Cosentyx® (secukinumab)
(Subcutaneous/Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

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

Indication	Max Units
Enthesitis-Related Arthritis	Loading: • 150 mg at weeks 0, 1, 2, 3, 4 Maintenance: • 150 mg every 28 days
Plaque Psoriasis and Adult Psoriatic Arthritis with co-existent Plaque Psoriasis	Loading: • 300 mg at weeks 0, 1, 2, 3, 4 Maintenance: • 300 mg every 28 days
Psoriatic Arthritis and Ankylosing Spondylitis	**Subcutaneous Administration** • Loading: 150 mg at weeks 0, 1, 2, 3, 4 • Maintenance: 300 mg every 28 days **Intravenous Administration** • Loading: 750 billable units at week 0 • Maintenance: 375 billable units every 28 days
Non-Radiographic Axial Spondyloarthritis	**Subcutaneous Administration** • Loading: 150 mg at weeks 0, 1, 2, 3, 4 • Maintenance: 150 mg every 28 days **Intravenous Administration**

Indication	Max Units
	• Loading: 750 billable units at week 0 • Maintenance: 375 billable units every 28 days
Hidradenitis Suppurativa	Loading: • 300 mg at weeks 0, 1, 2, 3, 4 Maintenance: • 300 mg every 14 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; **AND**
- Provider will confirm that member is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria [1]

- Member 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**
- Provider will confirm member will not receive live vaccines during therapy; **AND**
- Member does not have an active infection, including clinically important localized infections; **AND**
- Member is not on concurrent treatment with another biologic therapy or targeted synthetic therapy; **AND**

Plaque Psoriasis (PsO) † [1,13,26,27,32-34,43]

- Member 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 10% 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 pruritus; **AND**
- Member meets ALL of the following **¥**:

- Member 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**
- Member 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**
- Member 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) ; **AND**

¥ Note: *For members already established on biologic therapy, targeted synthetic therapy, or those with > 10% BSA involvement, trial and failure of topical agents, non-biologic systemic agents, and phototherapy is not required.*

For Commercial Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), Cosentyx SC£ (secukinumab), ustekinumab SC^, Tremfya SC (guselkumab), Skyrizi SC (risankizumab), or Otezla (apremilast); **OR** • Patient is continuing treatment
****Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz*** ***£ Note: Cosentyx SC refers to the self-administered formulation*** ***^Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)***
For Medicaid Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), Cosentyx SC£ (secukinumab), or ustekinumab SC^; **OR** • Patient is continuing treatment
****Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz*** ***£Note: Cosentyx SC refers to the self-administered formulation*** ***^Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)***

Adult Psoriatic Arthritis (PsA) † [1,12,28,35,44,45,51]

- Documented moderate to severe active disease; **AND**
  - For members with predominantly axial disease OR enthesitis, a failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory drug (NSAID), unless use is contraindicated; **OR**

- For members with peripheral arthritis OR dactylitis, a failure of at least a 3-month trial of ONE conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, sulfasalazine, leflunomide, or hydroxychloroquine, etc.); **OR**
- Member is already established on biologic or targeted synthetic therapy for the treatment of PsA; **AND**

- May be used as a single agent or in combination with methotrexate; **AND**

Note: *Members new to subcutaneous Cosentyx 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)*

For Commercial Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), Cosentyx SC£ (secukinumab), ustekinumab SC^, Tremfya SC (guselkumab), Xeljanz¥ (tofacitinib), Rinvoq¥ (upadacitinib), Skyrizi SC (risankizumab), or Otezla (apremilast); **OR** • Patient is continuing treatment
Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz £***Note: Cosentyx SC refers to the self-administered formulation*** ^***Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)*** ¥ ***Note: Products are indicated in those who have had an inadequate response or intolerance to one or more TNF blockers***
For Medicaid Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), Cosentyx SC£ (secukinumab), or ustekinumab SC^; **OR** • Patient is continuing treatment
Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz £***Note: Cosentyx SC refers to the self-administered formulation*** ^***Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)***

Juvenile Psoriatic Arthritis (JPsA) † [1,36,37]

- Member 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**
  - Member 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 a conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.); **OR**

- Member is already established on biologic or targeted synthetic therapy for the treatment of JPsA; **AND**

For Commercial Members Only
• For pediatric patients aged ≥ 2 years, patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: Cosentyx SC[£] (secukinumab), Rinvoq[¥] (upadacitinib), or Enbrel (etanercept); **OR** • For pediatric patients aged ≥ 6 years, patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: Cosentyx SC[£] (secukinumab), Rinvoq[¥] (upadacitinib), Enbrel (etanercept), or ustekinumab SC^
[£] ***Note: Cosentyx SC refers to the self-administered formulation*** [¥] ***Note: Rinvoq (upadacitinib) is indicated in those who have had an inadequate response or intolerance to one or more TNF blockers*** ***^Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)***
For Medicaid Members Only
• For pediatric patients aged ≥ 2 years, patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: Cosentyx SC[£] (secukinumab) or Enbrel (etanercept); **OR** • For pediatric patients aged ≥ 6 years, patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: Cosentyx SC[£] (secukinumab), Enbrel (etanercept), or ustekinumab SC^
[£] ***Note: Cosentyx SC refers to the self-administered formulation*** ***^Note: Preferred products are Selarsdi SC (ustekinumab-aekn), Yesintek SC (ustekinumab-kfce), and Steqeyma SC (ustekinumab-stba)***

Ankylosing Spondylitis (AS) † [1,11,30,46]

- Documented active disease; **AND**
  - Member had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory drugs (NSAIDs) over 4 weeks (in total), unless use is contraindicated; **OR**
  - Member is already established on biologic or targeted synthetic therapy for the treatment of AS; **AND**

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

For Commercial Members Only
• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), Cosentyx SC[£] (secukinumab), Rinvoq[¥] (upadacitinib), or Xeljanz[¥] (tofacitinib); **OR**

- Patient is continuing treatment

***Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz**

£ ***Note: Cosentyx SC refers to the self-administered formulation***

¥ ***Note: Products are indicated in those who have had an inadequate response or intolerance to one or more TNF blockers***

For Medicaid Members Only

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab*, Enbrel (etanercept), or Cosentyx SC£ (secukinumab); **OR**
- Patient is continuing treatment

***Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz**

£ ***Note: Cosentyx SC refers to the self-administered formulation***

Non-Radiographic Axial Spondyloarthritis (nr-axSpA) † [1,30,46]

- Member 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**
- Member is without definitive radiographic evidence of structural damage on sacroiliac joints; **AND**
- Documented active disease; **AND**
  - Member had an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory drugs (NSAIDs) unless use is contraindicated; **OR**
  - Member is already established on biologic or targeted synthetic therapy for the treatment of nr-axSpA; **AND**

For Commercial Members Only

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Cosentyx SC£ (secukinumab) or Rinvoq¥ (upadacitinib); **OR**
- Patient is continuing treatment

£ ***Note: Cosentyx SC refers to the self-administered formulation***

¥ ***Note: Rinvoq (upadacitinib) is indicated in those who have had an inadequate response or intolerance to one or more TNF blockers***

For Medicaid Members Only

- Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Cosentyx SC£ (secukinumab); **OR**
- Patient is continuing treatment

£ ***Note: Cosentyx SC refers to the self-administered formulation***

Enthesitis-Related Arthritis (ERA) † [1,36,37]

- Member is 4 years of age to < 18 years of age; **AND**
- Documented moderate to severe active polyarticular disease; **AND**
    - Member 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 conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, leflunomide, sulfasalazine, etc.); **OR**
    - Member is already established on biologic or targeted synthetic therapy for the treatment of ERA; **AND**

• Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of Cosentyx SC[£] (secukinumab); **OR** • Patient is continuing treatment
[£] ***Note: Cosentyx SC refers to the self-administered formulation***

Hidradenitis Suppurativa (HS) † [1,48]

- Member is at least 12 years of age; **AND**
- Member has moderate to severe disease; **AND**
- Member has a total of at least 5 inflammatory lesions (i.e. abscesses and/or inflammatory nodules); **AND**
- Member's inflammatory lesions affect at least 2 distinct anatomic areas; **AND**

Patient must try and have an inadequate response, contraindication, or intolerance to at least a three (3) month trial of ONE of the following: adalimumab* or Cosentyx SC[£] (secukinumab).
Note: Preferred products are Hadlima (adalimumab-bwwd) and adalimumab-adaz [£] ***Note: Cosentyx SC refers to the self-administered formulation***

*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 member *(UVB only)* – Photosensitizing medications *(PUVA only)* – Severe liver, renal, or cardiac disease *(PUVA only)* – Young age < 12 years old *(PUVA only)* – Anatomical location has been deemed ineligible for phototherapy (i.e., face, genital, scalp, or nail)
Note: *Members who do not have access to phototherapy will be reviewed on a case-by-case basis*

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

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based upon the following criteria:

- Member 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 (e.g., TB, serious bacterial, viral, and fungal infections, HBV reactivation, etc.), hypersensitivity reactions (e.g. anaphylaxis, urticaria, angioedema), etc.; **AND**

Plaque Psoriasis (PsO) [10,26,27,43,49,50]

- 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 ≤ 1%), and/or an improvement on a disease activity scoring tool [e.g. Psoriasis Area and Severity Index (PASI) score ≤ 3, physician's global assessment (PGA) score ≤ 1, etc.].

Adult Psoriatic Arthritis (PsA) [9,29,45,52]

- 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, improvement on imaging (X-ray, ultrasound, or MRI), and/or an improvement on a disease activity scoring tool; **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 member 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) [1,38,39,52]

- 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, improvement on imaging (X-ray, ultrasound, or MRI), 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) [42,46]

- 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. ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS) or an improvement of ≥ 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 member 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) [31,46]

- 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. ≥ 1.1 improvement on the Ankylosing Spondylitis Disease Activity Score (ASDAS), achievement of an ASDAS-Major Improvement (ASDAS-MI e.g. improvement of ≥ 2.0 in the ASDAS and/or reaching the lowest possible ASDAS), improvement of ≥ 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 ≥40% improvement and an absolute improvement from baseline of ≥2 units in ≥3 of 4 domains without any worsening in the remaining domain)].

Enthesitis-Related Arthritis (ERA) [1,38,39]

- 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) [1,48]

- Disease response as indicated by 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**
- Adult members only: 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 member 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 [1]

Indication	Dose
Plaque Psoriasis (PsO)	**Adults**

Indication	Dose
	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. ***Note:*** *For some members, a dosage of 150 mg may be acceptable.* **Pediatric Members ≥ 6 years of age** • Weight < 50 kg: 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 75 mg every 4 weeks • Weight ≥ 50 kg: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 150 mg every 4 weeks ***Note:*** *Only the subcutaneously administered products may be used for this indication.*
Adult Psoriatic Arthritis (PsA) with co-existent Plaque Psoriasis (PsO)	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. ***Note:*** • *For some members, a dosage of 150 mg may be acceptable.* • *Only the subcutaneously administered products may be used for this indication.*
Psoriatic Arthritis (PsA)	**Adults – Subcutaneous Administration** With loading dose: • 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter Without a loading dose: • 150 mg by subcutaneous injection every 4 weeks ***Note****: Cosentyx may be administered with or without a loading dose for ADULT members for this indication. If the member 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.* **Adults – Intravenous Administration** With loading dose: • 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter Without a loading dose: • 1.75 mg/kg by intravenous infusion every 4 weeks ***Note****: Cosentyx may be administered with or without a loading dose for ADULT members 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.*

Indication	Dose
	Pediatric Members ≥ 2 years of age– Subcutaneous Administration • Weight ≥ 15 kg and < 50 kg: 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter • Weight ≥ 50 kg: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter
Ankylosing Spondylitis (AS)	**Subcutaneous Administration** With loading dose: • 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter Without a loading dose: • 150 mg by subcutaneous injection every 4 weeks ***Note**: Cosentyx may be administered with or without a loading dose for this indication. If the member 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.* **Intravenous Administration** With loading dose: • 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter Without a loading dose: • 1.75 mg/kg by intravenous infusion every 4 weeks ***Note**: 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.*
Non-Radiographic Axial Spondyloarthritis (nr-axSpA)	**Subcutaneous Administration** With loading dose: • 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter Without a loading dose: • 150 mg by subcutaneous injection every 4 weeks ***Note**: Cosentyx may be administered with or without a loading dose for this indication.* **Intravenous Administration** With loading dose: • 6 mg/kg by intravenous infusion at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter

Indication	Dose
	Without a loading dose: • 1.75 mg/kg by intravenous infusion every 4 weeks ***Note**: 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.*
Enthesitis-Related Arthritis (ERA)	• Weight ≥ 15 kg and < 50 kg: 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter • Weight ≥ 50 kg: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter ***Note:** Only the subcutaneously administered products may be used for this indication.*
Hidradenitis Suppurativa	**Adults** • 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by 300 mg every 4 weeks. • *If the member 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.* **Pediatric Members ≥ 12 years of age** • Weight ≥ 30 kg and < 90 kg: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter • Weight ≥ 90 kg: 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter ***Note:** Only the subcutaneously administered products may be used for this indication.*
NOTE: • UnoReady pens, Sensoready pens and prefilled syringes are for subcutaneous use only. • Solution in vials is for intravenous use in adult members only. • Adult members may self-administer COSENTYX or be injected by a caregiver after proper training in subcutaneous injection technique. • Pediatric members should not self-administer COSENTYX. An adult caregiver should prepare and inject COSENTYX after proper training in subcutaneous injection technique. • Intravenous infusion is only for use by a healthcare professional in a healthcare setting.	

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3247 – Injection, secukinumab, intravenous, 1 mg; 1 billable unit = 1 mg *(IV formulation ONLY)*
- J3590 – Unclassified biologics *(SQ formulation ONLY)*
- C9399 – Unclassified drugs or biologicals *(SQ formulation ONLY)*

NDC(s):

- Subcutaneous
  - 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 members less than 50 kg; carton of 1): 00078-1056-xx
- Intravenous
  - 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; March 2026. Accessed March 2026.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

Subcutaneous

ICD-10	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

ICD-10	ICD-10 Description
L40.54	Psoriatic juvenile arthropathy
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
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
M08.90	Juvenile arthritis, unspecified
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

ICD-10	ICD-10 Description
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
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
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis of lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis of sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine
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

ICD-10	ICD-10 Description
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

Intravenous

ICD-10	ICD-10 Description
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region
M45.2	Ankylosing spondylitis of cervical region
M45.3	Ankylosing spondylitis of cervicothoracic region
M45.4	Ankylosing spondylitis of thoracic region
M45.5	Ankylosing spondylitis of thoracolumbar region
M45.6	Ankylosing spondylitis of lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis of sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine
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

ICD-10	ICD-10 Description
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)

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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