



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, authorized generic)

REVIEW DATE: 07/18/2024

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

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 split.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).

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.

Drug Quantity Limits

Brand (generic)	FDA-Approved Dosing	Availability	Retail Maximum Quantity per Rx	Home Delivery 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	90 tablets
		200 mg tablets	30 tablets	90 tablets
		300 mg tablets	30 tablets	90 tablets
ConZip® (tramadol extended-release capsules, authorized generic)		100 mg capsules	30 capsules	90 capsules
		200 mg capsules	30 capsules	90 capsules
		300 mg capsules	30 capsules	90 capsules

Opioids – Tramadol Extended-Release Products Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Tramadol 100 mg extended-release tablets and tramadol 100 mg extended-release capsules (ConZip, authorized generic)

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 at retail or 270 tablets or capsules at home delivery (300 mg/day).

Tramadol 200 mg extended-release tablets and tramadol 200 mg extended-release capsules (ConZip, authorized generic)

No overrides recommended.

Tramadol 300 mg extended-release tablets and tramadol 300 mg extended-release capsules (ConZip, authorized generic)
No overrides recommended.

REFERENCES

1. Tramadol hydrochloride extended-release tablets [prescribing information]. Cranbury, NJ: Sun; December 2023.
2. ConZip® extended-release capsules [prescribing information]. Alpharetta, GA: Vertical; December 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	07/17/2023
Annual Revision	Tramadol 150 mg extended-release capsules removed from the policy (obsolete).	07/18/2024

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