DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Taltz Drug Quantity Management Policy – Per Days
- Taltz® (ixekizumab subcutaneous injection – Eli Lilly and Company)

REVIEW DATE: 09/04/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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

Taltz, an interleukin (IL)-17A antagonist, is indicated for the following uses:[1]
- **Ankylosing spondylitis**, in adults with active disease.
- **Non-radiographic axial spondyloarthritis**, in adults with active disease and objective signs of inflammation.
- **Plaque psoriasis**, in patients ≥ 6 years of age with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in adults with active disease.

Dosing

Taltz is administered as a subcutaneous (SC) injection.[1] The recommended dose varies by indication:

- **Adult Plaque Psoriasis:** 160 mg (two 80 mg injections) at Week 0, followed by 80 mg at Weeks 2, 4, 6, 8, 10, and 12, then 80 mg once every 4 weeks.

- **Pediatric Plaque Psoriasis (patients 6 to < 18 years of age):**

Patient's Weight	Starting Dose (Week 0)	Dose Every 4 Weeks Thereafter

> 50 kg	160 mg (two 80 mg injections)	80 mg
25 to 50 kg	80 mg	40 mg
< 25 kg	40 mg	20 mg

- **Psoriatic Arthritis:** 160 mg (two 80 mg injections) at Week 0, followed by 80 mg once every 4 weeks. For psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for plaque psoriasis.

- **Ankylosing Spondylitis:** 160 mg (two 80 mg injections) at Week 0, followed by 80 mg once every 4 weeks.

- **Non-radiographic Axial Spondyloarthritis:** 80 mg once every 4 weeks.

Availability

Taltz is available as an 80 mg/mL solution in a single-dose, prefilled auto-injector supplied in cartons of one, two, or three auto-injectors. It is also available as 20 mg/0.25 mL, 40 mg/0.5 mL, and 80 mg/mL single-dose prefilled syringes supplied in cartons containing one syringe each.

Policy Statement

This Drug Quantity Management program has been developed to manage potential premature dose escalation of Taltz. If the Drug Quantity Management rule is not met at the point of service, coverage will be determined by the Criteria below. 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
Taltz® (ixekizumab subcutaneous injection)	20 mg/0.25 mL prefilled syringe	0.25 mL (1 syringe)	0.75 mL (3 syringes)
	40 mg/0.5 mL prefilled syringe	0.5 mL (1 syringe)	1.5 mL (3 syringes)
	80 mg/mL prefilled syringe	1 mL (1 syringe)	3 mL (3 syringes)
	80 mg/mL prefilled auto-injector	1 mL (1 autoinjector)	3 mL (3 autoinjectors)

Inflammatory Conditions – Taltz 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

Taltz 20 mg/0.25 mL prefilled syringes

No overrides recommended.

Taltz 40 mg/0.5 mL prefilled syringes
No overrides recommended.

Taltz 80 mg/mL prefilled syringes and auto-injectors

1. If the patient is ≥ 18 years of age and is initiating treatment for psoriatic arthritis or ankylosing spondylitis or requires additional induction dosing for psoriatic arthritis or ankylosing spondylitis, as verified by the absence of claims for Taltz in the past 130 days, approve a one-time override for 2 mL (2 syringes or 2 auto-injectors) at retail or 4 mL (4 syringes or 4 auto-injectors) at home delivery.

2. If the patient is ≥ 18 years of age and is initiating treatment for plaque psoriasis or requires additional induction dosing for plaque psoriasis, as verified by the absence of claims for Taltz in the past 130 days, approve a one-time override for 4 mL (4 syringes or 4 auto-injectors), followed by an approval of 2 mL (2 syringes or 2 auto-injectors) per 28 days for up to 84 days at retail or a one-time override for 8 mL (8 syringes or 8 auto-injectors) at home delivery.

3. If the patient is ≥ 18 years of age and is currently completing induction dosing for plaque psoriasis, approve an override for the requested quantity, not to exceed 2 mL (2 syringes or 2 auto-injectors) per 28 days for up to 84 days at retail or a one-time override for the requested quantity, not to exceed 8 mL (8 syringes or 8 auto-injectors) at home delivery.

4. If the patient is < 18 years of age, weighs > 50 kg, and is initiating treatment for plaque psoriasis or requires additional induction dosing for plaque psoriasis, as verified by the absence of claims for Taltz in the past 130 days, approve a one-time override for 2 mL (2 syringes or 2 auto-injectors) at retail or 4 mL (4 syringes or 4 autoinjectors) at home delivery.

REFERENCES

1. Taltz® subcutaneous injection [prescribing information]. Indianapolis, IN: Eli Lilly; August 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/01/2023
Early Annual Revision	**Taltz 20 mg/0.25 mL prefilled syringes:** New quantity limits of 0.25 mL (1 syringe) per 28 days at retail and 0.75 mL (3 syringes) per 84 days at home delivery were added to the policy. No clinical overrides apply. **Taltz 40 mg/0.5 mL prefilled syringes:** New quantity limits of 0.5 mL (1 syringe) per 28 days at retail and 1.5 mL (3 syringes) per 84 days at home delivery were added to the policy. No clinical overrides apply.	09/04/2024

	Taltz 80 mg/mL prefilled auto-injectors and prefilled syringes: Existing override criteria were clarified to approve for a patient who requires additional induction dosing for psoriatic arthritis, ankylosing spondylitis, or plaque psoriasis. Previously, criteria approved for a patient initiating therapy only. Additionally, a new override was added to approve the requested quantity, not to exceed 2 mL (2 syringes or 2 auto-injectors) per 28 days for up to 84 days at retail or a one-time override for the requested quantity, not to exceed 8 mL (8 syringes or 8 auto-injectors) at home delivery, if the patient is ≥ 18 years of age and is currently completing the 12-week induction dosing for plaque psoriasis.	