

# Cosentyx® (secukinumab) (Subcutaneous/Intravenous)

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## I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

## II. Dosing Limits

### A. Quantity Limit (max daily dose) [NDC Unit]:

- Cosentyx 300 mg single-dose UnoReady Pen/prefilled syringe for subcutaneous injection:
  - Loading: 1 pen/prefilled syringe at weeks 0, 1, 2, 3, 4
  - Maintenance: 1 pen/prefilled syringe every 14 days
- Cosentyx 150 mg single-dose Sensoready Pen/prefilled syringe for subcutaneous injection:
  - Loading: 2 pens/prefilled syringes/vials at weeks 0, 1, 2, 3, 4
  - Maintenance: 2 pens/prefilled syringes/vials every 14 days
- Cosentyx 75 mg single-dose prefilled syringe for subcutaneous injection (for pediatric patients less than 50 kg):
  - Loading: 1 prefilled syringe at weeks 0, 1, 2, 3, 4
  - Maintenance: 1 prefilled syringe every 28 days
- Cosentyx 125 mg single-dose vial for intravenous infusion:
  - Loading: 6 vials at week 0
  - Maintenance: 3 vials every 28 days

### B. Max Units (per dose and over time) [HCPCS Unit]:

Indication	Max Units
Enthesitis-Related Arthritis	<u>Loading:</u> <ul style="list-style-type: none"> <li>• 150 mg at weeks 0, 1, 2, 3, 4</li> </ul> <u>Maintenance:</u> <ul style="list-style-type: none"> <li>• 150 mg every 28 days</li> </ul>
Plaque Psoriasis and Adult Psoriatic Arthritis with co-existent Plaque Psoriasis	<u>Loading:</u> <ul style="list-style-type: none"> <li>• 300 mg at weeks 0, 1, 2, 3, 4</li> </ul> <u>Maintenance:</u> <ul style="list-style-type: none"> <li>• 300 mg every 28 days</li> </ul>

Indication	Max Units
Psoriatic Arthritis and Ankylosing Spondylitis	<p><b><u>Subcutaneous Administration</u></b></p> <ul style="list-style-type: none"> <li>• Loading: 150 mg at weeks 0, 1, 2, 3, 4</li> <li>• Maintenance: 300 mg every 28 days</li> </ul> <p><b><u>Intravenous Administration</u></b></p> <ul style="list-style-type: none"> <li>• Loading: 750 billable units at week 0</li> <li>• Maintenance: 375 billable units every 28 days</li> </ul>
Non-Radiographic Axial Spondyloarthritis	<p><b><u>Subcutaneous Administration</u></b></p> <ul style="list-style-type: none"> <li>• Loading: 150 mg at weeks 0, 1, 2, 3, 4</li> <li>• Maintenance: 150 mg every 28 days</li> </ul> <p><b><u>Intravenous Administration</u></b></p> <ul style="list-style-type: none"> <li>• Loading: 750 billable units at week 0</li> <li>• Maintenance: 375 billable units every 28 days</li> </ul>
Hidradenitis Suppurativa	<p><u>Loading:</u></p> <ul style="list-style-type: none"> <li>• 300 mg at weeks 0, 1, 2, 3, 4</li> </ul> <p><u>Maintenance:</u></p> <ul style="list-style-type: none"> <li>• 300 mg every 14 days</li> </ul>

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

#### Universal Criteria <sup>1</sup>

- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment; **AND**
- Will not be administered concurrently with live vaccines; **AND**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient is not on concurrent treatment with another IL-inhibitor, TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib, etc.); **AND**

#### Adult Plaque Psoriasis (PsO) † <sup>1,13,26,32-34,43</sup>

- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:

- Involvement of at least 3% of body surface area (BSA); **OR**
- Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
- Incapacitation or serious emotional consequences due to plaque location (e.g., hands, feet, head and neck, or genitalia, etc.) or with intractable pruritis; **AND**
- Patient did not respond adequately (or is not a candidate) to a 4-week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, tapinarof, roflumilast, retinoic acid derivatives, and/or vitamin D analogues); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least one non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
- Patient did not respond adequately (or is not a candidate\*) to a 3-month minimum trial of phototherapy (i.e., psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)

### **Pediatric Plaque Psoriasis (PsO) †** <sup>1,13,26,27,32-34</sup>

- Patient is at least 6 years of age; **AND**
- Documented moderate to severe plaque psoriasis for at least 6 months with at least one of the following:
  - Involvement of at least 3% of body surface area (BSA); **OR**
  - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
  - Incapacitation or serious emotional consequences due to plaque location (e.g., hands, feet, head and neck, or genitalia, etc.) or with intractable pruritis; **AND**
- Patient did not respond adequately (or is not a candidate) to a 4-week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, roflumilast, retinoic acid derivatives, and/or Vitamin D analogues); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least one non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
- Patient did not respond adequately (or is not a candidate\*) to a 3-month minimum trial of phototherapy (i.e., psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)

### **Adult Psoriatic Arthritis (PsA) †** <sup>1,12,28,35,44,45</sup>

- Documented moderate to severe active disease; **AND**
  - For patients with predominantly axial disease, a trial and failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; **OR**
  - For patients with peripheral arthritis, dactylitis OR active enthesitis, a trial and failure of at least a 3-month trial of ONE oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, etc.; **AND**
- May be used as a single agent or in combination with an oral non-biologic DMARD (e.g., methotrexate, etc.)

**Note:** Patients new to therapy must initiate treatment at the lower dosing regimen of the 150 mg dose before increasing to the 300 mg dose (unless they have co-existent plaque psoriasis)

### **Juvenile Psoriatic Arthritis (JPsA) †** <sup>1,36,37</sup>

- Patient is at least 2 years of age; **AND**
- Documented moderate to severe active polyarticular disease; **AND**
- May be used as a single agent or in combination with methotrexate; **AND**
- Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

### **Ankylosing Spondylitis (AS) †** <sup>1,11,30,46</sup>

- Documented active disease; **AND**
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs) over 4 weeks (in total), unless use is contraindicated

**Note:** Patients new to therapy must initiate treatment at the lower dosing regimen of the 150 mg dose before increasing to the 300 mg dose

### **Non-Radiographic Axial Spondyloarthritis (nr-axSpA) †** <sup>1,30,46</sup>

- Patient has objective signs of inflammation noted by an elevation of C-reactive protein (CRP) above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging (MRI); **AND**
- Patient is without definitive radiographic evidence of structural damage on sacroiliac joints; **AND**
- Documented active disease; **AND**
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs) unless use is contraindicated

### **Enthesitis-Related Arthritis (ERA) †** <sup>1,36,37</sup>

- Patient is 4 years of age to < 18 years of age; **AND**
- Documented moderate to severe active polyarticular disease; **AND**
- Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) OR an oral disease-modifying anti-rheumatic agent (DMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.)

### **Hidradenitis Suppurativa (HS) †** <sup>1,48</sup>

- Patient has moderate to severe disease; **AND**
- Patient has a total of at least 5 inflammatory lesions (i.e. abscesses and/or inflammatory nodules); **AND**

- Patient's inflammatory lesions affect at least 2 distinct anatomic areas

**\*Examples of contraindications to phototherapy (PUVA or UVB) include the following:**  
23,24,27

- Xeroderma pigmentosum
- Other rare photosensitive genodermatoses (e.g., trichothiodystrophy, Cockayne syndrome, Bloom syndrome, Rothmund-Thomson syndrome) (*UVB only*)
- Genetic disorders associated with increased risk of skin cancer (e.g., Gorlin syndrome, oculocutaneous albinism) (*UVB only*)
- Pregnancy or lactation (*PUVA only*)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (*PUVA only*), or treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (*UVB only*)
- Photosensitizing medications (*PUVA only*)
- Severe liver, renal, or cardiac disease (*PUVA only*)
- Young age < 12 years old (*PUVA only*)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication; ◻ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe exacerbations or new onset of inflammatory bowel disease, severe infections, hypersensitivity reactions (e.g. anaphylaxis, urticaria), etc.; **AND**

##### **Adult Plaque Psoriasis (PsO)** <sup>10,26,43</sup>

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement  $\leq 1\%$ ), and/or an improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and  $\geq 4$ -point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started].

##### **Pediatric Plaque Psoriasis (PsO)** <sup>10,27</sup>

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement  $\leq 1\%$ ), and/or an improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and  $\geq 4$ -point reduction in the children's Dermatology Life Quality Index (cDLQI) from when treatment started].

### **Adult Psoriatic Arthritis (PsA)** <sup>9,29,45</sup>

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool [e.g. defined as an improvement in at least 2 of the 4 Psoriatic Arthritis Response Criteria (PsARC), 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria]; **AND**
- Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
  - Shown an initial improvement or response to therapy; **AND**
  - Responded to therapy (by treatment week 8) with subsequent loss of response or continued active disease; **AND**
    - Received loading doses and a minimum of one maintenance dose at the dose and interval specified below; **OR**
    - Received a minimum of two maintenance doses at the dose and interval specified below

### **Juvenile Psoriatic Arthritis (JPsA)** <sup>1,38,39</sup>

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

### **Ankylosing Spondylitis (AS)** <sup>42,46</sup>

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, morning stiffness, and/or an improvement on a disease activity scoring tool [e.g.  $\geq 1.1$  improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of  $\geq 2$  on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)]; **AND**
- Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
  - Shown an initial improvement or response to therapy; **AND**
  - Responded to therapy (by treatment week 8) with subsequent loss of response or continued active disease; **AND**
    - Received loading doses and a minimum of one maintenance dose at the dose and interval specified below; **OR**
    - Received a minimum of two maintenance doses at the dose and interval specified below

### Non-Radiographic Axial Spondyloarthritis (nr-AxSpA) <sup>31,46</sup>

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as total back pain, physical function, reduction of C-reactive protein, and/or an improvement on a disease activity scoring tool [e.g.  $\geq 1.1$  improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS), achievement of an ASDAS-Major Improvement (ASDAS-MI e.g. improvement of  $\geq 2.0$  in the ASDAS and/or reaching the lowest possible ASDAS), improvement of  $\geq 2$  on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), improvement of the Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL) score from baseline, or an ASAS40 response (defined as a  $\geq 40\%$  improvement and an absolute improvement from baseline of  $\geq 2$  units in  $\geq 3$  of 4 domains without any worsening in the remaining domain)].

### Enthesitis-Related Arthritis (ERA) <sup>1,38,39</sup>

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, and/or an improvement on a disease activity scoring tool [e.g. an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score (JADAS) or the American College of Rheumatology (ACR) Pediatric (ACR-Pedi 30) of at least 30% improvement from baseline in three of six variables].

### Hidradenitis Suppurativa (HS) <sup>1,48</sup>

- Disease response as indicated by improvement in a reduction in total abscess and inflammatory nodule count and/or reduction in skin pain, and/or an improvement on a disease activity scoring tool [e.g. a 50% or greater reduction in abscess and inflammatory nodule count with no increase in the number of abscesses or draining fistulas compared with baseline Hidradenitis Suppurativa Clinical Response (HiSCR)]; **AND**
- Dose escalation (up to the maximum dose and frequency specified below) may occur upon clinical review on a case by case basis provided that the patient has:
  - Shown an initial improvement or response to therapy; **AND**
  - Responded to therapy (by treatment week 8) with subsequent loss of response or continued active disease; **AND**
    - Received loading doses and a minimum of one maintenance dose at the dose and interval specified below; **OR**
    - Received a minimum of two maintenance doses at the dose and interval specified below

## V. Dosage/Administration <sup>1</sup>

Indication	Dose
Plaque Psoriasis (PsO)	<u>Adults</u>



Indication	Dose
	<p>300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. Each 300 mg dose may be given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.</p> <p><b>Note:</b> For some patients, a dosage of 150 mg may be acceptable.</p> <p><b><u>Pediatric Patients ≥ 6 years of age</u></b></p> <ul style="list-style-type: none"> <li>▪ Weight &lt; 50 kg: 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks</li> <li>▪ Weight ≥ 50 kg: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks</li> </ul> <p><b>Note:</b> Only the subcutaneously administered products may be used for this indication.</p>
<p>Adult Psoriatic Arthritis (PsA) with co-existent Plaque Psoriasis (PsO)</p>	<p>300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. Each 300 mg dose may be given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• For some patients, a dosage of 150 mg may be acceptable.</li> <li>• Only the subcutaneously administered products may be used for this indication.</li> </ul>
<p>Psoriatic Arthritis (PsA)</p>	<p><b><u>Adults – Subcutaneous Administration</u></b></p> <p><u>With loading dose:</u></p> <ul style="list-style-type: none"> <li>• 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</li> </ul> <p><u>Without a loading dose:</u></p> <ul style="list-style-type: none"> <li>• 150 mg by subcutaneous injection every 4 weeks</li> </ul> <p><b>Note:</b> Cosentyx may be administered with or without a loading dose for ADULT patients for this indication. If the patient continues to have active psoriatic arthritis, increasing the SUBCUTANEOUS dose to 300 mg every 4 weeks may be considered (see criteria in section IV). Each 300 mg dose may be given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.</p> <p><b><u>Adults – Intravenous Administration</u></b></p> <p><u>With loading dose:</u></p> <ul style="list-style-type: none"> <li>• 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter</li> </ul> <p><u>Without a loading dose:</u></p> <ul style="list-style-type: none"> <li>• 1.75 mg/kg by intravenous infusion every 4 weeks</li> </ul> <p><b>Note:</b> Cosentyx may be administered with or without a loading dose for ADULT patients for this indication. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in adults with PsA.</p>



Indication	Dose
	<p><b><u>Pediatric Patients ≥ 2 years of age– Subcutaneous Administration</u></b></p> <ul style="list-style-type: none"> <li>▪ Weight ≥ 15 kg and &lt; 50 kg: 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</li> <li>▪ Weight ≥ 50 kg: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</li> </ul>
Ankylosing Spondylitis (AS)	<p><b><u>Subcutaneous Administration</u></b></p> <p><u>With loading dose:</u></p> <ul style="list-style-type: none"> <li>• 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</li> </ul> <p><u>Without a loading dose:</u></p> <ul style="list-style-type: none"> <li>• 150 mg by subcutaneous injection every 4 weeks</li> </ul> <p><b>Note:</b> Cosentyx may be administered with or without a loading dose for this indication. If the patient continues to have active ankylosing spondylitis, increasing the dose to 300 mg every 4 weeks may be considered (see criteria in section IV). Each 300 mg dose may be given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.</p> <p><b><u>Intravenous Administration</u></b></p> <p><u>With loading dose:</u></p> <ul style="list-style-type: none"> <li>• 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter</li> </ul> <p><u>Without a loading dose:</u></p> <ul style="list-style-type: none"> <li>• 1.75 mg/kg by intravenous infusion every 4 weeks</li> </ul> <p><b>Note:</b> Cosentyx may be administered with or without a loading dose for this indication. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in adults with AS.</p>
Non-Radiographic Axial Spondyloarthritis (nr-axSpA)	<p><b><u>Subcutaneous Administration</u></b></p> <p><u>With loading dose:</u></p> <ul style="list-style-type: none"> <li>• 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</li> </ul> <p><u>Without a loading dose:</u></p> <ul style="list-style-type: none"> <li>• 150 mg by subcutaneous injection every 4 weeks</li> </ul> <p><b>Note:</b> Cosentyx may be administered with or without a loading dose for this indication.</p> <p><b><u>Intravenous Administration</u></b></p> <p><u>With loading dose:</u></p> <ul style="list-style-type: none"> <li>• 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter</li> </ul> <p><u>Without a loading dose:</u></p>

Indication	Dose
	<ul style="list-style-type: none"> <li>1.75 mg/kg by intravenous infusion every 4 weeks</li> </ul> <p><b>Note:</b> Cosentyx may be administered with or without a loading dose for this indication. Total doses exceeding 300 mg per infusion are not recommended for the 1.75 mg/kg maintenance dose in adults with nr-axSpA.</p>
Enthesitis-Related Arthritis (ERA)	<ul style="list-style-type: none"> <li>Weight ≥ 15 kg and &lt; 50 kg: 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</li> <li>Weight ≥ 50 kg: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter</li> </ul> <p><b>Note:</b> Only the subcutaneously administered products may be used for this indication.</p>
Hidradenitis Suppurativa	<p>300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks.</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>If the patient does not adequately respond, increasing the dose to 300 mg every 2 weeks may be considered (see criteria in section IV). Each 300 mg dose may be given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.</li> <li>Only the subcutaneously administered products may be used for this indication.</li> </ul>
<p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>UnoReady pens, Sensoready pens and prefilled syringes are for subcutaneous use only.</li> <li>Solution in vials is for intravenous use in adult patients only.</li> <li>Adult patients may self-administer COSENTYX or be injected by a caregiver after proper training in subcutaneous injection technique.</li> <li>Pediatric patients should not self-administer COSENTYX. An adult caregiver should prepare and inject COSENTYX after proper training in subcutaneous injection technique.</li> <li>Intravenous infusion is only for use by a healthcare professional in a healthcare setting.</li> </ul>	

## VI. Billing Code/Availability Information

### HCPCS Code(s):

- J3590 – Unclassified biologics
- C9399 – Unclassified drugs or biologicals (*Discontinue use on 04/01/2024 for the IV formulation ONLY*)
- C9166 – Injection, secukinumab, intravenous, 1 mg; 1 billable unit = 1 mg (*Effective 04/01/2024 for the IV formulation ONLY*)

### NDC(s):

- Cosentyx 300 mg/2 mL single-dose UnoReady® Pen (carton of 1) for subcutaneous injection: 00078-1070-xx

- Cosentyx 150 mg/mL single-dose Sensoready® Pen (carton of 1 or 2) for subcutaneous injection: 00078-0639-xx
- Cosentyx 300 mg/2 mL single-dose prefilled syringe (carton of 1) for subcutaneous injection: 00078-1070-xx
- Cosentyx 150 mg/mL single-dose prefilled syringe (carton of 1 or 2) for subcutaneous injection: 00078-0639-xx
- Cosentyx 75 mg/0.5 mL single-dose prefilled syringe for subcutaneous injection (for pediatric patients less than 50 kg; carton of 1): 00078-1056-xx
- Cosentyx 125 mg/5 mL solution in a single-dose vial for dilution prior to intravenous injection (carton of 1): 00078-1168-xx

## VII. References

1. Cosentyx [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; October 2023. Accessed November 2023.
2. Langley RG, Elewski BE, Lebwohl M, et al. Secukinumab in plaque psoriasis—results of two phase 3 trials. *N Engl J Med*. 2014 Jul 24;371(4):326-38. Doi: 10.1056/NEJMoa1314258. Epub 2014 Jul 9.
3. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012 Jan;148(1):95-102.
4. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol*. 2008 May;58(5):826-50. Doi: 10.1016/j.jaad.2008.02.039.
5. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 2. Psoriatic arthritis: overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008 May;58(5):851-64.
6. Gossec L, Smolen JS, Ramiro S, et al. European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update. *Ann Rheum Dis*. 2015 Dec 7. Pii: annrheumdis-2015-208337. Doi: 10.1136/annrheumdis-2015-208337.
7. Ward MM, Deodhar, A, Akl, EA, et al. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis Rheumatol*. 2015 Sep 24. Doi: 10.1002/art.39298.
8. Smith CH, Jabbar-Lopez ZK, Yiu ZK, et al. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017. *Br J Dermatol*. 2017 Sep;177(3):628-636. Doi: 10.1111/bjd.15665.
9. National Institute for Health and Care Excellence. NICE 2017. Certolizumab pegol and secukinumab for treating active psoriatic arthritis after inadequate response to DMARDs.

Published 24 May 2017. Technology Appraisal Guidance [TA445].

<https://www.nice.org.uk/guidance/ta445>. Accessed June 2023.

10. 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. Doi: 10.1016/j.jaad.2016.10.017.
11. Van Der Heijde D, Ramiro S, Landewé R, et al. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. *Annals of the Rheumatic Diseases* Published Online First: 13 January 2017. Doi: 10.1136/annrheumdis-2016-210770.
12. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis Rheumatol*. 2019 Jan;71(1):5-32. Doi: 10.1002/art.40726.
13. 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. <https://doi.org/10.1016/j.jaad.2018.11.057>.
14. 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; 172:484.
15. Paul C, Lacour JP, Tedremets L, et al. Efficacy, safety and usability of secukinumab administration by autoinjector/pen in psoriasis: a randomized, controlled trial (JUNCTURE). *J Eur Acad Dermatol Venereol* 2015; 29:1082.
16. McInnes IB, Mease PJ, Kirkham B, et al. Secukinumab, a human anti-interleukin-17A monoclonal antibody, in patients with psoriatic arthritis (FUTURE 2): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet* 2015; 386:1137.
17. Mease PJ, McInnes IB, Kirkham B, et al. Secukinumab Inhibition of Interleukin-17A in Patients with Psoriatic Arthritis. *N Engl J Med* 2015; 373:1329.
18. Mease P, van der Heijde D, Landewé R, et al. Secukinumab improves active psoriatic arthritis symptoms and inhibits radiographic progression: primary results from the randomised, double-blind, phase III FUTURE 5 study. *Ann Rheum Dis*. 2018;77(6):890–897. Doi:10.1136/annrheumdis-2017-212687.
19. Sieper J, Deodhar A, Marzo-Ortega H, et al. 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; 76:571.
20. Baeten D, Sieper J, Braun J, et al. Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. *N Engl J Med* 2015; 373:2534.
21. Pavelka K, Kivitz A, Dokoupilova E, et al. Efficacy, safety, and tolerability of secukinumab in patients with active ankylosing spondylitis: a randomized, double-blind phase 3 study, MEASURE 3. *Arthritis Res Ther* 2017; 19:285.
22. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2016 Mar 16 - . Identifier NCT02696031, Study of Efficacy and Safety of Secukinumab in Patients With Non-

radiographic Axial Spondyloarthritis (PREVENT); 2016 Mar 2. Available from:

<http://clinicaltrials.gov/ct/show/NCT00287391?order=1>

23. Richard EG. (2022). Psoralen plus ultraviolet A (PUVA) photochemotherapy. In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Dec 01, 2022. Accessed on: November 2, 2023. Available from [https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20\(PUVA\)%20photochemotherapy&source=search\\_result&selectedTitle=1~150&usage\\_type=default&display\\_rank=1](https://www.uptodate.com/contents/psoralen-plus-ultraviolet-a-puva-photochemotherapy?search=Psoralen%20plus%20ultraviolet%20A%20(PUVA)%20photochemotherapy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1).
24. Hoönigsmann H. (2023). UVB therapy (broadband and narrowband). In Elmets CA, Corona R (Eds.), *UptoDate*. Last updated: Jan 18, 2023; Accessed on November 2, 2023. Available from [https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20\(broadband%20and%20narrowband&source=search\\_result&selectedTitle=1~80&usage\\_type=default&display\\_rank=1#H10844627](https://www.uptodate.com/contents/uvb-therapy-broadband-and-narrowband?search=UVB%20therapy%20(broadband%20and%20narrowband&source=search_result&selectedTitle=1~80&usage_type=default&display_rank=1#H10844627).
25. Bodemer C, Kaszuba A, Kingo K, et al. Secukinumab demonstrates high efficacy and a favourable safety profile in paediatric patients with severe chronic plaque psoriasis: 52-week results from a Phase 3 double-blind randomized, controlled trial. *J Eur Acad Dermatol Venereol*. 2021 Apr;35(4):938-947. Doi: 10.1111/jdv.17002.
26. Smith CH, Yiu ZZN, Bale T, et al; British Association of Dermatologists' Clinical Standards Unit. British Association of Dermatologists guidelines for biologic therapy for psoriasis 2020: a rapid update. *Br J Dermatol*. 2020 Oct;183(4):628-637. Doi: 10.1111/bjd.19039.
27. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020 Jan;82(1):161-201. Doi: 10.1016/j.jaad.2019.08.049.
28. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020 Jun;79(6):700-712. Doi: 10.1136/annrheumdis-2020-217159.
29. Mease PJ. Measures of psoriatic arthritis: Tender and Swollen Joint Assessment, Psoriasis Area and Severity Index (PASI), Nail Psoriasis Severity Index (NAPSI), Modified Nail Psoriasis Severity Index (mNAPSI), Mander/Newcastle Enthesitis Index (MEI), Leeds Enthesitis Index (LEI), Spondyloarthritis Research Consortium of Canada (SPARCC), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Leeds Dactylitis Index (LDI), Patient Global for Psoriatic Arthritis, Dermatology Life Quality Index (DLQI), Psoriatic Arthritis Quality of Life (PsAQOL), Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), Psoriatic Arthritis Response Criteria (PsARC), Psoriatic Arthritis Joint Activity Index (PsAJAI), Disease Activity in Psoriatic Arthritis (DAPSA), and Composite Psoriatic Disease Activity Index (CPDAI). *Arthritis Care Res (Hoboken)*. 2011 Nov;63 Suppl 11:S64-85. Doi: 10.1002/acr.20577.
30. 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):1599-1613. Doi: 10.1002/art.41042.

31. Deodhar A, Blanco R, Dokoupilová E, et al. Improvement of Signs and Symptoms of Nonradiographic Axial Spondyloarthritis in Patients Treated With Secukinumab: Primary Results of a Randomized, Placebo-Controlled Phase III Study. *Arthritis Rheumatol*. 2021 Jan;73(1):110-120. Doi: 10.1002/art.41477.
32. National Institute for Health and Care Excellence. NICE 2017. Psoriasis: assessment and management. Published 24 October 2012. Clinical guideline [CG153]. <https://www.nice.org.uk/guidance/CG153>. Accessed June 2023.
33. National Institute for Health and Care Excellence. NICE 2013. Psoriasis. Published 06 August 2013. Quality standard [QS40]. <https://www.nice.org.uk/guidance/qs40>. Accessed June 2023.
34. Elmets CA, Lim HW, Stoff B, 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*. 2019 Sep;81(3):775-804. Doi: 10.1016/j.jaad.2019.04.042.
35. American Academy of Dermatology Work Group. 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 Jul;65(1):137-74. Doi: 10.1016/j.jaad.2010.11.055.
36. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. *Arthritis Care & Research*, Vol. 71, No. 6, June 2019, pp 717–734 DOI 10.1002/acr.23870.
37. Ringold S, Weiss PF, Beukelman T, et al. 2013 update of the 2011 American College of Rheumatology recommendations for the treatment of juvenile idiopathic arthritis: recommendations for the medical therapy of children with systemic juvenile idiopathic arthritis and tuberculosis screening among children receiving biologic medications. *Arthritis Rheum*. 2013 Oct;65(10):2499-512.
38. Ringold S, Bittner R, Neggi T, et al. Performance of rheumatoid arthritis disease activity measures and juvenile arthritis disease activity scores in polyarticular-course juvenile idiopathic arthritis: Analysis of their ability to classify the American College of Rheumatology pediatric measures of response and the preliminary criteria for flare and inactive disease. *Arthritis Care Res (Hoboken)*. 2010 Aug;62(8):1095-102.
39. Consolaro A, Giancane G, Schiappapietra B, et al. Clinical outcome measures in juvenile idiopathic arthritis. *Pediatric Rheumatology* 18 April 2016 14:23.
40. Ruperto N, Foeldvari I, Alexeeva E, et al. Efficacy and Safety of Secukinumab in Enthesitis-related Arthritis and Juvenile Psoriatic Arthritis: Primary Results from a Randomised, Double-blind, Placebo-controlled, Treatment Withdrawal, Phase 3 Study (JUNIPERA). *Annals of the Rheumatic Diseases* 2021;80:201-202.
41. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. *Arthritis Rheumatol*. 2022 Apr;74(4):553-569. doi: 10.1002/art.42037.



42. National Institute for Health and Care Excellence (NICE). Spondyloarthritis. Quality standard [QS170]. Published: 28 June 2018 <https://www.nice.org.uk/guidance/qs170/chapter/Quality-statements>. Accessed June 2023.
43. Elmets CA, Korman NL, Prater EF, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021 Feb; 84(2):432-470. Doi: 10.1016/j.jaad.2020.07.087
44. Baraliakos X, Gossec L, Pournara E et al. Secukinumab in patients with psoriatic arthritis and axial manifestations: results from the double-blind, randomised, phase 3 MAXIMISE trial. Ann Rheum Dis 2020;79: 35–36. Doi: 10.1136/annrheumdis-2020-218808
45. Tucker L, Allen A, Chandler D, et al. The 2022 British Society for Rheumatology guideline for the treatment of psoriatic arthritis with biologic and targeted synthetic DMARDs. Rheum 2022 Sept; 61(9): e255–e266. Doi: 10.1093/rheumatology/keac295
46. Ramiro S, Nikiphorou E, Sepriano A, et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis. 2023 Jan; 82(1):19–34. doi:10.1136/ard-2022-223296.
47. 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;81(1):91-101. doi:10.1016/j.jaad.2019.02.068.
48. 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 Mar 4;401(10378):747-761. doi: 10.1016/S0140-6736(23)00022-3.

## Appendix 1 – Covered Diagnosis Codes

ICD-10 Codes	ICD-10 Description
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
M08.811	Other juvenile arthritis, right shoulder
M08.812	Other juvenile arthritis, left shoulder



ICD-10 Codes	ICD-10 Description
M08.819	Other juvenile arthritis, unspecified shoulder
M08.821	Other juvenile arthritis, right elbow
M08.822	Other juvenile arthritis, left elbow
M08.829	Other juvenile arthritis, unspecified elbow
M08.831	Other juvenile arthritis, right wrist
M08.832	Other juvenile arthritis, left wrist
M08.839	Other juvenile arthritis, unspecified wrist
M08.841	Other juvenile arthritis, right hand
M08.842	Other juvenile arthritis, left hand
M08.849	Other juvenile arthritis, unspecified hand
M08.851	Other juvenile arthritis, right hip
M08.852	Other juvenile arthritis, left hip
M08.859	Other juvenile arthritis, unspecified hip
M08.861	Other juvenile arthritis, right knee
M08.862	Other juvenile arthritis, left knee
M08.869	Other juvenile arthritis, unspecified knee
M08.871	Other juvenile arthritis, right ankle and foot
M08.872	Other juvenile arthritis, left ankle and foot
M08.879	Other juvenile arthritis, unspecified ankle and foot
M08.88	Other juvenile arthritis, other specified site
M08.89	Other juvenile arthritis, multiple sites
M08.9A	Juvenile arthritis, unspecified, other specified site
M08.911	Juvenile arthritis, unspecified, right shoulder
M08.912	Juvenile arthritis, unspecified, left shoulder
M08.919	Juvenile arthritis, unspecified, unspecified shoulder
M08.921	Juvenile arthritis, unspecified, right elbow
M08.922	Juvenile arthritis, unspecified, left elbow
M08.929	Juvenile arthritis, unspecified, unspecified elbow
M08.931	Juvenile arthritis, unspecified, right wrist
M08.932	Juvenile arthritis, unspecified, left wrist
M08.939	Juvenile arthritis, unspecified, unspecified wrist
M08.941	Juvenile arthritis, unspecified, right hand
M08.942	Juvenile arthritis, unspecified, left hand

ICD-10 Codes	ICD-10 Description
M08.949	Juvenile arthritis, unspecified, unspecified hand
M08.951	Juvenile arthritis, unspecified, right hip
M08.952	Juvenile arthritis, unspecified, left hip
M08.959	Juvenile arthritis, unspecified, unspecified hip
M08.961	Juvenile arthritis, unspecified, right knee
M08.962	Juvenile arthritis, unspecified, left knee
M08.969	Juvenile arthritis, unspecified, unspecified knee
M08.971	Juvenile arthritis, unspecified, right ankle and foot
M08.972	Juvenile arthritis, unspecified, left ankle and foot
M08.979	Juvenile arthritis, unspecified, unspecified ankle and foot
M08.98	Juvenile arthritis, unspecified, vertebrae
M08.99	Juvenile arthritis, unspecified, multiple sites
M45.AB	Non-radiographic axial spondyloarthritis of multiple sites in spine
M45.A0	Non-radiographic axial spondyloarthritis of unspecified sites in spine
M45.A1	Non-radiographic axial spondyloarthritis of occipito-atlanto-axial region
M45.A2	Non-radiographic axial spondyloarthritis of cervical region
M45.A3	Non-radiographic axial spondyloarthritis of cervicothoracic region
M45.A4	Non-radiographic axial spondyloarthritis of thoracic region
M45.A5	Non-radiographic axial spondyloarthritis of thoracolumbar region
M45.A6	Non-radiographic axial spondyloarthritis of lumbar region
M45.A7	Non-radiographic axial spondyloarthritis of lumbosacral region
M45.A8	Non-radiographic axial spondyloarthritis of sacral and sacrococcygeal region

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

<b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b>		
<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC