

August 16, 2017

RE: Opana ER® (oxymorphone ER) Discontinuation from Market Effective September 1, 2017

Dear SoonerCare Provider,

The purpose of this fax is to provide information regarding communications from the U.S. Food and Drug Administration (FDA) regarding the availability of Opana ER® (oxymorphone hydrochloride extended-release). On June 8, 2017, the U.S. Food and Drug Administration (FDA) requested that Endo Pharmaceuticals remove its opioid pain medication, reformulated Opana ER®, from the market due to post-marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation.¹ This increase in injection abuse of reformulated Opana ER® has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy).¹

Based on the request from the FDA, Endo Pharmaceuticals announced that **shipments of Opana ER® will end on September 1, 2017** to enable time for patients currently taking Opana ER® to work with their physicians to convert to an appropriate alternative treatment. Please note that generic formulations of Opana ER® are not abuse deterrent and the FDA is also evaluating abuse patterns of the generic and other opioids and will take further action if necessary.

Please work with your patients currently taking Opana ER® on transitioning to another opioid product (or similar pain relieving medication), or if appropriate, discontinuing opioid therapy. New starts of either brand or generic Opana ER® will no longer be approved.

Updated versions of prior authorization criteria for long-acting narcotic analgesic medications can be downloaded from www.okhca.org/rx-pa, then clicking "Central Nervous System/Behavioral Health". Please note all members currently receiving Opana ER® and switching to an alternative opioid medication may require a manual prior authorization request from the prescriber.

Prior authorization request forms can be found online at www.okhca.org/forms (PHARM-4).

Thank you for the services you provide to Oklahomans insured by SoonerCare!

References:

1. U.S. Food and Drug Administration (FDA) News Release: FDA Requests Removal of Opana ER for Risk Related to Abuse. Available online at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>. Issued 06/08/2017. Last Accessed 07/26/2017.
2. American Pharmacists Association. Endo Says Shipments of Oxymorphone Hydrochloride ER Will End September 1. Available online at: <https://www.pharmacist.com/article/endo-says-shipments-oxymorphone-hydrochloride-er-will-end-september-1>. Issued 07/24/2017. Last Accessed 07/26/2017.