Drug Coverage Policy

Effective Date……07/01/2025
Coverage Policy Number…… DQM002
Policy Title… Cosentyx Subcutaneous Drug Quantity Management Policy – Per Days

Inflammatory Conditions – Cosentyx Subcutaneous Drug Quantity Management Policy – Per Days

- Cosentyx® (secukinumab subcutaneous injection – Novartis)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview
Cosentyx, an interleukin (IL)-17A antagonist, is indicated in the following conditions:[1]

- **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in patients ≥ 2 years of age with active disease.
- **Ankylosing spondylitis**, in adults with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.
- **Enthesitis-related arthritis** in patients ≥ 4 years of age with active disease.
- **Hidradenitis suppurativa**, in adults with moderate to severe disease.

Dosing
Cosentyx is administered by subcutaneous (SC) injection.[1]

- **Ankylosing Spondylitis:** Administer with or without a loading dose.
    - With a loading dose: 150 mg at Weeks 0, 1, 2, 3, and 4, then 150 mg once every 4 weeks (Q4W) thereafter.
    - Without a loading dose: 150 mg Q4W.
    - If the patient continues to have active ankylosing spondylitis, consider 300 mg Q4W.
- **Plaque Psoriasis:**
    - Adults: 300 mg at Weeks 0, 1, 2, 3, and 4, followed by 300 mg Q4W. For some patients, 150 mg Q4W may be acceptable.
    - Pediatric patients ≥ 6 years of age: Dose is based on body weight and is administered at Weeks 0, 1, 2, 3, and 4 followed by Q4W dosing. The dose is 75 mg for patients weighing < 50 kg and is 150 mg for patients weighing ≥ 50 kg.
        - **Psoriatic Arthritis:** Cosentyx may be administered with or without methotrexate.
            - Adults with coexistent moderate to severe plaque psoriasis: Use the dosing and administration recommendations for plaque psoriasis.
            - Other adults with psoriatic arthritis: Administer with or without a loading dose.
                - With a loading dose: 150 mg at Weeks 0, 1, 2, 3, and 4, then 150 mg Q4W thereafter.
                - Without a loading dose: 150 mg Q4W.
        - If the patient continues to have active psoriatic arthritis, consider 300 mg Q4W.
    - Pediatric patients ≥ 2 years of age: Dose is based on body weight and is administered at Weeks 0, 1, 2, 3, and 4 followed by Q4W dosing. The dose is 75 mg for patients weighing ≥ 15 kg and < 50 kg and is 150 mg for patients weighing ≥ 50 kg.
- **Non-radiographic axial spondyloarthritis:** Administer with or without a loading dose.
    - With a loading dose: 150 mg at Weeks 0, 1, 2, 3, and 4, then 150 mg Q4W thereafter.
    - Without a loading dose: 150 mg Q4W.
- **Enthesitis-related arthritis:** Dose is based on body weight and is administered at Weeks 0, 1, 2, 3, and 4, followed by Q4W dosing. The dose is 75 mg for patients weighing ≥ 15 kg and < 50 kg and is 150 mg for patients weighing ≥ 50 kg.
- **Hidradenitis suppurativa:** 300 mg at Weeks 0, 1, 2, 3, and 4, then 300 mg Q4W thereafter.
    - If the patient does not adequately respond, the dose may be increased to 300 mg Q2W.

Availability
Cosentyx is available in the following forms:

- 300 mg/2 mL single-dose UnoReady pen (cartons contain one pen).

- 300 mg/2 mL single-dose prefilled syringe (cartons contain one prefilled syringe)
- 150 mg/mL single-dose SensoReady pen (cartons contain either one or two pens).
- 150 mg/mL single-dose prefilled syringe (cartons contain either one or two prefilled syringes).
- 75 mg/0.5 mL single-dose prefilled syringe (cartons contain one prefilled syringe) [for pediatric patients who weigh < 50 kg].

Of note, Cosentyx is also available as a 125 mg/5 mL intravenous (IV) solution. The IV solution is not targeted in this policy.

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Policy Statement
This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Cosentyx, and to manage potential premature dose escalation. If the Drug Quantity Management rule is not met at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity Per 84 Days
Cosentyx® (secukinumab subcutaneous injection)	300 mg/2 mL UnoReady pen	2 mL (1 pen)	6 mL (3 pens)
	300 mg/2 mL prefilled syringe	2 mL (1 prefilled syringe)	6 mL (3 prefilled syringes)
	150 mg/mL prefilled syringe	1 mL (1 prefilled syringe)	3 mL (3 prefilled syringes)
	150 mg/mL SensoReady pen	1 mL (1 pen)	3 mL (3 pens)
	75 mg/0.5 mL prefilled syringe	0.5 mL (1 prefilled syringe)	1.5 mL (3 prefilled syringes)

Exceptions to the quantity limits listed above are covered as medically necessary when the following criteria are met. Any other exception is considered not medically necessary.

CRITERIA

Cosentyx 300 mg prefilled syringes or UnoReady pens

1. If the patient is initiating treatment for plaque psoriasis or hidradenitis suppurativa OR requires additional induction dosing for plaque psoriasis or hidradenitis suppurativa, as verified by the absence of claims for Cosentyx in the past 130 days, approve a one-time override for 10 mL (5 prefilled syringes or pens) at retail or 14 mL (7 prefilled syringes or pens)at home delivery.

2. If the patient requires a dose of 300 mg once every 2 weeks for hidradenitis suppurativa, approve 4 mL (2 prefilled syringes or pens) per 28 days at retail or 12 mL (6 prefilled syringes or pens) per 84 days at home delivery.

Cosentyx 150 mg prefilled syringes or SensoReady pens

1. If the patient is initiating treatment for ankylosing spondylitis, non-radiographic axial spondyloarthritis, psoriatic arthritis, or enthesitis-related arthritis OR requires additional induction dosing for ankylosing spondylitis, non-radiographic axial spondyloarthritis, psoriatic arthritis, or enthesitis-related arthritis as verified by the absence of claims for Cosentyx in the past 130 days, approve a one-time override for 5 mL (5 prefilled syringes or pens) at retail or 7 mL (7 prefilled syringes or pens) at home delivery.
2. If the patient is initiating treatment for plaque psoriasis or hidradenitis suppurativa OR requires additional induction dosing for plaque psoriasis or hidradenitis suppurativa, as verified by the absence of claims for Cosentyx in the past 130 days, approve a one-time override for 10 mL (10 prefilled syringes or pens) at retail or 12 mL (12 prefilled syringes or pens) at home delivery.

Cosentyx 75 mg prefilled syringes

1. If the patient is initiating treatment for plaque psoriasis, psoriatic arthritis, or enthesitis-related arthritis OR requires additional induction dosing for plaque psoriasis, psoriatic arthritis, or enthesitis-related arthritis, as verified by the absence of claims for Cosentyx in the past 130 days, approve a one-time override for 2.5 mL (5 prefilled syringes) at retail or 3 mL (6 prefilled syringes or pens) at home delivery.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

References

1. Cosentyx® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; August 2024.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	07/01/2025

The policy effective date is in force until updated or retired.