

Topic: Fentanyl products non-preferred in Illinois Medicaid

As a result of safety concerns, effective August 15, 2016, fentanyl transdermal patches will require prior approval for all fee-for-service HFS participants. Long-acting opioid therapy options on the Preferred Drug List are extended-release morphine oral tablets and Embeda capsules.

Background:

Despite continued warnings from the Food and Drug Administration (FDA), fentanyl transdermal patches continue to be prescribed inappropriately to treat acute pain in opiate-naïve patients, sometimes in large doses.¹ Fentanyl patches have also been associated with safety-related problems when used for chronic pain. The Center for Disease Control (CDC) recently published a guideline for using opioid narcotics in the management of chronic pain.² Safety-related problems with fentanyl are highlighted in the guideline. Fentanyl patches have slow absorption over the initial 72 hours, and dosing is expressed as mcg/h which may be confusing to patients and result in accidental overdoses. The guideline advises that fentanyl patches should be prescribed only by providers familiar with the pharmacokinetics and dosing of fentanyl. The CDC states that primary care clinicians report having concerns about opioid pain medication misuse, patient addiction, insufficient training in prescribing opioids, and the stress of managing patients with chronic pain. These factors may be large contributors to inappropriate use, as over half of all opioid prescriptions in the United States are written by primary care clinicians.

In 2012, the FDA reported that fentanyl patches were linked to 1,890 reports of serious harm, and 60% of these reports were related to medication errors.³ The medication errors included prescribing errors, inappropriate placement of patches by patients, replacement of patches at wrong time intervals, and accidental exposure to patches in children. The FDA and CDC have reported 10 pediatric deaths due to accidental fentanyl exposure.

In addition to the medication errors associated with fentanyl use, cases of serotonin syndrome in the FDA Adverse Event Reporting System (FAERS) database were reported more frequently with fentanyl used at the recommended doses.⁴ The FDA is requiring the addition of a new statement in the Warnings and Precautions section of the drug label.

Next steps

After fentanyl is removed from the PDL on August 15, 2016, requests for fentanyl will require prior approval. Patients currently using fentanyl chronically will have a short-term approval placed on file to ease the transition into the Pain Management Program for long-term opioid use. In the next few weeks, prescribers will receive a patient-specific fax from HFS regarding the review of continued coverage of fentanyl. Prescribers will be asked to provide clinical data to help in the determination of appropriateness of chronic opioid therapy and safety of fentanyl therapy. Please respond as soon as possible with requests for information to facilitate uninterrupted pain management, if deemed appropriate. If necessary, HFS will work with prescribers to convert your patient to preferred long-acting opioid therapy or to taper the patient off opioid therapy and optimize other pain control options.

References

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2. Center for Disease Control. CDC Guideline for prescribing opioids for chronic pain-United States, 2016. <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>. Accessed July 15, 2016.
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