



## Prior Authorization Approval Criteria

### *Embeda (Morphine/Naltrexone Extended Release Capsules)*

**Generic name:** Morphine/Naltrexone Extended Release Capsules

**Brand name:** Embeda

**Medication class:** narcotic, opioid

**FDA-approved uses:** Indicated for the management of chronic, moderate to severe pain when a continuous around the clock opioid analgesic is needed for an extended period of time

**Available dosage forms:** **Capsules - morphine/naltrexone:** 20mg/0.8mg, 30mg/1.2mg, 50mg/2mg, 60mg/2.4mg, 80mg/3.2mg, and 100mg/4mg

**Usual dose:** May be administered once or twice a day starting at 10mg or 20mg in opioid naïve patients. In patients taking other oral morphine formulations, the same total daily morphine dose can be administered as Embeda once or divided twice daily.

<b>Approximate cost:</b> (based on AWP 2010)	Strength	cost/pill	cost/30 pills
	20mg	4.72	141.60
	30mg	5.13	153.90
	40mg	8.57	257.10
	60mg	10.26	307.80
	80mg	13.67	410.10
	100mg	17.15	514.50

**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.
- Failed/intolerant to at least one FCHP preferred opioids including long acting morphine sulfate (Avinza, MS Contin, Oramorph SR), or fentanyl patches.
- Clinically documented chronic pain.
- Patient must have a history of drug abuse or a history of tampering with substances for abuse.

**Contraindication:**

- Known hypersensitivity to morphine, morphine salts, naltrexone, or in any situation where opioids are contraindicated.
- 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 Embeda.

- Patient has not tried alternative FCHP preferred agents
- Patient is on Suboxone or Subutex

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 06/09/10