Prior Authorization Approval Criteria

Kadian (Morphine Sulfate Extended Release Capsules)

Generic name:  Morphine Sulfate Extended Release Capsules
Brand name:  Kadian
Medication class:  narcotic, opioid
FDA-approved uses:  Indicated for the management of moderate to severe pain when a continuous around the clock opioid analgesic is needed for an extended period of time
Available dosage forms:  10 mg, 20mg, 30mg, 50mg, 60mg, 80mg, 100mg, and 200mg capsules.
Usual dose:  May be administered once or twice a day starting at 10mg or 20mg in opioid naïve patients.

Approximate cost:  (based on AWP 2010)

<table>
<thead>
<tr>
<th>Strength</th>
<th>cost/pill</th>
<th>cost/30 pills</th>
</tr>
</thead>
<tbody>
<tr>
<td>10mg</td>
<td>3.87</td>
<td>116.02</td>
</tr>
<tr>
<td>20mg</td>
<td>4.66</td>
<td>139.72</td>
</tr>
<tr>
<td>30mg</td>
<td>5.07</td>
<td>151.96</td>
</tr>
<tr>
<td>40mg</td>
<td>8.46</td>
<td>253.94</td>
</tr>
<tr>
<td>60mg</td>
<td>10.13</td>
<td>303.91</td>
</tr>
<tr>
<td>80mg</td>
<td>12.38</td>
<td>371.44</td>
</tr>
<tr>
<td>100mg</td>
<td>16.93</td>
<td>507.88</td>
</tr>
<tr>
<td>200mg</td>
<td>33.86</td>
<td>1015.76</td>
</tr>
</tbody>
</table>

Duration of therapy:  To be determined based on patients needs.

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Clinically documented acute or chronic pain.
- The 100mg and 200mg capsules are for opioid tolerant patients.
- Must have cancer pain.
  - Must have tried and failed or was intolerant to long acting morphine sulfate, methadone, or fentanyl patches.
- Or
- Must have non-cancer pain.
  - Must have functional impairment
  - Must have clear treatment goals
  - Must have failed or was intolerant to at least 2 non-opioid therapies such as:
    - APAP/NSAIDs/Cox-2 agent
    - Anticonvulsants
    - Muscle relaxants
    - Antidepressants
    - Corticosteroids
    - Topical analgesics
Must have tried and failed or was intolerant to long acting morphine sulfate, methadone, or fentanyl patches.

Criteria for continuation of therapy:
- Patient’s pain has been recently re-assessed and there continues to be a medical need for the medication.
- Patient is tolerating and responding to medication.
- Patient has improved functioning and is meeting treatment goals.
- Patient is not exhibiting addictive behaviors and is not being treated for substance abuse.

Contraindication:
- Known hypersensitivity to morphine, morphine salts or any of the capsule components.
- In any situation where opioids are contraindicated such as respiratory depression and in patients with severe bronchial asthma or hypercarbia.
- In any patient with a known or suspected paralytic ileus.

Not approved if:
- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of Kadian
- Patient has known past or current substance abuse potential
- Patient has not tried alternative FCHP preferred agents
- Patient is being treated for substance abuse (including treatment with buprenorphine or buprenorphine-naloxone).

FCHP Pharmacy and Therapeutics Committee approval: ____________________________

Date: ________________

Adopted: 03/10/10
Revised 12/18/12