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

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19, 2/18/20

Pradaxa is a direct thrombin inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

Preauthorization Criteria:

VCHCP requires that:

Pradaxa is approved for prophylactic prevention of stroke in patients with non-valvular atrial fibrillation per the American College of Cardiology/.American Heart Assn. and the European Society of Cardiology guidelines for Antithrombotic Therapy for Patients with Atrial Fibrillation when warfarin is contraindicated or anticoagulation control is difficult due to patient physiologic issues or poor patient compliance with adherence to taking medication or INR testing.

Dosing: Creatinine clearance over 30 ml/min – 150 mg orally
Creatinine clearance 15-30 - 75 mg orally BID
Capsules are not to be chewed, broken or opened.
For invasive procedures or surgery Pradaxa should be temporarily discontinued. If CrCl is greater that 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

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

Temporary discontinuation – avoid lapses in therapy to minimize risk of stroke.
P- gb inducers and inhibitors – avoid coadministration of rifampin with Pradaxa because of effects on dabigatran exposure.

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

Patient Counseling Information:

Instructions to patients:

Take Pradaxa exactly as prescribed.
Remind patients not to discontinue Pradaxa without talking to the health care provider who prescribed it.
Advise patients not to chew or break the capsules before swallowing them and not to open the capsules and take the pellets alone.

Bleeding:
Inform patients that they may bleed more easily, may bledd longer, and should call their health care provider for any signs or symptoms of bleeding.

Instruct patients to seek emergency care right away if they have any of the following, which may be a sign or symptom of serious bleeding:

Unusual bruising (bruises that appear without known cause or that get bigger)
Pink or brown urine
Red or black, tarry stools
Coughing up blood
Vomiting blood, or vomit that looks like coffee grounds

Instruct patients to call their health care provider or to get prompt medical attention if they experience any signs or symptoms of bleeding:

Pain, swelling or discomfort in a joint
Headaches, dizziness or weakness
Reoccurring nose bleeds
Unusual bleeding from gums
Bleeding from a cut that takes a long time to stop
Menstrual bleeding or vaginal bleeding that is heavier than normal

Gastrointestinal Adverse Reactions
Instruct patients to call their health care provider if they experience any signs or symptoms of dyspepsia or gastritis:

Dyspepsia, (upset stomach), burning or nausea
Abdominal pain or discomfort
Epigastric discomfort, GERD (gastric indigestion)

Invasive or Surgical Procedures:

Instruct patient to inform their health care provider that they are taking Pradaxa before any invasive procedure(including dental procedures) is scheduled.

Concomitant Medications
Ask patients to list all prescription medications, over the counter medsications, or dietary supplements they are taking or plan to take so their health care provider knows about other treatments that may affect bleeding risk or dabigatron exposure.

Preauthorization Criteria:

1. Pradaxa (package insert). Ridgefield CT: Boehringer Ingelheim; October 2010.
2. Express Scripts Prior Authorization Policy – Pradaxa; February 16, 2011
3. FusterV, Ryden LE, Cannom DS, et al ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation- executive summary: A report of the American College of Cardiology/ American Heart Association Task Force on practice guidelines and the European Society of Cardiology Committee for practice guidelines (writing committee to revise the 2001 guidelines for the management of patients with atrial fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. Circulation 2006;114:700-752.

References

1. Pradaxa. Prescribing information. Boehringer Ingelheim. March 2012.
2. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM231720.pdf

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