Clinical Edit Criteria Proposal

Drug/Drug Class: Butorphanol Clinical Edit
Date: June 29, 2011
Prepared for: MO HealthNet
Prepared by: MO HealthNet

☐ New Criteria  ☒ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate and prudent use of butorphanol within the MO HealthNet Pharmacy program.

Butorphanol is a morphine-like synthetic opioid analgesic. It is most closely structurally related to levorphanol and is available only in injectable and intranasal spray formulations. Butorphanol exhibits partial agonist and antagonist activity at the μ opioid receptor and agonist activity at the κ opioid receptor. Stimulation of these receptors on central nervous system neurons causes an intracellular inhibition of adenylate cyclase, closing of influx membrane calcium channels, and opening of membrane potassium channels. This leads to hyperpolarization of the cell membrane potential and suppression of action potential transmission of ascending pain pathways. κ-agonism can cause dysphoria at therapeutic or supertherapeutic doses. This gives butorphanol a lower potential for abuse than other opioid drugs. Butorphanol has FDA approved indications for: pain, labor pain, anesthesia maintenance in balanced anesthesia as an adjunct and premedication for procedures. It is often used in the treatment of migraines but this is not an FDA approved indication. On a mg-to-mg basis, Butorphanol is 5 to 8 times more potent as an analgesic than morphine and 30 to 50 times more potent than meperidine.

Why was this Issue Selected:

Setting & Population: Patients 18 years of age and older

Type of Criteria: ☐ Increased risk of ADE  ☐ Non-Preferred Agent
☐ Appropriate Indications  ☐ Other:

Data Sources: ☐ Only administrative databases  ☒ Databases + Prescriber-supplied
Program-Specific Information:

- **Drug Claims Expense**
  - Butorphanol Nasal Spray: 1,188 $51,547.00
  - Butorphanol Injection: 50 $854.00

  **Totals**: 1,238 $52,401.00


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**Setting & Population**

- Age range: Patients 18 years of age or older
- Gender: males and females

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**Approval Criteria**

- Appropriate diagnosis (see diagnosis table – Appendix A)
- Doses not exceeding recommended maximum doses.

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### Approval Diagnoses (Appendix A)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Submitted ICD-9 Diagnoses</th>
<th>Inferred Drugs**</th>
<th>Date Range</th>
<th>Client Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>140 – 208</td>
<td>NA</td>
<td>2 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td>Antineoplastics</td>
<td>12 months</td>
<td></td>
</tr>
<tr>
<td>Chronic nonmalignant 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>Non-opioid analgesics</td>
<td>90 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migraine</td>
<td>625.4</td>
<td>5-HT1 Serotonin Receptor Agonists</td>
<td>1 year</td>
<td></td>
</tr>
<tr>
<td></td>
<td>346.0 – 346.9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*see Appendix B for product-specific list of Inferred Drugs*

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**Denial Criteria**

- Use of more than six canisters per 30 days
  - 15ml per month
  - Patients under 18 years of age

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**Required Documentation**

<table>
<thead>
<tr>
<th>Laboratory results:</th>
<th>Progress notes:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

**MedWatch form:**

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Clinical Edit Criteria Proposal 2
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Disposition of Edit

- **Denial:** Edit 682 “Clinical Edit”

References