



## Drug Quantity Management – Per Rx Tapentadol immediate-release oral tablets (Nucynta®) Dispensing Limit

### Table of Contents

National Formulary Medical Necessity .....	1
Conditions Not Covered.....	2
References .....	2
Revision History .....	2

### Product Identifier(s)

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

#### Nucynta 50 mg, 75 mg, 100 mg

Maximum quantity per RX = 181 tablets

Nucynta is available in three tablet strengths (50 mg, 75 mg, and 100 mg). Nucynta is indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults. Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals. Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic experience, and risk factors for addiction, abuse and misuse. The recommended initial dosing of Nucynta is 50 mg to 100 mg every 4 to 6 hours depending upon the pain intensity. On the first day of dosing, the second dose may be administered as soon as one 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 greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended. Continually reevaluate patients to assess the maintenance of pain control and the relative incidence of adverse reactions, as well as monitoring for the development of addiction, abuse or misuse. There is no dosage adjustment recommended for patients with mild or moderate renal impairment or mild hepatic impairment. The 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.

Hence, 181 tablets are adequate for a 30-day supply at maximum recommended dosing frequency of every 4 hours (6 doses per day) plus incorporating the additional dose given one hour after the first, if needed, on the first day of treatment. Exceptions are allowed in certain situations

#### Criteria

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

All approvals are provided for 12 months in duration unless otherwise noted below.

#### **Nucynta 50 mg & 75 mg**

1. For individuals titrating the Nucynta dose utilizing the 50 mg or 75 mg tapentadol immediate-release strength, approve the quantity requested to allow for a 30-day supply per dispensing.
2. Exceptions can be made when an individual is taking a dose that does not correspond to a commercially-available dosage form [that is, the dose requires multiple same strength tablets be used OR would otherwise require two (or more) strengths to be used]. For example, an individual is not able to obtain adequate pain relief at a daily dose of 450 mg per day and needs to be increased to 525 mg per day. Approve the quantity requested, not to exceed 600 mg/day (plus 700 mg/day for the first day of therapy).

#### **Nucynta 100 mg**

1. No overrides recommended.

### **Conditions Not Covered**

Any other exception is considered not medically necessary.

### **References**

1. Nucynta® [prescribing information]. Stoughton, MA: Collegium Pharmaceutical, Inc.; October 2019.

### **Revision History**

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Reviewed by Clinical Specialists. No changes to criteria.	03/27/2020

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Cigna Behavioral Health, Inc., Cigna Health Management, Inc., QualCare, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2021 Cigna.