Drug Quantity Management – Per Rx
Opioids – Nucynta® (tapentadol immediate-release oral tablets)

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Product Identifier(s)

Effective 1/1/23 to 4/11/23: 110350

Effective 4/12/23: 35681

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

This Drug Quantity Management program has been developed to promote dose consolidation, prevent stockpiling and waste, and address potential order entry error of Nucynta. 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

Product	Strength and Form	Maximum Quantity per Rx
Nucynta® (tapentadol tablets)	50 mg tablets	181 tablets*
	75 mg tablets	181 tablets*
	100 mg tablets	181 tablets*

* 181 tablets is adequate for a 30-day supply at the maximum recommended dosing frequency of every 4 hours (6 doses per day) plus incorporation of the additional dose given 1 hour after the first, if needed, on the first day of treatment.

Criteria

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

Nucynta 50 mg

1. If the individual is titrating the dose of Nucynta utilizing the 50 mg Nucynta immediate-release tablets, approve a one-time override for a quantity sufficient for a 30-day supply.

2. If the individual is taking a dose that does not correspond to a commercially-available dosage form (e.g., requires multiple same strength tablets be used OR requires two or more strengths to be used), approve the quantity requested, not to exceed 600 mg/day (plus 700 mg/day for the first day of therapy) for a 30-day supply per dispensing.

Nucynta 75 mg

1. If the individual is titrating the dose of Nucynta utilizing the 75 mg Nucynta immediate-release tablets, approve a one-time override for a quantity sufficient for a 30-day supply.

2. If the individual is taking a dose that does not correspond to a commercially-available dosage form (e.g., the dose requires multiple same strength tablets be used OR requires two or more strengths to be used), approve the quantity requested, not to exceed 600 mg/day (plus 700 mg/day for the first day of therapy) for a 30-day supply per dispensing.

Nucynta 100 mg

No overrides recommended.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Nucynta is indicated for the management of **acute pain** in adults severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[1]

Dosing

The recommended initial dose of Nucynta is 50 mg to 100 mg every 4 to 6 hours depending upon the pain intensity.[1] On Day 1, the second dose may be administered as soon as 1 hour after the first dose, if adequate pain relief is *not* attained with the first dose. Subsequent dosing is 50 mg, 75 mg, or 100 mg every 4 to 6 hours and should be adjusted to maintain adequate analgesia with acceptable tolerability. Daily doses > 700 mg on the first day of therapy and > 600 mg on subsequent days have not been studied and are not recommended. Patients should continue to be assessed for the maintenance of pain control and the relative incidence of adverse reactions, as well as monitored for the development of addition, abuse or misuse. The lowest effective dosage for the shortest duration consistent with individual patient treatment goals should be used.

There is no dosage adjustment recommended for patients with mild or moderate renal impairment or mild hepatic impairment.[1] Use in patients with severe renal impairment or severe hepatic impairment is not recommended. Nucynta should be used with caution in patients with moderate hepatic impairment and should be initiated at 50 mg with the interval between doses no less than every 8 hours (maximum of 3 doses in 24 hours). Elderly patients are more likely to have decreased renal and hepatic function, therefore, consideration should be given to starting elderly patients with the lower range of recommended doses.

There are no standard opioid tapering schedules suitable for all patients.[1] For patients on Nucynta who are physically opioid-dependent, the taper should be initiated by a small enough increment (e.g., no greater than

10% to 25% of the total daily dose) to avoid withdrawal symptoms, and proceed with dose-lowering at an interval of every 2 to 4 weeks. Patients who have been taking opioids for briefer periods of time may tolerate a more rapid taper. It may be necessary to provide the patient with lower dosage strengths to accomplish a successful taper.

Availability
Nucynta is available in three tablet strengths: 50 mg, 75 mg, and 100 mg.[1]

References

1. Nucynta® [prescribing information]. Stoughton, MA: Collegium Pharmaceutical; March 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No changes to criteria.	04/22/2022