DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

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

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.
- **Plaque psoriasis**, in pediatric patients ≥ 6 years of age and ≥ 20 kg with moderate to severe disease 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]

Adults with Behcet's Disease, Plaque Psoriasis, or Psoriatic Arthritis

The 5-day recommended titration schedule is in Table 1 below.[1] Following the 5-day titration, the recommended maintenance dose in adults is 30 mg twice daily

(BID) starting on Day 6. The dosage of Otezla should be reduced to 30 mg once daily (QD) in patients with severe renal impairment (creatinine clearance CrCl] < 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.

Pediatric Patients with Plaque Psoriasis

The recommended dose of Otezla in pediatric patients is based on body weight.[1] The initial titration schedule is in Table 2 below. Following the 5-day titration, the recommended maintenance dose is 30 mg BID in pediatric patients weighing ≥ 50 kg and 20 mg BID in pediatric patients weighing 20 kg to < 50 kg. In patients with severe renal impairment (CrCl < 30 mL per minute), the recommended dose of Otezla is 30 mg QD if the patient weighs ≥ 50 kg or 20 mg QD if the patient weighs 20 kg to < 50 kg. 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 2. Otezla Titration Schedule.[1]

Body Weight	Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & Thereafter	
	AM	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**	**AM**	**PM**
≥ 50 kg	10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg
20 kg to < 50 kg	10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg

AM – Morning; PM – Evening.

Availability

Otezla is available as:

- 20 mg tablets supplied in bottles of 60 tablets each
- 30 mg tablets supplied in bottles of 60 tablets each
- 28-day Starter Pack (20 mg BID dose) containing: 4 x 10 mg tablets and 51 x 20 mg tablets
- 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 (discontinued)
- 28-day Starter Pack (30 mg BID dose) containing: 4 x 10 mg tablets, 4 x 20 mg tablets, and 47 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)	20 mg tablets	60 tablets per 30 days	180 tablets per 90 days
	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) [discontinued]	27 tablets per 365 days	
	28-day Starter Pack (20 mg BID dose) (4 x 10 mg and 51 x 20 mg tablets)	55 tablets per 365 days	
	28-day Starter Pack (30 mg BID dose) (4 x 10 mg, 4 x 20 mg, and 47 x 30 mg tablets)	55 tablets per 365 days	

BID – Twice daily.

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 20 mg tablets
No overrides recommended.

Otezla 30 mg tablets
No overrides recommended.

Otezla Starter Pack (14-day) [discontinued]

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 27 tablets (one 14-day Starter Pack) at retail or home delivery.

Otezla Starter Pack (28-day [20 mg BID dose])

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 55 tablets (one 28-day Starter Pack) at retail or home delivery.

Otezla Starter Pack (28-day [30 mg BID dose])

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 55 tablets (one 28-day Starter Pack) at retail or home delivery.

REFERENCES

1. Otezla® tablets [prescribing information]. Thousand Oaks, CA: Amgen; April 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/04/2024
Early Annual Revision	**Otezla 20 mg tablets**: New quantity limits were added of 60 tablets per 30 days at retail and 180 tablets per 90 days at home delivery. No clinical overrides apply. **Otezla Starter Pack 28-day (20 mg BID dose):** New quantity limit was added of 55 tablets (1 pack) per 365 days at retail and home delivery. An override to provide a one-time override for one 28-day Starter Pack (55 tablets) at retail or home delivery applies if the patient requires additional induction dosing, as verified by the absence of claims for Otezla in the past 130 days.	09/04/2024