



## Prior Authorization Approval Criteria

### *Pradaxa (dabigatran)*

<b>Generic name:</b>	dabigatran
<b>Brand name:</b>	Pradaxa
<b>Medication class</b>	anticoagulant
<b>FDA-approved uses:</b>	Reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation
<b>Available dosage forms:</b>	75mg and 150mg capsules
<b>Usual dose:</b>	150mg twice daily if CrCl > 30 ml/min 75 mg twice daily if CrCl 15-30 ml/min Dosing cannot be recommended for CrCl<15ml/min
<b>Approximate monthly cost:</b> (based on AWP 2010)	\$243.00 per month
<b>Duration of therapy:</b>	to be determined by physician

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Must have tried and failed or intolerant to warfarin.
- Being used to reduce risk of stroke and systemic thromboembolism in patients with non-valvular atrial fibrillation.
- Must provide recent CrCl or scr and patient weight.

**Caution:**

- Temporarily discontinue Pradaxa 1-2 days before surgery, and then restart promptly.

**Contraindication:**

- Active pathological bleeding.
- History of a serious hypersensitivity reaction to Pradaxa.

**Not approved if:**

- Patient does not meet the above stated criteria.
- Have any contraindications to the use of Pradaxa.

**Special considerations:**

- GI bleeding is greater with dabigatran but warfarin was shown to have a higher rate of intracranial bleeding. No monitoring, minimal drug/food interactions. However, the risk of MI and lack of long term safety data on chronic use is concerning.
- Failure or intolerance may include poor INR control on warfarin or patients with a prior stroke or transient ischemic attack (TIA).

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 12/08/10  
Rev. 09/07/11