Clinical Edit Criteria Proposal

Drug/Drug Class: Combunox® Tablets Clinical Edit
Date: November 16, 2005
Prepared for: Missouri Medicaid

☑ New Criteria  ☐ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Combunox® (oxycodone and ibuprofen combination tablets).

Combunox® is a branded drug product containing oxycodone and ibuprofen that is indicated for short-term relief of acute moderate to severe pain. Each Combunox tablet contains 5mg Oxycodone and 400mg Ibuprofen. The side effect profile for this product, including risk of abuse, gastrointestinal bleed, dizziness, and nausea, mirror the side effect profile for each individual ingredient.

The combination product is 30% more expensive than the MAC’d individual products filled separately.

<table>
<thead>
<tr>
<th>Program-specific information:</th>
<th>Drug</th>
<th>Dosage Form</th>
<th>Cost per Dosage Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combunox®</td>
<td></td>
<td>5mg–400mg tab</td>
<td>$1.5000 AWP</td>
</tr>
</tbody>
</table>

Setting & Population: All patients.

Type of Criteria: ☐ Increased risk of ADE  ☑ Non-Preferred Agent  ☑ Appropriate Indications
Setting & Population

- Drug for review: Combunox® (oxycodone and ibuprofen tablets)
- Age range: All ages
- Gender: Male and female

Approval Criteria

Patient is unable to take generic tablet due to:

- Documented ADE/ADR to individual ingredient generic tablet therapy, or
- Trial and failure of individual oxycodone and ibuprofen tablet therapy in the past 45 days.

Denial Criteria

- Failure to meet approval criteria.

References

2. USPDI, Micromedex, 2005.