

## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

**POLICY:** Inflammatory Conditions – Otezla Drug Quantity Management Policy – Per Days

- Otezla® (apremilast tablets – Amgen)

**REVIEW DATE:** 12/19/2022

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### OVERVIEW

Otezla, an oral phosphodiesterase 4 (PDE4) inhibitor, is indicated for the following uses:<sup>1</sup>

- **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.<sup>1</sup> 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.**<sup>1</sup>

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.

**Automation:** None.

### 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 <sup>β</sup>	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	55 tablets per 365 days

### 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; December 2021.