Cosentyx® (secukinumab)
(Subcutaneous)

Document Number: IH-0229

Last Review Date: 08/03/2021
Date of Origin: 02/24/2015
Dates Reviewed: 02/2015, 01/2016, 01/2017, 01/2018, 08/2018, 08/2019, 03/2020, 07/2020, 07/2021, 08/2021

I. Length of Authorization

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

II. Dosing Limits

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

- Cosentyx 150 mg Sensoready Pen/prefilled syringe/single-use 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 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	Loading: • 150 mg at weeks 0, 1, 2, 3, 4 Maintenance: • 150 mg every 28 days
All Other Indications	Loading: • 300 mg at weeks 0, 1, 2, 3, 4 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**

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**
- Must 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, etc.); **AND**

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 systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **OR**
  - 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); **AND**

- Patient must have tried and failed treatment with at least four (4) of the following and at least three (3) different drug classes must have been tried and failed:
  - Enbrel, Humira, Otezla, Skyrizi, Stelara SQ, Taltz, Tremfya or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

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:
  - 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 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 systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **OR**
  - 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)

Psoriatic Arthritis (PsA) † [1,5,12,28,35]

- 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**
  - 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.

- Patient must have tried and failed treatment with at least three (3) of the following and at least two (2) different drug classes must have been tried and failed:
  - Enbrel, Humira, Otezla, Stelara SQ, Taltz, Tremfya, Xeljanz/Xeljanz XR or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

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)

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

- Patient must have tried and failed treatment with at least two of the following: Enbrel, Humira, Taltz, or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

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) † [1,30,31]

- 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) 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 anti-inflammatory agents (NSAIDs), unless use is contraindicated

- If the medication is being self-injected, patient must have tried and failed treatment with Cimzia and Taltz or a contraindication exists.
- **The use of samples and free goods do not qualify as an established clinical response.**

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

† 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, and anaphylactic or other serious allergic reactions, etc.; **AND**

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 a four-point reduction in the 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 a four-point reduction in the cDLQI from when treatment started.]

Psoriatic Arthritis [9]

- 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

Ankylosing Spondylitis [11]

- 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 and interval specified below

Non-radiographic Axial Spondyloarthritis [1,22]

- 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].

V. Dosage/Administration [1]

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 is given as 2 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 is given as 2 subcutaneous injections of 150 mg. For some patients, a dosage of 150 mg may be acceptable.
Psoriatic Arthritis	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. If the patient continues to have active psoriatic arthritis, increasing the dose to 300 mg may be considered.
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: 150 mg by subcutaneous injection every 4 weeks **Note**: 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 may be considered.
Non-Radiographic	With loading dose:

Indication	Dose
Axial Spondyloarthritis	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.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- Cosentyx 150 mg/mL Sensoready Pen (carton of 1 or 2): 00078-0639-xx
- Cosentyx 150 mg/mL prefilled syringe (carton of 1 or 2): 00078-0639-xx
- Cosentyx 75 mg/mL prefilled syringe (for pediatric patients less than 50 kg; carton of 1): 0078-1056-xx
- Cosentyx 150 mg lyophilized powder in a single-use vial (HCP use only): 00078-0657-xx

VII. References

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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.

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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
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy
M45.0	Ankylosing spondylitis of multiple sites in spine
M45.1	Ankylosing spondylitis of occipito-atlanto-axial region

ICD-10 Codes	ICD-10 Description
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 lumbar region
M45.7	Ankylosing spondylitis of lumbosacral region
M45.8	Ankylosing spondylitis sacral and sacrococcygeal region
M45.9	Ankylosing spondylitis of unspecified sites in spine
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
M46.88	Other specified inflammatory spondylopathies, sacral and sacrococcygeal region
M46.89	Other specified inflammatory spondylopathies, multiple sites in spine
M46.81	Other specified inflammatory spondylopathies, occipito-atlanto-axial 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: http://www.cms.gov/medicare-coverage-database/search/advanced-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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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