

Wyoming Drug Utilization Review

Long-acting Opioid Use in Opioid-Naïve Patients

Stephanie Kosinski, Pharm.D.

Long-acting opioids can be very useful medications when trying to control a patient's pain. These medications typically allow for better pain control due to their longer duration of action leading to less blood level fluctuation and fewer adverse effects. Because of these advantages, it would be appealing to use these medications in all patients for pain management, including for their post-operative pain. Use of long-acting opioids in patient who are opioid naïve is a cause

for concern as it is leading to death from respiratory depression in these patients. It is thought that respiratory depression is the cause of death in about 16,000 opioid-related mortalities in the United States in 2010. Although use of any long-acting opioid in these patients can lead to death, the medication that is causing most concern is the fentanyl transdermal patch.

Numerous case reports have been published regarding use of a fentanyl patch in opioid naïve patients. Often times the result of the use of fentanyl patches in these patients is death within hours of patch placement. Typically the patients that are being treated for post-operative pain are those who have undergone successful surgeries. Tragically these patients too often go to sleep and never wake up. Death does not always occur when fentanyl patches are used improperly; however,

the deaths that do occur could be avoided if proper prescribing practices were followed. The respiratory depression and risk of death seen in opioid naïve patients is increased when the patient suffers from preexisting respiratory compromise such as COPD and sleep apnea.

The Food and Drug Administration (FDA) has produced multiple warnings and taken several actions since 2005 to try and combat the use of long-acting opioids in opioid naïve patients, including adding these medications to its risk evaluation and mitigation strategies (REMS) program in April of 2011. A black box warning has been issued to be included on the packaging of all long-acting opioids about the dangerous risk of respiratory depression and death that can result from misuse of these medications. It is important to note that long-acting opioid preparations are intended to be used only in patients who are considered opioid tolerant. For a patient to be considered opioid tolerant, he or she must have been taking an opioid dose of at least 60mg of morphine equivalents per day for a minimum of one week duration.

Long-acting opioids really should not be used to treat acute pain, post-operative pain, or pain due to trauma in any patient. In September 2013, the FDA announced that it would require long-acting opioids to state that the use of these medications are indicated for severe pain management that is inadequately controlled with other treatment options and requires long-term, daily, around-the-clock opioid therapy. Very low doses of some long-acting opioids may successful be used in patients considered to be opioid naïve without major adverse effects, but fentanyl transdermal patches and extended-release hydromorphone should never be used due to the higher risk of respiratory depression associated with them. These medications have a strict contraindication for use in opioid naïve patients.

Prescribers need to keep in mind a few simple guidelines when prescribing long-acting opioids for patients in

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P & T Committee Meeting Update

The P&T Committee met for its quarterly business meeting on May 8, 2014.

Highlights of this meeting include:

All Hepatitis C agents will require prior authorization with the following information collected:

- Pre-screening for risky behaviors
- Treatment history
- Extent of liver fibrosis (Metavir score)
- Genotype

Those with Metavir scores of F0, F1, and F2 will be sent for further review as directed by the Department of Health. Use of Sovaldi and Olysio in combination will require additional review by Department of Health.

Naltrexone will be limited to those with a diagnosis of alcohol or opioid dependence.

Psychotropics in children aged 5 and under will require prior authorization with the exception of ADHD medications which are allowed down to

age 3. Requests may be sent for review by Seattle Children's as deemed appropriate by the Department of Health.

Prior authorization will be required for Adasuve and Zohydro ER.

Hetlioz will be limited to its FDA approved indication.

There was no evidence of safety and efficacy for Velporo, Anoro Ellipto or Orenitram compared to medications in their respective classes. The Department of Health will review cost information and determine placement on the preferred drug list in their respective classes.

All proposed prior authorization criteria will be posted for public comment at www.uwyo.edu/DUR. Comments may be sent by email to alewis13@uwyo.edu or by mail to: Wyoming Drug Utilization Review Board, Dept. 3375, 1000 E. University Avenue, Laramie, WY 82071. Comments should be received prior to June 30, 2014.

The next P&T Committee meeting will be held August 14, 2014 in Cheyenne. An agenda will be posted approximately two weeks prior to the meeting.

2014 P & T Committee Meeting Dates

Thursday, August 14
Thursday, November 13

*Meetings are held in Cheyenne at Laramie
County Community College, 10 am - 1 pm.*

See agenda on our website

www.uwyo.edu/DUR

for room number.

New P & T Committee Members

The P & T Committee welcomes Andrew Beaulieu, MD and Garrett Needham, RPh as new members. Dr. Beaulieu specializes in nephrology and practices in Cheyenne. He joined the P & T Committee in March 2014. Mr. Needham practices in Cheyenne. He joined the P & T Committee in November 2013.

Long-acting Opioid Use in Opioid-Naïve Patients, continued

order to keep them safe while fully controlling the patients' pain. When choosing to prescribe long-acting opioids and assessing a patient, it is important to keep the whole picture of the patient in mind, not just the acute issue, as well as the adverse effects associated with these medications to avoid unnecessary risk. As stated above, these medications are indicated for opioid tolerant patients so being able to recall what this means will help during patient assessment. When a patient is determined to be an appropriate candidate for long-acting opioid therapy, initiation of the medication should be done with the lowest dose and titrated up to the lowest effective dose for each patient. Duration of use should be considered during reevaluation of a patient's pain so that these medications are not used longer than necessary. To obtain more guidance on safe prescribing of long-acting opioids the FDA has issued its Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics which can be found at <http://www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf>.

Patient safety should be at the forefront of all prescribing practices including when prescribing in long-acting opioids. These medications are wonderful options for

controlling pain in patients who suffer from chronic pain issues. Prescribing and patient safety issues come into play when long-acting opioids are improperly used in patients with whom the medications were not intended, including the opioid naïve and those with acute or post-operative pain. The main adverse effect of concern with use of these medications is respiratory depression that can lead to death too often in this population of patients. These unnecessary results could be easily avoided by following the warnings and guidance put in place by the FDA to maintain patient safety at all times.

References

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2. Grissinger M. Inappropriate prescribing of fentanyl patches is still causing alarming safety problems. *P T*. Dec 2010; 35(12): 653-654.
3. US Food and Drug Administration. FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. US Food and Drug Administration Web site. Available at <http://www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf>. Accessed February 14, 2014.
4. US Food and Drug Administration. FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. US Food and Drug Administration Web site. Available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm367726.htm>. Accessed February 14, 2014.
5. Gregory TB. How to safely prescribe long-acting opioids. *J Fam Pract*. 2013 Dec;62(12 Suppl 1):S12-8.



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