

Prior Authorization DRUG Guidelines

**PRADAXA (DABIGATRAN)**

Effective Date: 5/24/11

Date Developed: 4/18/11 by C. Albert Reeves MD

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Pradaxa is a prodrug that is converted in vivo to the active dabigatran, a specific, reversible, direct thrombin inhibitor that inhibits both free and fibrin-bound thrombin. It inhibits coagulation by preventing thrombin-mediated effects, specifically, cleavage of fibrinogen to fibrin monomers, activation of factors V, VIII, XI, and XIII, and inhibition of thrombin-induced platelet aggregation.

**Preauthorization Criteria:**

**Deep venous thrombosis and pulmonary embolism treatment and prevention:** Treatment of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been treated with a parenteral anticoagulant for ~~5 to 10~~  $\geq 5$  days to reduce the risk of recurrence of DVT and PE in patients who have been previously treated.

**Nonvalvular atrial fibrillation:** Prevention of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

**Venous thromboembolism prophylaxis in total hip arthroplasty:** Prophylaxis of DVT and PE in patients who have undergone total hip arthroplasty (**Off-Label** for total knee arthroplasty)

**Dosing:** Creatinine clearance over 30 ml/min – 150 mg orally BID  
Creatinine clearance 15-30 - 75 mg orally BID

**NOTE:** -Patients  $\geq 75$  years, use with extreme caution or consider other treatment options

**NOTE:**

For invasive procedures or surgery Pradaxa should be temporarily discontinued. If CrCl is greater than 50 mL/min discontinue 1-2 days before surgery, if CrCl is less than 50mL/min discontinue 3-5 days before an invasive procedure or surgery. When possible Pradaxa should be restarted as soon as possible.

Discontinuation of Pradaxa increases the risk of strokes.

**Contraindications:**

Active pathological bleeding

History of serious hypersensitivity reaction to Pradaxa

**Precautions:**

Risk of bleeding – Pradaxa can cause serious and sometimes fatal bleeding. Monitor for bleeding and evaluate signs and symptoms of blood loss.

**GI/Bariatric surgery:** Evaluate the risk versus benefit of possible decreased drug absorption

**Kidney impairment:** dabigatran concentrations may increase in any degree of kidney impairment and increase the risk of bleeding; dabigatran concentrations may increase in any degree of kidney impairment and increase the risk of bleeding

**Valvular heart disease:** Use is not recommended in patients with valvular heart disease, including the presence of a bioprosthetic heart valve; use is contraindicated in patients with mechanical prosthetic heart valves.

**[US Boxed Warning]:** Upon premature discontinuation, the risk of thrombotic events is increased. If dabigatran must be discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider the use of another anticoagulant during the time of interruption.

**Adverse Reactions:**

Most common adverse reactions are gastritis-like symptoms and bleeding.

**Dosage Forms:** 75 mg, 110 mg, 150 mg

**References**

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