Drug Quantity Management – Per Days
Inflammatory Conditions – Taltz

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 108059

Effective 2/7/23: 79966

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.

National Formulary Medical Necessity

Drugs Affected

- Taltz® (ixekizumab subcutaneous injection)

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	Maximum Quantity per 28 Days
Taltz® (ixekizumab subcutaneous injection)	80 mg/mL prefilled auto-injector	1 auto-injector
	80 mg/mL prefilled syringe	1 syringe

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

1. If the individual is ≥ 18 years of age and is initiating treatment 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 syringes or 2 autoinjectors at retail or 4 syringes or 4 auto-injectors at home delivery.

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

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

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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] It is available as an 80 mg/mL solution in a single-dose 1 mL prefilled auto-injector and a single-dose 1 mL prefilled syringe. Taltz is supplied in cartons of one, two, or three auto-injectors and a carton of one prefilled syringe. When a 160 mg dose is needed, two 80 SC injections should be administered at separate sites. Taltz doses of 20 mg or 40 mg must be prepared and administered by a qualified healthcare professional and only the 80 mg/1 mL prefilled syringe should be used. 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.

References

1. Taltz® [prescribing information]. Indianapolis, IN: Eli Lilly; March 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery. No changes to criteria.	10/17/2022