DRUG QUANTITY MANAGEMENT POLICY – PER RX

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

REVIEW DATE: 05/08/2024

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

Nucynta is indicated for the management of **acute pain** in patients ≥ 6 years of age weighing ≥ 40 kg with pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.[1]

Dosing

Adult 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.

Pediatric Dosing

Nucynta may be dosed in patients who are ≥ 6 years of age who weigh ≥ 40 kg, and are able to swallow tablets.[1] In pediatric patients, the duration of treatment should not exceed 3 days as the safety and effectiveness of longer treatment have not been established.

- For patients who weigh 40 kg to 59 kg, the recommended dose of Nucynta is 50 mg every 4 hours. Do not exceed a maximum single dose of 50 mg. If the 50 mg dose does not provide adequate analgesia, the dose should not be increased to 75 mg. The prescriber should consider a different Nucynta product that allows more flexible dosing.
- For patients who weigh 60 kg to 79 kg, the recommended initial dose of Nucynta is 50 mg every 4 hours. If needed to maintain adequate analgesia, the dose may be increased to 75 mg once every 4 hours if tolerability is acceptable. Do not exceed a maximum single dose of 75 mg. Do not increase the dose to 100 mg if the 75 mg dose does not provide adequate analgesia. Again, consider an alternative Nucynta product.
- For patients who weigh ≥ 80 kg, the recommended initial dose of Nucynta is 50 mg every 4 hours. The dose may be increased as needed to 75 mg every 4 hours to maintain adequate analgesia. If needed, the dose may be increased to 100 mg every 4 hours. Do not exceed a maximum single dose of 100 mg. The maximum daily dose is 7.5 mg/kg/day. Daily doses > 600 mg have not been studied in pediatric patients and are not recommended.

Dose reductions may be considered over time as acute pain decreases. 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.

Dosing in Renal or Hepatic Impairment

Adult Patients

There is no dosage adjustment recommended for adults 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.

Pediatric Patients

Use of Nucynta in pediatric patients with any renal or hepatic impairment has not been studied and is not recommended.[1]

Tapering of Nucynta

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]

POLICY STATEMENT

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, unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Nucynta® (tapentadol tablets)	50 mg tablets	181 tablets*	543 tablets
	75 mg tablets	181 tablets*	543 tablets
	100 mg tablets	181 tablets*	543 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.

Opioids – Nucynta 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

Nucynta 50 mg tablets

1. If the patient is ≥ 18 years of age and 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 at retail or a 90-day supply at home delivery.

2. If the patient is ≥ 18 years of age and 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 per day (plus 700 mg per day for the first day of therapy) for a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Nucynta 75 mg tablets

1. If the patient is ≥ 18 years of age and 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 at retail or a 90-day supply at home delivery.

2. If the patient is ≥ 18 years of age and 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 per day (plus 700 mg per day for the first day of therapy) for a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery.

Nucynta 100 mg tablets
No overrides recommended.

REFERENCES

1. Nucynta® [prescribing information]. Stoughton, MA: Collegium; December 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes. Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.	04/24/2023
Annual Revision	**Nucynta 50 mg and 75 mg tablets:** Override criteria were updated to apply to a patient ≥ 18 years of age only.	05/08/2024