



Provided as a Client Service by Healthcare Solutions' Clinical Pharmacy Team

FDA Approves Belbuca™, a Buccal Film for Chronic Pain

Background:

On October 26th, 2015, BioDelivery Sciences International, Inc. and its partner Endo Pharmaceuticals Inc., announced that the US Food and Drug Administration (FDA) approved Belbuca™ buccal film.¹ Belbuca™ is indicated for use in patients with chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate. Belbuca™ will be available in seven strengths of 75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg, and 900 mcg. Belbuca™ is for oral buccal use only and is to be applied to the buccal mucosa every 12 hours.² The anticipated release date for this new product is first quarter of 2016.¹ Pricing information is not available at the time of this publication.

Impact to Our Customers:

Opioid medications were within the top 10 drugs by both spend and utilization for claims within Healthcare Solutions' book of business in 2014.³ Belbuca™ appears to exhibit a dose-ceiling effect which differs from many other opioids.² In addition, BioDelivery Sciences International, Inc. notes that Belbuca™ is a Schedule III controlled substance, meaning that it has been defined as having lower abuse potential than Schedule II drugs, a category that includes most opioid analgesics.¹

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:

1. BioDelivery Sciences International, Inc. (2015). FDA Approval of BELBUCA™ (CIII) (Buprenorphine HCl) Buccal Film for Chronic Pain Triggers Milestone Payment of \$50 Million to BioDelivery Sciences from Partner Endo Pharmaceuticals. [Press release]. Available at: <http://markets.financialcontent.com/ir/?Ticker=BDSI&GUID=30881247&Module=MediaViewer>
2. Belbuca™ [Package insert]. Malvern, Pennsylvania: Endo Pharmaceuticals Inc. Available at: http://www.endo.com/File%20Library/Products/Prescribing%20Information/BELBUCA_prescribing_information.html#section-12.1
3. Healthcare Solutions, Inc. (2015). 2015 Workers' Compensation Drug Trends Report. [Online]. Available at: http://issuu.com/healthcaresolutions0/docs/healthcare_solutions_2015_drug_tren

Healthcare Solutions' 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.

Disclaimer

This alert is offered as a general summary of information retrieved from a variety of sources, including scientific literature and clinical experience. We seek to provide useful, current reference material, but do not claim to provide a comprehensive review and cannot guarantee the accuracy of information presented. Opinions are those of individual authors, and do not necessarily represent the recommendation or endorsement of Healthcare Solutions. This communication does not constitute medical advice.

