

Clinical Edit Criteria Proposal

Drug/Drug Class: Nubain® Clinical Edit

Date: May 2, 2007

Prepared for:

Prepared by: Missouri Medicaid

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Nubain® (nalbuphine).

Why was this Issue Selected:

Nubain injectable is a branded drug product containing nalbuphine HCl. It is a synthetic opioid agonist-antagonist analgesic of the phenanthrene series indicated for the treatment moderate to severe pain both before and after surgery, and during childbirth. Nubain is a sterile solution used for subcutaneous, intramuscular, or intravenous injection. Unlike most opioid agonist-antagonist analgesics, Nubain is not a scheduled controlled substance. It can, however, be used and abused in a manner similar to other opioid agonists. Opioids are a class of medications that act on common receptors and are natural derivatives of morphine. Nalbuphine is chemically related to naloxone and the potent opioid analgesic, oxymorphone. They are some of the most potent medications available for treatment of most types of severe pain.

	Drug	Claims	Expense
Program-specific information:	• Nubain 10mg/ml	1050	\$8057.21
	• Nubain 20mg/ml	<u>4093</u>	<u>\$470,418.53</u>
	<i>Totals</i>	5143	\$478,475.74
<i>Nov05 – Oct 06</i>			

Setting & Population: Patients 18 years of age and older

Type of Criteria:

Increased risk of ADE **Non-Preferred Agent**

Appropriate Indications

Data Sources: Only administrative databases

Databases + Prescriber-supplied

Setting & Population

- Drug for review: Nubain® (nalbuphine)
- Age range: Patients 18 years of age and older
- Gender: Male and female

Approval Criteria

- Appropriate diagnosis – (may be subject to clinical review)
 - Cancer
 - Chronic Non-Malignant Pain (CNMP)

Approval Procedures

Condition	Submitted ICD-9 Diagnoses*	Inferred Drugs	Date Range	Client Approval (Initials)
Cancer	140 – 208	Antineoplastics	2 years	
Chronic Non-Malignant Pain (CNMP)	282 - 355 710 - 733.7	NA	1 year	
	NA	Non-opioid analgesics	90 days	

Denial Criteria

- Dosing schedule exceeding 160mg/day
- Lack of appropriate diagnoses
- Claims for patients under 18 years of age (require clinical consultant review)

References

1. Facts and Comparisons, pg. 807 - 813. 2006.
2. USPDI, Micromedex, 2006.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2006.

