



## Praxbind (idarucizumab) approved to reverse anticoagulant Pradaxa

### Background:

The US Food and Drug Administration (FDA) recently announced that Boehringer Ingelheim had received accelerated approval to begin marketing its new drug product Praxbind®<sup>1</sup>. Praxbind® is indicated for use in patients who are taking the anticoagulant Pradaxa® during emergency situations when there is a need to reverse the blood-thinning effects of Pradaxa®. In clinical studies the reversal effects of Praxbind® were evident within minutes after administration of 5 grams of Praxbind®.<sup>2</sup> Reversing the effect of Pradaxa® potentially exposes patients to the risk of blood clots and stroke. The labeling for Praxbind® recommends patients resume their anticoagulant therapy as soon as medically appropriate, as determined by their health care provider.<sup>1</sup> The price and anticipated release date for this new product is unknown at time of publication.

### Impact to Our Customers:

Specialty medications were outside the top 10 drugs by both spend and utilization for claims within Healthcare Solutions' book of business in 2014.<sup>3</sup> Pradaxa® is one of the least utilized anticoagulants within Healthcare Solutions' book of business.<sup>4</sup> It is unclear whether the release of Praxbind® will increase the utilization of Pradaxa® over other anticoagulants like warfarin and enoxaparin. At the current time, impact of Praxbind® to our customers is anticipated to be small due to the low utilization of Pradaxa® within our book of business.

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. U.S. Food and Drug Administration. (2015). FDA approves Praxbind, the first reversal agent for the anticoagulant Pradaxa. [Press release]. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm467300.htm>
2. Boehringer Ingelheim. (2015). FDA Approves Praxbind® (idarucizumab), Specific Reversal Agent for Pradaxa® (dabigatran etexilate). [Press Release]. Available at: [http://www.boehringer-ingenelheim.com/news/news\\_releases/press\\_releases/2015/19\\_october\\_2015\\_dabigatranetexilate.html](http://www.boehringer-ingenelheim.com/news/news_releases/press_releases/2015/19_october_2015_dabigatranetexilate.html)
3. Healthcare Solutions, Inc. (2015). 2015 Workers' Compensation Drug Trends Report. [Online]. Available at: [http://issuu.com/healthcaresolutions0/docs/healthcare\\_solutions\\_2015\\_drug\\_tren](http://issuu.com/healthcaresolutions0/docs/healthcare_solutions_2015_drug_tren)
4. Healthcare Solutions internal dataset, July 1, 2015 through September 30, 2015.

**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.*

