Neighborhood Health Plan OF RHODE ISLAND™
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Cosentyx (secukinumab) (Intravenous)

Effective Date: 07/01/2024
Review Date: 05/01/2024, 1/22/2025
Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed for 12 months.

II. Dosing Limits

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

- 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 Dose/Units
Psoriatic Arthritis, Ankylosing Spondylitis, and Non-Radiographic Axial Spondylarthritis	Intravenous Administration: • Loading: 750mg/units at weeks 0 • Maintenance:375mg/units every 28 days

III. Summary of Evidence:

Cosentyx IV (secukinumab) is a human interleukin-17A antagonist indicated for the treatment of adult patients with psoriatic arthritis (PsA), ankylosing spondylitis (AS), and non-radiographic axial spondyloarthritis (nr-axSpA). The effectiveness of intravenous Cosentyx in the treatment of adult patients with active PsA, AS and active nr-axSpA was extrapolated from the established effectiveness of subcutaneous Cosentyx in adult patients based on pharmacokinetic exposure. Cosentyx for IV administration is the first available IV treatment option approved for adults with PsA, AS, and nr-axSpA. Cosentyx IV is the first and only treatment in an IV formulation that targets and blocks interleukin-17A (IL-17A) and is the only IV non-tumor necrosis factor alpha option for these indications.

IV. Initial Approval Criteria[1]

Coverage is provided in the following conditions:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

- 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
- Will not be administered concurrently with live vaccines; AND
- Patient does not have an active infection, including clinically important localized infections; AND
- 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
- Cosentyx will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Stelaraustekinumab), Wezlana (ustekinumab-auub), Tremfya (guselkumab), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.)

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

- Patient is 2 years of age and older: AND
- Documented moderate to severe active disease; AND
- Cosentyx is prescribed by, or in consultation with, a specialist in dermatology or rheumatology; 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, etc.; AND
- Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab and at least a 6-month trial of ustekinumab at maximum tolerated doses

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

- Documented active disease; AND
- Cosentyx is prescribed by, or in consultation with, a specialist in rheumatology; 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; AND
- Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

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

- Cosentyx prescribed by, or in consultation with, a specialist in rheumatology.
- 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) over 4 weeks (in total) unless use is contraindicated; AND
- Member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at maximum tolerated doses

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

V. Renewal Criteria

Active psoriatic arthritis (PsA)

- Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
  - Number of swollen joints
  - Number of tender joints

- Dactylitis
- Enthesitis
- Skin and/or nail involvement

- Dose escalation (up to the maximum does 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 does 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

Active ankylosing spondylitis (AS) and active axial spondylarthritis

- Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active ankylosing spondylitis or active axial spondyloarthritis and who achieve or maintain positive clinical response with the requested medication as evidenced by low disease activity or improvement in signs and symptoms of the condition when there isimprovement in any of the following from baseline:
  - Functional status
  - Total spinal pain
  - Inflammation (e.g., morning stiffness)
- Dose escalation (up to the maximum does 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 does 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 and interval specified below

VI. Dosage/Administration

Indication	Dosing
Ankylosing Spondylitis	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)	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 nr-axSpA.
Psoriatic Arthritis	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 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.

VII. Billing Code/Availability Information

HCPCS Code(s):

J3247: Injection, secukinumab, intravenous, 1 mg

VIII. References

1. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
2. Menter A, Korman NJ, Elmets CA, et al. 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;65(1):137-174.
3. 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.* 2016;75(3):499-510.
4. 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(9999):1137-46.
5. Braun J, van den Berg R, Baraliakos, X et al. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis.* 2011;70:896–904.
6. 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: 10.1002/art.39298. [Epub ahead of print].
7. Baeten D, Sieper J, Braun J, et al. Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. *N Engl J Med.* 2015;373(26):2534-48.

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)	
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Cosentyx was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Cosentyx according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.