

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI Number:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP
2

Diagnosis	<input type="checkbox"/> Acute pain, moderate to severe	<input type="checkbox"/> Other (please state): _____ _____ _____
Clinical Consideration	<input type="checkbox"/> Patient requires greater than 60 tablets for this acute pain episode (please state reason): _____ <input type="checkbox"/> Patient requires additional quantity (not to exceed a 10 day supply) for a different acute pain episode (documentation required).	<input type="checkbox"/> Patient is not a candidate for other immediate-release analgesics (please state reason): _____ _____ _____
Physician Specialty	Please state specialty: _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Nucynta [®] (tapentadol) Strength _____ Sig _____ Qty _____ Refills _____	
	We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.	

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

 Prescriber Signature Date

STEP
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
 970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

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RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Nucynta (tapentadol)

CLASSIFICATION

- Opioid analgesic

DESCRIPTION

- Tapentadol exerts analgesic activity by binding to mu-opioid receptors and inhibiting norepinephrine reuptake and is indicated for the treatment of moderate to severe acute pain in adult patients
- Pivotal trials of tapentadol included two Phase III trials of a 72 hour duration and one phase III trial of a 10 day duration
- Tapentadol is considered to have equivalent pain relieving efficacy to immediate-release oxycodone 15mg (based on established non-inferiority in a phase III trial)
- Due to its mechanism of action, tapentadol may cause less GI disturbance (ie. Constipation) less conventional opioid analgesics

FORMULARY COVERAGE

Prior authorization:	Not required for up to 60 tablets per 30 day period; Required if quantity exceeds 60 tablets within that 30 day period.
Good Health Formulary:	T2
Commercial Formulary:	T2
Medicare Part D coverage:	T3

COVERAGE CRITERIA

Nucynta (tapentadol) meets the definition of **medical necessity** for the following:

- Acute pain of moderate to severe intensity
- Duration of therapy 10 days or less
- Documentation must be provided stating reason patient is not a candidate for other immediate-release analgesics
- Documentation required if patient requires quantity exceeding 60 tablets in a 30 day period for the same acute pain or a different acute pain episode within that 30 day period.

Nucynta (tapentadol) is considered **experimental** for the following:

- Chronic pain control

Required Provider Specialty:

- Provider experienced in acute pain management

DOSAGE/ADMINISTRATION:

Adult dosing (safety and efficacy has not been established in pediatric patients):

- Moderate to severe pain, acute: (initial) 50 mg, 75 mg, or 100 mg ORALLY every 4-6 hr; may give a second dose 1 hr after the first dose if necessary; MAX dose of 700 mg/day on the first day of therapy.
- Moderate to severe pain, acute: (maintenance) 50 mg, 75 mg, or 100 mg ORALLY every 4-6 hr; individualize dose based on pain intensity; MAX dose of 600 mg/day.

Dose adjustments:

- Mild or moderate renal impairment: no dosage adjustment necessary
- Severe renal impairment: use not recommended
- Mild hepatic impairment: no dosage adjustment necessary
- Moderate hepatic impairment: initial dose of 50 mg ORALLY every 8 hr or longer; MAX of 3 doses/24 hr
- Severe hepatic impairment: use not recommended

PRECAUTIONS:

- Contraindications:
 - Concomitant or recent (within 14 days) MAOI use
 - Hypercapnia, severe or acute bronchial asthma, or significant respiratory depression, in unmonitored settings or without resuscitative equipment
 - Paralytic ileus, known or suspected
- Abrupt discontinuation; may result in severe withdrawal symptoms
- Abuse potential; risk of addiction, misuse, or diversion
- Biliary tract disease, including acute pancreatitis; may cause spasm of the sphincter of Oddi
- Concomitant use with CNS depressants (e.g. tranquilizers, sedatives, hypnotics, alcohol), other mu-opioid agonist analgesics, general anesthetics, or phenothiazines
- Concomitant use with serotonergic drugs (eg, SSRIs, serotonin norepinephrine reuptake inhibitors, MAOIs, tricyclic antidepressants, triptans)
- Head injury, intracranial lesions, or preexisting increased intracranial pressure; increased risk of raised cerebrospinal fluid pressure with opioid analgesics
- Hepatic impairment, moderate; dose reduction recommended
- Hepatic impairment, severe; use not recommended
- Respiratory depression may occur; increased risk in patients who are elderly or debilitated or those with conditions accompanied by pulmonary disease, hypercapnia, or decreased respiratory drive (e.g. asthma, chronic obstructive pulmonary disease, cor pulmonale, severe obesity, sleep apnea syndrome, myxedema, kyphoscoliosis, CNS depression, or coma)
- Seizure disorder or any condition increasing the risk of seizures

Billing/Coding information

- n/a

COST

AWP (March 2010):

- 50 mg (30): \$65.10
- 75 mg (30): \$76.20
- 100 mg (30): \$101.70

AWP (February 2012):

- 50 mg (30): \$74.40
- 75 mg (30): \$87.35
- 100 mg (30): \$116.31

COMMITTEE APPROVAL:

- July 29, 2009 - Approved
- March 24, 2010 - Quantity limit review changed to 45 per 31 day supply for all lines of business
- October 5, 2011 – Quantity limit changed to 60 per 31 day supply for all lines of business

GUIDELINE UPDATE INFORMATION:

03/2010	Policy creation

REFERENCES:

- DRUGDEX®, accessed 04/06/2010.
- Product Information: NUCYNTA™ immediate-release oral tablets, tapentadol immediate-release oral tablets. PriCara, Raritan, NJ, 2009.