Zohydro Reformulated with Abuse-deterrent Properties

Background:

On 1/30/2015, the US Food and Drug Administration (FDA) announced that Zogenix Inc. had received approval to begin marketing its new formulation of the drug product Zohydro® ER.¹ Zohydro® ER is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.² The new formulation contains the ingredient BeadTek™. BeadTek™ is a formulation technology designed to provide abuse-deterrent properties. Products containing BeadTek™ immediately form a viscous gel when crush or dissolved in liquids. Transition to Zohydro® ER with BeadTek™ is expected to occur in the second quarter of 2015 for all prescribed strengths ranging from 10 mg to 50 mg, without disruption to patients currently on therapy.¹ Information regarding pricing was not available at the time of publication.

Impact to Our Customers:

Zohydro ER was originally approved by the FDA in October 2013.³ Since then, the drug has been at the center of ongoing controversy, with consumer groups and attorneys general of numerous states asking the FDA to reverse its approval of the drug.⁴ A major criticism of Zohydro ER has been that it was not available in abuse-resistant formulation. In October 2014, Zogenix announced submission of a supplemental New Drug Application for a modified formulation of Zohydro ER designed to have abuse-deterrent properties.⁵ Healthcare Solutions’ Pharmacy and Therapeutics Committee (P&T) will evaluate whether to recommend coverage status of this medication in the future; at this time, however, the medication will require a prior authorization on our drug formularies.

For questions regarding this eAlert or to learn more about our Clinical Rx Services please contact your dedicated Account Executive.

Sources:


Provided as a client service, Cypress Care’s clinical pharmacist team actively monitors and communicates timely news and announcements from the FDA affecting prescription drug management. We are committed to notifying you of important information as well as offering consultation on how these updates may impact your claimants and pharmacy management program.

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