Cosentyx™ (secukinumab)
(Subcutaneous)

Document Number: IH-0229

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Cosentyx 150 mg Sensoready Pen/prefilled syringe:
  - Loading: 2 pens/prefilled syringes at weeks 0, 1, 2, 3, 4
  - Maintenance: 2 pens/prefilled syringes every 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

Indication	Max Units
Plaque Psoriasis & Psoriatic Arthritis with co-existent plaque psoriasis	Loading: • 150 mg single-use vial: 2 single-use vials (300 mg) at weeks 0, 1, 2, 3, 4 Maintenance: • 150 mg single-use vial: 2 single-use vials (300 mg) every 28 days
Psoriatic Arthritis	Loading: • 150 mg single-use vial: 1 single-use vial at weeks 0, 1, 2, 3, 4 Maintenance: • 150 mg single-use vial: 1 single-use vial every 28 days **Note:** for psoriatic arthritis with inadequate response to the 150 mg dosing, 300 mg may be considered
Ankylosing Spondylitis	Loading: • 150 mg single-use vial: 1 single-use vial at weeks 0, 1, 2, 3, 4 Maintenance: • 150 mg single-use vial: 1 single-use vial every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Adult patient (18 years or older); **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Must not be administered concurrently with live vaccines; **AND**
- Patient is free of any clinically important active 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**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**

Plaque Psoriasis †

- 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 due to plaque location (i.e., head and neck, palms, soles or genitalia); **AND**
- Patient did not respond adequately (or is not a candidate) to a 3 month 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 1 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); **AND**
  - Patient did not respond adequately (or is not a candidate) to a 3 month minimum trial of at least 1 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) †

- Documented moderate to severe active disease; **AND**

- For patients with predominantly axial disease OR active enthesitis and/or dactylitis, an adequate trial and failure of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated; **OR**
- For patients with peripheral arthritis, 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; **AND**

- Patient must have experienced an inadequate response (e.g., have active psoriatic arthritis) to an adequate trial on the 150 mg dose before increasing to the 300 mg dose (unless they have co-existent plaque psoriasis)

Ankylosing Spondylitis †

- Documented active disease; **AND**
- Patient had an adequate trial and failure to a 1 month trial of at least TWO (2) non-steroidal anti-inflammatory agents (NSAIDs), unless use is contraindicated

† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe exacerbations of inflammatory bowel disease, severe infections, and anaphylactic or other serious allergic reactions; **AND**
- Patient is receiving ongoing monitoring for presence of TB or other active infections; **AND**

Plaque Psoriasis

- 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

Psoriatic Arthritis

- 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.]

Ankylosing Spondylitis

- 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)]

V. Dosage/Administration

Indication	Dose
Plaque Psoriasis & 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 at weeks 0, 1, 2, 3, & 4 and every 4 weeks thereafter Without a loading dose: 150 mg 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 at weeks 0, 1, 2, 3, & 4 and every 4 weeks thereafter Without a loading dose: 150 mg every 4 weeks **Note**: Cosentyx may be administered with or without a loading dose for this indication.

VI. Billing Code/Availability Information

Jcode:

- 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 150 mg lyophilized powder in a single-use vial (HCP use only): 00078-0657-xx

VII. References

1. Cosentyx [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation; June 2018. Accessed June 2018.
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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.
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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
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

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) 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/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.

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