

Cosentyx® (secukinumab)

(Subcutaneous)

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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:
 - Loading: 1 pen/prefilled syringe at weeks 0, 1, 2, 3, 4
 - Maintenance: 1 pen/prefilled syringe every 28 days
- Cosentyx 150 mg single-dose Sensoready Pen/prefilled syringe/vial:
 - Loading: 2 pens/prefilled syringes/vials at weeks 0, 1, 2, 3, 4
 - Maintenance: 2 pens/prefilled syringes/vials every 28 days
- Cosentyx 75 mg single-dose prefilled syringe (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

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

Indication	Max Units
Non-Radiographic Axial Spondyloarthritis and Enthesitis-Related Arthritis	Loading: • 150 mg at weeks 0, 1, 2, 3, 4 Maintenance: • 150 mg every 28 days
Plaque Psoriasis and Psoriatic Arthritis with co-existent Plaque Psoriasis	Loading: • 300 mg at weeks 0, 1, 2, 3, 4 Maintenance: • 300 mg every 28 days



Indication	Max Units	
	Loading:	
Psoriatic Arthritis and	• 150 mg at weeks 0, 1, 2, 3, 4	
Ankylosing Spondylitis	Maintenance:	
	• 300 mg every 28 days	

III. Initial Approval Criteria 1

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 ¹

- 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 TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib, upadacitinib, etc.); AND

Adult Plaque Psoriasis † 1,13,26,32-34

- 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 (i.e., 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, 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



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without approval.

• 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 † 1,13,26,27,32-34

- 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:
 - o Involvement of at least 3% of body surface area (BSA); **OR**
 - o Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
 - o Incapacitation or serious emotional consequences due to plaque location (i.e., hands, feet, head and neck, or genitalia, etc.) or with intractable pruritus; **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, 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) † 1,12,28,35

- Documented moderate to severe active disease; AND
 - For patients with predominantly axial disease OR active enthesitis, a trial and failure of at least a 4 week trial of ONE non-steroidal anti-inflammatory agent (NSAID), unless use is contraindicated; OR
 - o For patients with peripheral arthritis or dactylitis, 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 (i.e., 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 † 1,36,37

- 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 † 1,11,30

- 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) † 1,30

- 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
- Patient has active disease as defined by a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) ≥4 and spinal pain ≥40 on the Visual Analog Scale (VAS); AND
- Patient had an adequate trial and failure of at least TWO (2) non-steroidal antiinflammatory agents (NSAIDs), unless use is contraindicated

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

- 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.)

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

- Xeroderma pigmentosum
- 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; Φ Orphan Drug



IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. 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, anaphylactic or other serious allergic reactions, etc.; AND

Adult Plaque Psoriasis 10,26

• 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. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and ≥ 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started.]

Pediatric Plaque Psoriasis 10,27

• 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. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and ≥ 4-point reduction in the children's Dermatology Life Quality Index (cDLQI) from when treatment started.]

Adult Psoriatic Arthritis 9,29

- 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 <u>and</u> interval specified below



Juvenile Psoriatic Arthritis 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].

Ankylosing Spondylitis 11,42

- 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 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 <u>and</u> interval specified below

Non-radiographic Axial Spondyloarthritis 1,31

• 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].

V. Dosage/Administration ¹

Indication	Dose	
Indication	Dose	
Plaque Psoriasis	Adults 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. For some patients, a dosage of 150 mg may be acceptable. Pediatric Patients ≥ 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	
Psoriatic Arthritis with co- existent Plaque Psoriasis	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. For some patients, a dosage of 150 mg may be acceptable.	
Psoriatic Arthritis	Adults With loading dose: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, & 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 patients for this indication. If the patient continues to have active psoriatic arthritis, increasing the dose to 300 mg every 4 weeks may be considered. Each 300 mg dose may be given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg. Pediatric Patients ≥ 2 years of age Weight ≥ 15 kg and < 50 kg: 75 mg by subcutaneous injection at Weeks 0, 1, 2, 3, & 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	With loading dose: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, & 4 and every 4 weeks thereafter Without a loading dose:	



Indication	Dose	
	increasing the dose to 300 mg every 4 weeks may be considered. Each 300 mg dose may be given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.	
Non- Radiographic Axial Spondyloarthritis	With loading dose: 150 mg by subcutaneous injection at Weeks 0, 1, 2, 3, & 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.	
Enthesitis- Related Arthritis		

VI. Billing Code/Availability Information

HCPCS Code:

- J3590 Unclassified biologics
- C9399 Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)

NDC(s):

- Cosentyx 300 mg/2 mL single-dose UnoReady Pen (carton of 1): 00078-1070-xx
- Cosentyx 150 mg/mL single-dose Sensoready Pen (carton of 1 or 2): 00078-0639-xx
- Cosentyx 300 mg/2 mL single-dose prefilled syringe (carton of 1): 00078-1070-xx
- Cosentyx 150 mg/mL single-dose prefilled syringe (carton of 1 or 2): 00078-0639-xx
- Cosentyx 75 mg/0.5 mL single-dose prefilled syringe (for pediatric patients less than 50 kg; carton of 1): 00078-1056-xx
- Cosentyx 150 mg lyophilized powder in a single-dose vial (HCP use only): 00078-0657-xx

VII. References

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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



ICD-10 Codes	ICD-10 Description	
L40.53	Psoriatic spondylitis	
L40.59	Other psoriatic arthropathy	
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	
M08.9A	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	



ICD-10 Codes	ICD-10 Description	
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.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	
M46.80	Other specified inflammatory spondylopathies, site unspecified	
M46.81	Other specified inflammatory spondylopathies, occipito-atlanto-axial region	
M46.82	Other specified inflammatory spondylopathies, cervical region	
M46.83	Other specified inflammatory spondylopathies, cervicothoracic region	
M46.84	Other specified inflammatory spondylopathies, thoracic region	
M46.85	Other specified inflammatory spondylopathies, thoracolumbar region	
M46.86	Other specified inflammatory spondylopathies, lumbar region	
M46.87	Other specified inflammatory spondylopathies, lumbosacral region	



ICD-10 Codes	ICD-10 Description
M46.88	Other specified inflammatory spondylopathies, sacral and sacrococcygeal region
M46.89	Other specified inflammatory spondylopathies, multiple sites in spine

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

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, 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	

