

DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Opioids – Tramadol Extended-Release Products Drug Quantity Management Policy – Per Rx
- tramadol hydrochloride extended-release tablets – generic only
 - ConZip® capsules (tramadol hydrochloride extended-release capsules – Vertical)
 - tramadol hydrochloride extended-release capsules – branded generic to ConZip
 - tramadol hydrochloride extended-release capsules (150 mg strength) – branded generic (obsolete 8/2020)

REVIEW DATE: 07/13/2022

OVERVIEW

Extended-release tramadol is indicated in adults for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.¹⁻³

Dosing

Extended-release tramadol produces a continuous release of tramadol, therefore should be taken once daily (QD). Refer to the Drug Quantity Limit table below for dosing and availability of the extended-release tramadol products. Extended-release tramadol products should be swallowed whole, not crushed, chewed or spilt.¹⁻³

Availability

Tramadol extended-release tablets are available in three strengths (100 mg, 200 mg, and 300 mg). ConZip and tramadol extended-release capsules (branded generic) are also available in three strengths (100 mg, 200 mg, and 300 mg). Tramadol extended-release 150 mg capsules have been available but are obsolete (August 2020).

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote dose consolidation of tramadol. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Automation: None.

Drug Quantity Limits

Brand (generic)	FDA-Approved Dosing	Availability	Maximum Quantity per Rx
tramadol extended-release tablets (generic only)	<ul style="list-style-type: none"> • <u>Not currently receiving tramadol IR</u>: 100 mg QD, then titrated up by 100 mg increments every 5 days according to need and tolerance. • <u>Currently receiving tramadol IR</u>: The 24-hour tramadol IR dose should be calculated and the patient initiated on a total daily dose of tramadol ER rounded down to the next lowest 100 mg increment. The dose should be adjusted according to need and tolerance. • The dose should not exceed 300 mg per day. • When a patient no longer requires therapy, taper the dose gradually, by 25% to 50% every 2 to 4 days. 	100 mg tablets	30 tablets
ConZip® (tramadol extended-release capsules)		200 mg tablets	30 tablets
		300 mg tablets	30 tablets
		100 mg capsules	30 capsules
tramadol extended-release capsules (branded generic)		200 mg capsules	30 capsules
		300 mg capsules	30 capsules
tramadol extended-release capsules	<ul style="list-style-type: none"> • <u>Not currently receiving tramadol IR</u>: 100 mg QD, then titrated up to 150 mg, 200 mg, and then to 300 mg every 5 days according to need and tolerance. • <u>Currently receiving tramadol IR</u>: The 24-hour tramadol IR dose should be calculated and the patient initiated on a total daily dose of tramadol extended-release rounded down to the next lowest 100 mg dose increment. The dose should be adjusted according to need and tolerance. • Do not be administer a dose > 300 mg/day. • When a patient no longer requires therapy, taper the dose gradually, by 25% to 50% every 2 to 4 days. 	150 mg capsules	60 capsules

CRITERIA

Tramadol extended-release 100 mg tablets, ConZip 100 mg capsules, and tramadol extended-release 100 mg capsules

1. If the patient’s dose is being titrated (to a higher or lower dose), approve a one-time override for the requested quantity not to exceed 90 tablets or capsules (300 mg/day).

Tramadol extended-release 200 mg tablets, ConZip 200 mg capsules, tramadol extended-release 200 mg capsules

No overrides recommended.

Tramadol extended-release 300 mg tablets and ConZip 300 mg capsules, tramadol extended-release 300 mg capsules

No overrides recommended.

Tramadol extended-release 150 mg capsules

No overrides recommended.

REFERENCES

1. Tramadol hydrochloride extended-release tablets [prescribing information]. Cranbury, NJ: Sun; June 2021.
2. ConZip® extended-release capsules [prescribing information]. Sayerville, NJ: Vertical; September 2021.
3. Tramadol hydrochloride extended-release capsules [prescribing information]. Bridgewater, NJ: Trigen; October 2019.

