

TrendsRx® Brand Alert: Pre-Approval

Pradaxa® (dabigatran)

Drug Approval

- Pradaxa [Boehringer Ingelheim] is an oral anticoagulant pending approval by the U.S. Food and Drug Administration (FDA) for the prevention of stroke in patients with atrial fibrillation (AFib).
- On September 20, 2010, the U.S. FDA Cardiovascular and Renal Drugs Advisory Committee unanimously voted in favor of approving Pradaxa for stroke prevention in patients with AFib.

Mechanism of Action

- Thrombin is an enzyme that activates fibrin, a protein that helps form blood clots.
- Dabigatran blocks the activity of thrombin and helps to prevent clot formation.

Background

- AFib is the most common type of abnormal heart rhythm. In AFib, the heart beats quickly and irregularly, leading to inefficient pumping of the blood.
- AFib can increase the risk of stroke. During AFib, blood can pool in the atria of the heart allowing blood clots to form. A stroke may occur if a blood clot breaks off and travels to the brain.
- More than 2 million people in the United States have AFib; the risk of AFib increases with increasing age.

Adverse Effects

- The most common adverse effects experienced by patients taking Pradaxa were upset stomach, shortness of breath, dizziness, swelling, fatigue and diarrhea.
- Major bleeding events have been reported with Pradaxa.
- In a clinical trial performed in patients with AFib, the rate of myocardial infarction was higher in patients receiving Pradaxa than in those receiving warfarin. The reason for this finding is unclear.

Anticipated Approval and Launch Date

- The FDA is expected to review the New Drug Application for Pradaxa by October 2010.
- Launch is anticipated in Q4 2010.

Selected Medications Available in the Class

- Generic agents: warfarin (various manufacturers)

Contact CVS Caremark

For more information, please call your CVS Caremark account representative or CaremarkConnect® at 1-800-237-2767.



Expected Budget Impact

- CVS Caremark anticipates initial moderate market utilization of Pradaxa as this agent provides a convenient route of administration with a novel mechanism of action and the potential for reduced laboratory monitoring as compared with currently available oral anticoagulants. The single indication may initially limit Pradaxa's overall usage; however, it is highly likely to replace current warfarin use in stroke prevention.
- CVS Caremark will continue to monitor the long-term budget effects of Pradaxa's introduction into the pharmaceutical marketplace.

Comments

- Pradaxa is an oral anticoagulant that offers a convenient route of administration and reduced laboratory monitoring.
- A clinical trial found that patients with AFib receiving Pradaxa had similar or lower rates of stroke and major bleeding than patients receiving warfarin, depending on the dose of Pradaxa used.
- A Risk Evaluation and Mitigation Strategy (REMS) program for Pradaxa is expected to be instituted upon the product's approval.

CVS Caremark Response

- CVS Caremark recognizes the unique needs of plan participants with AFib.
- Subsequent to approval, Pradaxa will be considered for inclusion in Utilization Management clinical solutions to help ensure appropriate use of Pradaxa; these solutions may include prior authorization for indication programs.
- Please contact your CVS Caremark clinical account team for more information regarding clinical solutions for Pradaxa.

References

1. Boehringer Ingelheim. FDA Advisory Committee unanimously recommends approval of dabigatran etexilate for stroke prevention in atrial fibrillation. Press release. September 20, 2010. Available at: http://us.boehringer-ingelheim.com/news_events/press_releases/press_release_archive/2010/september_20_20101.html. Accessed 2010 September 21.
2. Connolly SJ, Ezekowitz MD, Yusuf S et al. Dabigatran versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2009; 361:1139-51.
3. National Heart Lung and Blood Institute. What is atrial fibrillation? Available at http://www.nhlbi.nih.gov/health/dci/Diseases/af/af_what.html. Accessed 2010 September 17.
4. National Institute of Neurological Disorders and Stroke. NINDS stroke information page. Available at: <http://www.ninds.nih.gov/disorders/stroke/stroke.htm>. Accessed 2010 September 17.
5. U.S. Food and Drug Administration. Briefing information for the September 20, 2010 Meeting of the Cardiovascular and Renal Drugs Advisory Committee. Available at: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/ucm226008.htm>. Accessed 2010 September 21.

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