VENTURA COUNTY
HEALTH CARE PLAN

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~~ ≥5 days ~~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 ≥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

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