Clinical Edit Criteria Proposal

Drug/Drug Class: Short Acting Opioids Clinical Edit
Date: March 14, 2017 (previously updated 4/17/2013)
Prepared for: MO HealthNet
Prepared by:

☐ New Criteria ☒ Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of short-acting opioids.

Short-acting opioids (i.e. immediate- or regular-release oral morphine, hydromorphone, oxycodone, and codeine) are indicated for short-term relief of moderate to severe pain on an “as needed” basis. These medications are often used in conjunction with a long acting opioid to help relieve breakthrough pain. Although highly effective for pain control, these substances carry with them the potential for harm from adverse drug events and/or overdose. Opioid drugs also have substantial misuse liability and are often implicated among persons who have developed a substance misuse disorder. Concomitant use of benzodiazepines significantly increases the risk of harm from opioids.

Why was this Issue Selected:

In March 2016, the Centers for Disease Control and Prevention (CDC) released their Guideline for Prescribing Opioids for Chronic Pain. Although these guidelines focus on managing chronic pain, they emphasize the need for prescribers to be more judicious in the initiation and continuation, selection, and monitoring of opioids and other medications for acute pain. As part of the efforts to protect patients from the possible adverse effects of opioid medications and their subsequent diversion and misuse, MO HealthNet Division will continue to clinically edit the use of these controlled substances. Preventative activities include limiting prescription amounts and frequency of dispensing. Limiting or reducing “morphine-equivalent-doses” helps avoid harmful effects of opioids and promotes patient safety.

Setting & Population: All patients
**Type of Criteria:**
- Increased risk of ADE
- Appropriate Indications
- Non-Preferred Agent
- Other:

**Data Sources:**
- Only administrative databases
- Databases + Prescriber-supplied

**Program-Specific Information:**
- Short-Acting Opioid Analgesics - See Appendix A and Appendix B

### Setting & Population
- Age range: All patients
- Claims for patients under 18 years of age are subject to clinical review.
- Gender: males and females

### Approval Criteria

<table>
<thead>
<tr>
<th>Condition</th>
<th>Inferred Drugs</th>
<th>Date Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>NA</td>
<td>2 years</td>
</tr>
<tr>
<td></td>
<td>Antineoplastics</td>
<td>12 months</td>
</tr>
<tr>
<td>Chronic nonmalignant pain (CNMP)</td>
<td>NA</td>
<td>2 years</td>
</tr>
<tr>
<td></td>
<td>Non-opioid analgesics</td>
<td>90 days</td>
</tr>
<tr>
<td>Acute Pain</td>
<td>--</td>
<td>90 days</td>
</tr>
</tbody>
</table>

- Appropriate diagnoses – (may be subject to clinical review)
  - Cancer
  - Chronic Non-Malignant Pain (CNMP)
  - Acute Pain
- Documented compliance on current therapy regimen (Subject to Clinical Consultant Review)
- **Claims not exceeding quantity limitations established in Appendix A for adults and Appendix B for patients under age 18 years**
- First claim for opioid product in past 90 days, meets dose and age requirements, and is for ≤ 7 day supply
- Agent must be appropriate for age
Denial Criteria

- Lack of appropriate diagnoses
- **First claim for opioid product in the past 90 days and for > 7 days**
- Daily dose exceeds maximum established daily dose for an agent
- **On Refill, must have exhausted 85% of previous day’s supply**
- Therapy will be denied if no approval criteria are met
  - Patient with claim for Suboxone (brand or generic) or Subutex within the last 45 days

Required Documentation

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

<table>
<thead>
<tr>
<th>MedWatch form:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Disposition of Edit

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

References

1. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65 (March 15, 2016); (No. RR-1):1–49. DOI: [http://dx.doi.org/10.15585/mmwr.rr6501e1](http://dx.doi.org/10.15585/mmwr.rr6501e1)
4. USPDI, Micromedex Online; 2017.
### Adult Dosing Chart

<table>
<thead>
<tr>
<th>Short Acting Opioid Drugs</th>
<th>Maximum # of Units per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine Sulfate 15 mg Oral tablet (360 mg)</td>
<td>24 tablets</td>
</tr>
<tr>
<td>Codeine Sulfate 15 mg / 2.5 mL Solution (360 mg)</td>
<td>60 mL</td>
</tr>
<tr>
<td>Codeine Sulfate 30 mg Oral tablet (360 mg)</td>
<td>12 tablets</td>
</tr>
<tr>
<td>Codeine Sulfate 30 mg / 5 mL Solution (360 mg)</td>
<td>60 mL</td>
</tr>
<tr>
<td>Codeine Sulfate 30 mg / 5 mL Solution (360 mg)</td>
<td>60 mL</td>
</tr>
<tr>
<td>Codeine Sulfate 60 mg Oral tablet (360 mg)</td>
<td>6 tablets</td>
</tr>
<tr>
<td><strong>Hydromorphone Hydrochloride 1 mg/mL Solution (40 mg)</strong></td>
<td><strong>40 mL</strong></td>
</tr>
<tr>
<td><strong>Hydromorphone Hydrochloride 2 mg Tablet (40 mg)</strong></td>
<td><strong>20 tablets</strong></td>
</tr>
<tr>
<td><strong>Hydromorphone Hydrochloride 4 mg Tablet (40 mg)</strong></td>
<td><strong>10 tablets</strong></td>
</tr>
<tr>
<td><strong>Hydromorphone Hydrochloride 8 mg Tablet (40 mg)</strong></td>
<td><strong>5 tablets</strong></td>
</tr>
<tr>
<td>Hydromorphone Hydrochloride 3 mg Rectal Suppository</td>
<td>4 suppositories</td>
</tr>
<tr>
<td>Levorphanol 2 mg Tablet (24 mg)</td>
<td>12 tablets</td>
</tr>
<tr>
<td>Meperidine Hydrochloride 50 mg/5 mL Oral solution</td>
<td>60 mL</td>
</tr>
<tr>
<td>Meperidine Hydrochloride 50 mg Oral tablet (600 mg)</td>
<td>12 tablets</td>
</tr>
<tr>
<td>Meperidine Hydrochloride 100 mg Oral tablet (600 mg)</td>
<td>6 tablets</td>
</tr>
<tr>
<td>Methadone Hydrochloride 5 mg/5 mL Solution (120 mg)</td>
<td>120 mL</td>
</tr>
<tr>
<td>Methadone Hydrochloride 10 mg/5 mL Solution (120 mg)</td>
<td>60 mL</td>
</tr>
<tr>
<td>Methadone Hydrochloride 10 mg/mL Concentrated Soln (120 mg)</td>
<td>12 mL</td>
</tr>
<tr>
<td>Methadone Hydrochloride 5 mg Tablet (120 mg)</td>
<td>24 tablets</td>
</tr>
<tr>
<td>Methadone Hydrochloride 10 mg Tablet (120 mg)</td>
<td>12 tablets</td>
</tr>
<tr>
<td>Methadone Hydrochloride 40 mg Orally Disintegrating Tablet (120 mg)</td>
<td>3 tablets</td>
</tr>
<tr>
<td><strong>Methadone Hydrochloride 10 mg/5 mL Solution (120 mg)</strong></td>
<td><strong>60 mL</strong></td>
</tr>
<tr>
<td>Short Acting Opioid Drugs</td>
<td>Maximum # of Units per Day</td>
</tr>
<tr>
<td>------------------------------------------------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Morphine Sulfate 20 mg/5 mL Solution (120 mg)</td>
<td>30 mL</td>
</tr>
<tr>
<td>Morphine Sulfate 100 mg/5 mL Solution (120 mg)</td>
<td>6 mL</td>
</tr>
<tr>
<td>Morphine Sulfate 15 mg Immediate-Release Tablet (120 mg)</td>
<td>8 tablets</td>
</tr>
<tr>
<td>Morphine Sulfate 30 mg Immediate-Release Tablet (120 mg)</td>
<td>4 tablets</td>
</tr>
<tr>
<td>Morphine Sulfate 5 mg Rectal Suppository (30 mg)</td>
<td>6 suppositories</td>
</tr>
<tr>
<td>Morphine Sulfate 10 mg Rectal Suppository (60 mg)</td>
<td>6 suppositories</td>
</tr>
<tr>
<td>Morphine Sulfate 20 mg Rectal Suppository (120 mg)</td>
<td>6 suppositories</td>
</tr>
<tr>
<td>Morphine Sulfate 30 mg Rectal Suppository (120 mg)</td>
<td>4 suppositories</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 5 mg/5 mL Oral solution (120 mg)</td>
<td>120 mL</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 20 mg/mL Oral solution (120 mg)</td>
<td>6 mL</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 5 mg Oral capsule (120 mg)</td>
<td>24 Capsules</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 5 mg Oral tablet (120 mg)</td>
<td>24 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 5 mg Oral tablet (120 mg)</td>
<td>24 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 7.5 mg Oral tablet (120 mg)</td>
<td>16 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 10 mg Oral tablet (120 mg)</td>
<td>12 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 15 mg Oral tablet (120 mg)</td>
<td>8 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 20 mg Oral tablet (120 mg)</td>
<td>6 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 30 mg Oral tablet (120 mg)</td>
<td>4 tablets</td>
</tr>
<tr>
<td>Oxymorphone Hydrochloride 5 mg Oral tablet (40 mg)</td>
<td>8 tablets</td>
</tr>
<tr>
<td>Oxymorphone Hydrochloride 10 mg Oral tablet (40 mg)</td>
<td>4 tablets</td>
</tr>
</tbody>
</table>

**OPIOID AGONIST-ANTAGONIST ANALGESICS**

| Butorphanol Tartrate 10 mg/mL Nasal Spray | 0.5 mL |

*Buprenorphine Hydrochloride Sublingual tablets are not included in this edit because they are included in the Opiate-Dependence Step Therapy Edit*
## Pediatric Dosing Chart

<table>
<thead>
<tr>
<th>Short Acting Opioid Drugs</th>
<th>Children Maximum Daily Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine Sulfate 15 mg Oral tablet</td>
<td>24 tablets</td>
</tr>
<tr>
<td>Codeine Sulfate 30 mg Oral tablet</td>
<td>12 tablets</td>
</tr>
<tr>
<td>Codeine Sulfate 60 mg Oral tablet</td>
<td>6 tablets</td>
</tr>
<tr>
<td>Hydromorphone Hydrochloride 1 mg/mL Solution</td>
<td>12 tablets</td>
</tr>
<tr>
<td>Hydromorphone Hydrochloride 2 mg Tablet</td>
<td>6 tablets</td>
</tr>
<tr>
<td>Morphine Sulfate 10 mg/5 mL Solution</td>
<td>30ml</td>
</tr>
<tr>
<td>Morphine Sulfate 20 mg/5 mL Solution</td>
<td>15ml</td>
</tr>
<tr>
<td>Morphine Sulfate 100 mg/5 mL Solution</td>
<td>4ml</td>
</tr>
<tr>
<td>Morphine Sulfate 15 mg Immediate-Release Tablet</td>
<td>2 tablets</td>
</tr>
<tr>
<td>Morphine Sulfate 5 mg Rectal Suppository</td>
<td>6 suppositories</td>
</tr>
<tr>
<td>Morphine Sulfate 10 mg Rectal Suppository</td>
<td>6 suppositories</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 5 mg/5 mL Oral solution</td>
<td>30ml</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 20 mg/mL Oral solution</td>
<td>1.5ml</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 5 mg Oral capsule</td>
<td>6 capsules</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 5 mg Oral tablet</td>
<td>6 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 10 mg Oral tablet</td>
<td>3 tablets</td>
</tr>
<tr>
<td>Oxycodone Hydrochloride 15 mg Oral tablet</td>
<td>2 tablets</td>
</tr>
<tr>
<td>Pentazocine Hydrochloride 50 mg, Naloxone 0.5 mg Tablet</td>
<td>12 tablets</td>
</tr>
</tbody>
</table>
Appendix C
Diagnosis codes used to identify positive history of acute pain in the past 90 days

Appendix D
GCNs used to identify history of claim for Suboxone® or Subutex® (Brand or Generic) in the past 45 days

Appendix E
Diagnosis codes used to identify positive history of cancer in the past 2 years

Appendix F
GCNs used to infer diagnosis of cancer in the past 1 year

Appendix G
Diagnosis codes used to identify positive history of CNMP in the past 2 years

Appendix H
GCNs used to identify history of opioids in past 90 days (Drug Subject 209248)