DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Inflammatory Conditions – Otezla Drug Quantity Management Policy – Per Days
- Otezla® (apremilast tablets – Amgen)

REVIEW DATE: 01/04/2024

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

Otezla, an oral phosphodiesterase 4 (PDE4) inhibitor, is indicated for the following uses:[1]
- **Behcet's disease**, in adults with oral ulcers.
- **Plaque psoriasis**, in adults who are candidates for phototherapy or systemic therapy.
- **Psoriatic arthritis** in adults with active disease.

Dosing

Otezla is administered orally without regard to meals. It requires a titration period to reduce gastrointestinal adverse events.[1] The 5-day titration schedule is in Table 1 below. Following the 5-day titration, the recommended maintenance dose is 30 mg twice daily (BID) starting on Day 6. The dosage of Otezla should be reduced to 30 mg once daily in patients with severe renal impairment (creatinine clearance < 30 mL per minute estimated by the Cockcroft–Gault equation). For initial dosage titration in this population, it is recommended that Otezla be titrated using only the morning schedule listed in the table below and the evening doses should be skipped.

Table 1. Otezla Titration Schedule.[1]

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & Thereafter	
AM	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

AM – Morning; PM – Evening.

Availability

Otezla is available as:

- 30 mg tablets supplied in bottles of 60.
- 14-day Starter Pack containing: 4 x 10 mg tablets, 4 x 20 mg tablets, and 5 x 30 mg tablets with an additional 14 x 30 mg tablets.
- 28-day Starter Pack containing: 4 x 10 mg tablets, 4 x 20 mg tablets, and 5 x 30 mg tablets with an additional 42 x 30 mg tablets.

POLICY STATEMENT

This Drug Quantity Management program has been developed to manage potential premature dose escalation of Otezla. 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 the duration noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity	Home Delivery Maximum Quantity
Otezla® (apremilast tablets)	30 mg tablets	60 tablets per 30 days	180 tablets per 90 days
	14-day starter pack (4 x 10 mg, 4 x 20 mg, and 5 x 30 mg tablets, with an additional 14 x 30 mg tablets)	27 tablets per 365 days	
	28-day starter pack (4 x 10 mg, 4 x 20 mg, and 5 x 30 mg, with an additional 42 x 30 mg tablets)	55 tablets per 365 days	

Inflammatory Conditions – Otezla 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

Otezla 30 mg tablets

No overrides recommended.

Otezla Starter Pack (14-day or 28-day)

1. If the patient requires additional induction dosing, as verified by the absence of claims for Otezla in the past 130 days, approve a one-time override for one 14-day Starter Pack (27 tablets) or one 28-day Starter Pack (55 tablets) at retail or home delivery.

REFERENCES

1. Otezla® tablets [prescribing information]. Thousand Oaks, CA: Amgen; July 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	No criteria changes. Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	12/19/2022
Annual Revision	No criteria changes.	01/04/2024