

Pharmacy Policy Bulletin

Title: Dabigatran (Pradaxa®)

Policy #: Rx.01.20

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ Intent:

Dabigatran (Pradaxa) is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

The use of Dabigatran (Pradaxa) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

▶ Description:

Dabigatran (Pradaxa) and its acyl glucuronides are competitive, direct thrombin inhibitors. Due to the fact thrombin (serine protease) enables the conversion of fibrinogen into fibrin during the coagulation cascade, its inhibition prevents the development of a thrombus. Both free and clot-bound thrombin, and thrombin-induced platelet aggregation are inhibited by the active moieties.

▶ Policy:

Dabigatran (Pradaxa) is approved when the following inclusion criteria is met:

- Documentation of use to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation

▶ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

▶ References:

Dabigatran [Package Insert] [Prescribing Information]. Boehringer Ingelheim Pharmaceuticals, Inc., October 2010.

Lexi-Drugs. Lexi-Comp Online. <http://www.lexi.com/>. Accessed November 9, 2010.

Micromedex® Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Micromedex; 2010. Available from: <http://www.thomsonhc.com/>.

Facts and Comparison. Facts and Comparison Online. <http://www.factsandcomparisons.com/>. Accessed November 9, 2010.

Connolly SJ, et al. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med* 2009; 361:1139-51.

Eriksson BI, Dahl OE, Ahnfelt L, et al. Dose escalating safety study of a new oral direct thrombin inhibitor, dabigatran etexilate, in patients undergoing total hip replacement: BISTRO I. *J Thromb Haemost*. 2004;2(9):1573-1580.


Eriksson BI, Dahl OE, Rosencher N, et al; RE-NOVATE Study Group. Dabigatran etexilate versus enoxaparin for prevention of venous thromboembolism after total hip replacement: a randomised, double-blind, non-inferiority trial. *Lancet*. 2007;370(9591):949-956.

Eriksson BI, Dahl OE, Rosencher N, et al; RE-MODEL Study Group. Oral dabigatran etexilate vs. subcutaneous enoxaparin for the prevention of venous thromboembolism after total knee replacement: the RE-MODEL randomized trial. *J Thromb Haemost*. 2007;5(11):2178-2185.

Ginsberg JS, Davidson BL, Comp PC, et al; RE-MOBILIZE Writing Committee. Oral thrombin inhibitor dabigatran etexilate vs. North American enoxaparin regimen for prevention of venous thromboembolism after knee arthroplasty surgery. *J Arthroplasty*. 2009;24(1):1

Eriksson BI, Dahl OE, Buller HR, et al; BISTRO II Study Group. A new oral direct thrombin inhibitor, dabigatran etexilate, compared with enoxaparin for prevention of thromboembolic events following total hip or knee replacement: the BISTRO II randomized trial. *J Thromb Haemost*. 2005;3(1):103-111.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Pradaxa	dabigatran

Cross References:

Policy Version Number: 1.00
P&T Approval Date: March 08, 2012
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