Clinical Edit Criteria Proposal

Drug/Drug Class: Nubain® Clinical Edit
Date: May 2, 2007
Prepared for: Missouri Medicaid

☑ New Criteria ☐ Revision of Existing Criteria

Executive Summary

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

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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nubain 10mg/ml</td>
<td>1050</td>
<td>$8057.21</td>
</tr>
<tr>
<td>Nubain 20mg/ml</td>
<td>4093</td>
<td>$470,418.53</td>
</tr>
<tr>
<td>Totals</td>
<td>5143</td>
<td>$478,475.74</td>
</tr>
</tbody>
</table>

Nov05–Oct 06

Setting & Population: Patients 18 years of age and older

Type of Criteria: ☑ Increased risk of ADE ☐ Non-Preferred Agent
☒ Appropriate Indications ☐
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)
  o Cancer
  o Chronic Non-Malignant Pain (CNMP)

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

Denial Criteria

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

References

2. USPDI, Micromedex, 2006.