Policies Repository

Independence Blue Cross

Policy Title	Tapentadol (Nucynta™)
Policy Number	FS.CLIN.23

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy

Tapentadol (Nucynta™) is indicated for the relief of moderate to severe acute pain in patients 18 years of age or older.

The use of tapentadol (Nucynta™) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description

Tapentadol (Nucynta™) is a centrally acting synthetic analgesic. The exact mechanism of action is unknown but it is thought to be due to mu-opioid agonist activity and the inhibition of norepinephrine reuptake. Currently there are several well established formulary alternatives available for the treatment of pain.

Policy Guideline Inclusion

Tapentadol (Nucynta™)is approved in patients 18

years of age and older when the following inclusion criteria is met:

- Documentation of a trial and failure of or contraindication/intolerance/allergy to two of the following agents:
  - Oxycodone IR
  - Hydromorphone
  - Morphine sulfate IR

Policy Guideline Exclusion

Tapentadol (Nucynta™)is denied when **any** of the following exclusion criteria are present:

- Age less than 18 years
- No documentation of a trial and failure of or contraindication/intolerance/allergy to two of the following agents:
  - Oxycodone IR
  - Hydromorphone
  - Morphine sulfate IR

Policy List of Applicable Drugs

Brand Name	Generic Name
Nucynta	Tapentadol

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Daniels S, Casson E, Stegmann JU, et al. A Randomized, double-blind placebo controlled phase 3 study of the relative efficacy and tolerability of tapentadol IR and oxycodone IR for acute pain. Current Medical Research and Opinion. 2009;25:1551-1561.

Facts and Comparisons website [Nucynta]. Available at www.factsandcomparisons.com. Accessed December 1, 2010.

Hartrick C, Van Hove I, Stegman JU. Efficacy and tolerability of Tapentadol IR and Oxycodone IR in patients awaiting primary joint replacement surgery for end-stage joint disease: A 10 day, Phase III randomized, double-blind, active and placebo controlled study. Clin Ther. 2009:31;260-271.

Micromedex website [Nucynta]. Available at www.micromedex.com. Accessed December 1, 2010.

Nucynta [package insert]. Raritan, NJ: PriCara; 2010.

Policy Link to Related Policies

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