

# MTF Formulary Management for Long Acting High Potency Narcotic Analgesics

Defense Health Agency Pharmacy Operations Division

Updated August 2015

## Bottom Line

- All long acting high potency narcotic analgesics have established efficacy in the short-term treatment of moderate to severe chronic pain.
- There is insufficient evidence to suggest that one long acting narcotic is superior to another in terms of efficacy or safety.
- All the long acting high potency narcotic analgesics are on the Uniform Formulary.
- The BCF selection remains generic sustained release morphine sulfate.

**Uniform Formulary Decision:** The Director, DHA, approved the recommendations from the August 2015 DoD P&T Committee meeting on October 30, 2015.

Uniform Formulary (UF) drugs		Nonformulary (NF) drugs
BCF drugs – MTFs <u>must</u> have on formulary	MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
<ul style="list-style-type: none"> <li>• Morphine Sulfate (MS Contin, generics)</li> </ul>	<ul style="list-style-type: none"> <li>• Fentanyl transdermal system (Duragesic, generics)</li> <li>• Hydrocodone ER (Hysingla ER, Zohydro ER)</li> <li>• Hydromorphone ER (Exalgo, generics)</li> <li>• Morphine ER (Avinza, Kadian, generics)</li> <li>• Morphine ER/naltrexone (Embeda)</li> <li>• Oxycodone CR (Oxycontin)</li> <li>• Oxymorphone ER (Opana ER)</li> <li>• Tapentadol ER (Nucynta ER)</li> </ul>	<ul style="list-style-type: none"> <li>• None</li> </ul>

## Clinical Summary

- Current guidelines do not state a preference for the use of one long acting (LA), high potency narcotic analgesic over another for the use in moderate to severe pain.
- The conclusions from the February 2007 review are still applicable, with no new evidence regarding the comparative effectiveness of the LA narcotics. (See <http://www.health.mil/PandT> for meeting minutes.)
- Two systematic reviews conducted to evaluate the comparative efficacy of the LA narcotic analgesics found insufficient evidence to suggest that one agent is superior to another in adult patients with chronic non-cancer pain.
- Meaningful conclusions regarding comparative efficacy cannot be drawn from indirect comparisons of the drugs from the placebo-controlled trials, given the heterogeneity in terms of study designs, patient populations, interventions, and assessed outcomes.

## Safety and Tolerability

- There is a shared Risk Evaluation Mitigation Strategy (REMS) access program for all the extended release (ER) and long acting (LA) narcotic analgesics. The shared REMS requires that manufacturers of ER or LA narcotic analgesics provide educational materials to prescribers and patients in an effort to reduce serious adverse events resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioids, while maintaining patient access to pain medications.
- All LA narcotic analgesics are rated as pregnancy category C.
- Fentanyl transdermal system is the only LA narcotic approved in younger children and adolescents (age 2 to 17 years). As of August 17, 2015, Oxycontin gained FDA-approval for use in children aged 11 years and older.
- In general, opioid-related adverse effects are similar for all the narcotics, with commonly reported effects being constipation, nausea, vomiting, dizziness, somnolence, and headache.

## Other Factors

- At equianalgesic doses, the LA high potency narcotic analgesics are interchangeable to a moderate degree for the treatment of moderate to severe pain. Incomplete cross-tolerance may occur when switching from one opioid to another, which may lead to greater than anticipated potency in the new opioid.
- Tapentadol ER is the only product with an indication for neuropathic pain associated with diabetic peripheral neuropathy.
- Fentanyl transdermal system and Exalgo are approved for use only in opioid-tolerant patients at all doses; opioid-naïve patients should not receive these two products. The other LA narcotic analgesics have starting recommendations for opioid-naïve patients, and restrict certain high doses for opioid-tolerant patients.

## Abuse-Deterrent Formulations

- Abuse deterrent formulations (ADFs) offer a potential barrier to abuse via intravenous and intranasal routes; however, they have yet to demonstrate the ability to prevent abuse altogether. Abusers can still overcome the technologies in these formulations by overconsumption. ADFs should be considered as part of a comprehensive approach to safe opioid prescribing.
- The products specifically labeled as abuse-deterrent include Embeda, Hysingla ER, and Oxycontin. The combination of oxycodone ER/naloxone (Targiniq ER; Purdue) is also labeled as abuse-deterrent, but has not yet launched commercially.

## References

- DoD P&T Committee minutes: <http://www.health.mil/PandT>
- Current/future drug classes under review by the DoD P&T Committee: <http://www.health.mil/PandT> (scroll down to: DoD P&T Committee Meeting Schedule)
- TRICARE formulary search tool: <http://www.health.mil/formulary>
- Prior Authorization/Medical Necessity forms: See formulary search tool above.
- Formulary Management Documents (including this one) available at: <http://www.health.mil/DoDPTResources>
- Point of contact for additional information: [dha.jbsa.pharmacy.list.poduf@mail.mil](mailto:dha.jbsa.pharmacy.list.poduf@mail.mil)

Long Acting High Potency Narcotic Analgesics: Price Comparison at MTF	
Drug	MTF cost/month (August 2015)
<b>Basic Core Formulary</b>	
Morphine Sulfate (MS Contin, generics)	<b>\$</b> Most Cost-Effective
<b>Uniform Formulary</b>	
Fentanyl transdermal system	<b>\$\$</b> Less Cost-Effective
Hydrocodone ER (Hysingla ER)	<b>\$\$\$</b> Less Cost-Effective
Hydrocodone ER (Zohydro ER)	<b>\$\$\$</b> Less Cost-Effective
Hydromorphone ER (Exalgo)	<b>\$\$\$</b> Less Cost-Effective
Morphine ER (Avinza, Kadian)	<b>\$\$\$</b> Less Cost-Effective
Morphine ER/naltrexone (Embeda)	<b>\$\$\$</b> Less Cost-Effective
Oxycodone CR (Oxycontin)	<b>\$\$\$</b> Less Cost-Effective
Oxymorphone ER (Opana)	<b>\$\$\$</b> Less Cost-Effective
Tapentadol ER (Nucynta ER)	<b>\$\$\$</b> Less Cost-Effective
<b>Nonformulary</b>	
<b>None</b>	
<b>Legend:</b>	
<b>\$</b>	= "Most Cost-Effective" represents Rx's with the <u>lowest cost</u> and or best clinical efficacy
<b>\$\$</b>	= "Less Cost-Effective" represents <u>higher cost</u> Rx's with similar clinical efficacy
<b>\$\$\$</b>	= "Less Cost-Effective" represents <u>next higher cost</u> Rx's with similar clinical efficacy
<b>\$\$\$\$</b>	= "Least Cost-Effective" represents Rx's with the <u>highest cost</u> with similar clinical efficacy