



Drug Quantity Management – Per Rx Opioids – Tramadol Extended-Release Products

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Product Identifier(s)

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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

- tramadol hydrochloride extended-release tablets – generic only
- ConZip® capsules (tramadol hydrochloride extended-release capsules)
- tramadol hydrochloride extended-release capsules – branded generic to ConZip
- tramadol hydrochloride extended-release capsules (150 mg strength) – branded generic (obsolete 8/2020)

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.

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. 	100 mg tablets	30 tablets
		200 mg tablets	30 tablets
		300 mg tablets	30 tablets
ConZip® (tramadol extended-release capsules)	<ul style="list-style-type: none"> • <u>Currently receiving tramadol IR</u>: The 24-hour tramadol IR dose should be calculated and the individual 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 an individual no longer requires therapy, taper the dose gradually, by 25% to 50% every 2 to 4 days. 	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 individual 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 an individual no longer requires therapy, taper the dose gradually, by 25% to 50% every 2 to 4 days. 	150 mg capsules	60 capsules

Criteria

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

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

1. If the individual'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.

Conditions Not Covered

Any other exception is considered not medically necessary.

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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy name changed to Tramadol Extended-Release Products DQM. Tramadol extended-release 100 mg tablets, ConZip 100 mg capsules, and tramadol extended-release 100 mg capsules. Criteria for a one-time override for patients titrating the dose was updated to approve a one-time override not to exceed 90 tablets or capsules (300 mg/day); these criteria were already in place. Criteria for patients taking a dose that does not correspond to a commercially available dosage form was removed. This criteria is not needed as the maximum dose is 300 mg/day.	07/13/2022

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