Saskatchewan
Ministry of
Health

Drug Plan and Extended Benefits Branch

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SASKATCHEWAN FORMULARY BULLETIN

Update to the 61st Edition of the Saskatchewan Formulary

Product	DIN	Pre-Markup ($)	Unit Price ($)

New Exception Drug Status (EDS) Listings Effective May 1, 2012:

Pradax tablet (dabigatran) (BOE)			
110mg tablet	02312441	1.6000	1.7360
150mg tablet	02358808	1.6000	1.7360

Inclusion Criteria:

At-risk patients with non-valvular atrial fibrillation (AF) who require the Drug Product for the prevention of stroke and systemic embolism **AND** in whom:

(a) Anticoagulation is inadequate following a reasonable trial on warfarin; **OR**
(b) Anticoagulation with warfarin is contraindicated or not possible due to inability to regularly monitor via International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home).

Exclusion Criteria:

Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate < 30 mL/min) **OR** ≥ 75 years of age and **without** documented stable renal function **OR** hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis; **OR** prosthetic heart valves.

Notes:

(a) Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate that is maintained for at least three months (i.e. 30-49 mL/min for 110 mg twice daily dosing or ≥ 50 mL/min for 150 mg twice daily dosing).
(b) At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥ 1.
(c) Inadequate anticoagulation is defined as INR testing results that are outside the desired INR range for at least 35% of the tests during the monitoring period (i.e. adequate anticoagulation is defined as INR test results that are within the desired INR range for at least 65% of the tests during the monitoring period).
(d) A reasonable trial on warfarin is defined as at least two months of therapy.
(e) Since renal impairment can increase bleeding risk, renal function should be regularly monitored. Other factors that increase bleeding risk should also be assessed and monitored (see product monograph).
(f) Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.

(g) There is currently no data to support that dabigatran provides adequate anticoagulation in patients with rheumatic valvular disease or those with prosthetic heart valves, so dabigatran is not recommended in these populations.

Additional Information
Dabigatran (Pradax) and Bleeding Patients

In order to best manage the risks to patients on dabigatran ("PRADAX"), the Ministry of Health has asked Saskatchewan's provincial transfusion medicine medical directors to develop a consensus-based clinical guidance document and algorithm, *Dabigatran (Pradax) and Bleeding Patients* (see attached). This guidance document was developed in consultation with specialists in the Saskatoon and Regina Qu'Appelle Health Regions and across the country, with consideration of the best-available evidence. It is recognized that this guidance document is based on evidence that is not yet fully developed and will be updated as more data becomes available. A copy of this document is available on the Saskatchewan Ministry of Health website at www.health.gov.sk.ca/transfusion-medicine.

This guidance document is intended to serve the needs of all health facilities in the province. The Ministry will be working with physicians and the health regions to develop an implementation plan that is appropriate to each hospital's classification level and the health services it provides.

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