTE: Please see Step 1a for preferred TNF inhibitors				
Rheumatoid Disorders						
Ankylosing Spondylitis (AS)	SQ: **Cosentyx,** Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Simponi, Taltz	N/A	N/A
Nonradiographic Axial Spondyloarthritis (nr-axSpA)	SQ: Cimzia, **Cosentyx**	Oral: Rinvoq	N/A	SQ: Taltz	N/A	N/A
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	SQ: Enbrel, Humira	Oral: Xeljanz	SQ: Actemra (Humira is required Step 1 agent)	N/A	SQ: Orencia	N/A
Psoriatic Arthritis (PsA)	SQ: **Cosentyx**, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	Oral: Rinvoq, Xeljanz, Xeljanz XR	N/A	SQ: Cimzia, Orencia, Simponi, Taltz	N/A	N/A
Rheumatoid Arthritis	SQ: Enbrel, Humira	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Actemra (Humira is required Step 1 agent)	Oral: Olumiant SQ: Cimzia, Kevzara, Kineret, Orencia, Simponi	N/A	N/A
Dermatological Disorders						
Hidradenitis Suppurativa (HS)	SQ: Humira	N/A	N/A	N/A	N/A	N/A

Psoriasis (PS)	SQ: **Cosentyx**, Enbrel, Humira, Skyrizi, Stelara, Tremfya Oral: Otezla	N/A	N/A	SQ: Cimzia, Ilumya	N/A	SQ: Siliq, Taltz Oral: Sotyktu
Inflammatory Bowel Disease						
Crohn's Disease	SQ: Humira, Skyrizi, Stelara	N/A	N/A	SQ: Cimzia (Humira is a required Step 1 agent)	N/A	N/A
Ulcerative Colitis	SQ: Humira, Stelara	Oral: Rinvoq, Xeljanz, Xeljanz XR	SQ: Simponi (Humira is required Step 1 agent)	N/A	Zeposia (Humira, Rinvoq Stelara, OR Xeljanz/Xeljanz XR are required Step agents)	N/A
Other						
Uveitis	SQ: Humira	N/A	N/A	N/A	N/A	N/A
Indications Without Prerequisite Biologic Immunomodulators						
Alopecia Areata (AA) Atopic Dermatitis Deficiency of IL-1 Receptor Antagonist (DIRA) Enthesitis Related Arthritis (ERA) Giant Cell Arteritis (GCA) Neonatal-Onset Multisystem Inflammatory Disease (NOMID) Systemic Juvenile Idiopathic Arthritis (SJIA) Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD	N/A	N/A	N/A	N/A	N/A	N/A

***Note**: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product

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

1. **ONE** of the following ("a", "b", or "c"):
    a. Information has been provided that indicates the member has been treated with secukinumab (starting on samples is not approvable) within the past 90 days

b. The prescriber states the member has been treated with 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. Secukinumab will be used for the treatment of an indication listed in Table 2, and **ALL** of the indication-specific criteria are met

ii. **EITHER** of the following ("I" or "II")

I. The member's age is within FDA labeling for the requested indication for secukinumab

II. The prescriber has provided information in support of using secukinumab for the member's age

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 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 secukinumab

4. Member has been tested for latent tuberculosis (TB) **AND**, if positive, the member has begun therapy for latent TB

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), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or Zeposia (ozanimod)

6. **ANY** of the following ("a", "b", or "c"):

a. The dosage does not exceed:

- Loading dose:
  - Adult PS and PS with PsA - 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

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 for at least 3 months

- QL: 300 mg/2 mL (2 x 150 mg/mL) pen - 2 pens/28 days
- QL: 300 mg/2 mL (2 x 150 mg/mL) syringe - 2 syringes/28 days

b. The requested quantity (dose) is greater than program's quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

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

Approval duration*:

- ERA, 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 2

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 for at least 3 months **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 for at least 3-months **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 for 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 for 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 for 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
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 secukinumab (Cosentyx) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for secukinumab has been previously approved by Florida Blue
2. Member has had clinical benefit with 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 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 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), Olumiant (baricitinib), Opzelura (ruxolitinib), Rinvoq (upadacitinib), Xeljanz (tofacitinib), and Xeljanz XR (tofacitinib extended release)]; Otezla (apremilast); Sotyktu (deucravacitinib); or Zeposia (ozanimod)
6. **ANY** of the following ("a", "b", "c", "d", or "e"):
    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

   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 for at least 3 months

   - QL: 300 mg/2 mL (2 x 150 mg/mL) pen - 2 pens/28 days
   - QL: 300 mg/2 mL (2 x 150 mg/mL) syringe - 2 syringes/28 days

d. The requested quantity (dose) is greater than program's quantity limit but does **NOT** exceed the maximum FDA labeled dose **OR** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a (for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

e. The requested quantity (dose) is greater that the program's quantity limit and greater than the maximum FDA labeled dose **AND** the maximum compendia-supported dose (i.e., DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a) for the requested indication, **AND** the prescriber has provided information in support of therapy with a higher dose for the requested indication (submitted copy required, e.g., 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
  - 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
    - For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.
    - For other psoriatic arthritis patients, administer with or without a loading dosage (for adults) or with a loading dosage (for pediatric patients) by subcutaneous injection.
        - 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
    - May be administered with or without methotrexate
- Adult patients with active ankylosing spondylitis
    - May be administered with or without a loading dosage.
        - 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.
- Adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation
    - 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
- Active enthesitis-related arthritis (ERA) in patients 4 years of age and older
    - 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

Dose Adjustments

Refer to prescribing information.

Drug Availability

- Injection: 150 mg/mL solution in a single-use Sensoready pen

- Injection: 150 mg/mL solution in a single-use prefilled syringe
- Injection: 75 mg/0.5 mL solution in a single-use prefilled syringe
- For Injection: 150 mg, lyophilized powder in a single-use vial for reconstitution for healthcare professional use only

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.
- **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.
- **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

J3590	Unclassified biologics

ICD-10 Diagnosis Codes That Support Medical Necessity

L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
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

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).

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
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:

Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy

Actemra (tocilizumab)
Adbry (tralokinumab-ldrm)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Cimzia (certolizumab)
Cinqair (reslizumab)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Humira (adalimumab)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Nucala (mepolizumab)
Orencia (abatacept)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)

Rituxan (rituximab)

Rituxan Hycela (rituximab/hyaluronidase human)

Ruxience (rituximab-pvvr)

Siliq (brodalumab)

Simponi (golimumab)

Simponi Aria (golimumab)

Skyrizi (risankizumab-rzaa)

Stelara (ustekinumab)

Taltz (ixekizumab)

Tezspire (tezepelumab-ekko)

Tremfya (guselkumab)

Truxima (rituximab-abbs)

Tysabri (natalizumab)

Xolair (omalizumab)

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 11/09/22.

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.