DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Cosentyx Subcutaneous Drug Quantity Management Policy – Per Days
- Cosentyx® (secukinumab subcutaneous injection – Novartis)

REVIEW DATE: 09/27/2023; selected revision 11/15/2023

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. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 a patients 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).
- 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.

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	1 pen	3 pens
	150 mg/mL prefilled syringe	2 prefilled syringes	6 prefilled syringes
	150 mg/mL SensoReady pen	2 pens	6 pens
	75 mg/0.5 mL prefilled syringe	1 prefilled syringe	3 prefilled syringes

Inflammatory Conditions – Cosentyx Subcutaneous Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Cosentyx 300 mg 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 exception for 5 pens at retail or 7 pens at home delivery.

2. If the patient requires a dose of 300 mg once every 2 weeks for hidradenitis suppurativa, approve 2 pens per 28 days at retail or 6 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

exception for 5 prefilled syringes or pens at retail or 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 exception for 10 prefilled syringes or pens at retail or 12 prefilled syringes or pens at home delivery.

3. If the patient requires a dose of 300 mg once every 2 weeks for hidradenitis suppurativa, approve 4 prefilled syringes or pens per 28 days at retail or 12 prefilled syringes or pens per 84 days 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 exception for 5 prefilled syringes at retail or 6 prefilled syringes or pens at home delivery.

REFERENCES

1. Cosentyx® subcutaneous injection [prescribing information]. East Hanover, NJ: Novartis; October 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	12/16/2022
Early Annual Revision	**Cosentyx 300 mg UnoReady pens:** Added new quantity limit to the policy of 1 pen per 28 days at retail or 3 pens per 84 days at home delivery. Added new exception criteria to approve a one-time exception for 5 pens at retail or 7 pens at home delivery if the patient is initiating treatment or requires additional induction dosing for plaque psoriasis.	09/27/2023
Selected Revision	Name of policy updated to "Inflammatory Conditions – Cosentyx Subcutaneous DQM Policy – Per Days". Previously, policy was named "Inflammatory Conditions – Cosentyx DQM Policy – Per Days". **Cosentyx 300 mg UnoReady pens:** New exception criteria were added to approve a one-time exception for 5 pens at retail or 7 pens at home delivery if the patient is initiating treatment for hidradenitis suppurativa or requires additional induction dosing for hidradenitis suppurativa. Additional criteria were added to approve 2 pens per 28 days at retail or 6 pens per 84 days at home delivery, if the patient requires a dose of 300 mg once every 2 weeks for hidradenitis suppurativa. **Cosentyx 150 mg prefilled syringes or SensoReady pens:** New exception criteria were added to approve a one-time exception for 10 prefilled syringes or pens at retail or 12 prefilled syringes or pens at home delivery if the patient is initiating treatment for hidradenitis suppurativa or requires additional induction dosing for hidradenitis suppurativa. Additional criteria were added to approve 4 prefilled syringes or pens per 28 days at retail or 12 prefilled syringes or pens per 84 days at home delivery, if the patient requires a dose of 300 mg once every 2 weeks for hidradenitis suppurativa.	11/15/2023