



BC PharmaCare Newsletter

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QuickLinks

Special Authority Coverage of Dabigatran (Pradax [®]).....	1
Special Services Fees.....	2
Benefits.....	2
Limited Coverage Drug Program Benefits	2
Non-Benefits	3

SPECIAL AUTHORITY COVERAGE OF DABIGATRAN (PRADAX[®])

Effective May 23, 2012, PharmaCare will cover dabigatran as a Limited Coverage benefit with the following Special Authority (SA) criteria:

- for the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation for whom:
 - a. anticoagulation is inadequate following at least a 2-month trial of warfarin; or
 - b. warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e., no access to INR testing services at a laboratory, clinic, pharmacy and at home).

The following patient groups are excluded from PharmaCare coverage for dabigatran for atrial fibrillation:

- a. patients with impaired renal function
- b. patients 75 years of age or over without documented stable renal function
- c. patients with hemodynamically significant rheumatic valvular heart disease, especially mitral stenosis
- d. patients with prosthetic heart valves

Detailed criteria are available on the PharmaCare website at www.health.gov.bc.ca/pharmacare/sa/criteria/restricted/dabigatran.html.

Continued on page 2...

The use of PharmaNet is not intended as a substitute for professional judgment. Information on PharmaNet is not exhaustive and cannot be relied upon as complete.

The absence of a warning about a drug or drug combination is not an indication that the drug or drug combination is safe, appropriate or effective in any given patient. Health care professionals should confirm information obtained from PharmaNet, and ensure no additional relevant information exists, before making patient care decisions.

SPECIAL AUTHORITY COVERAGE OF DABIGATRAN (PRADAX[®]), CONTINUED

Please note that PharmaCare coverage of dabigatran will NOT be provided for any other indication at this time (i.e., no coverage for prevention of venous thromboembolism in elective hip or knee surgery patients).

Coverage of dabigatran is subject to the usual rules of a patient's BC PharmaCare plan, including any deductible requirement. Retroactive coverage cannot be provided for prescriptions filled before SA approval is in place.

Notes

1. At-risk patients with atrial fibrillation are defined as those with a CHADS2 score of ≥ 1 .
2. 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).
3. 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 dabigatran product monograph).
4. Documented stable renal function is defined as creatinine clearance or estimated glomerular filtration rate maintained for at least 3 months (i.e., 30-49 mL/min for 110 mg twice daily dosing or ≥ 50 mL/min for 150 mg twice daily dosing).
5. 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.
6. Patients starting dabigatran should have ready access to appropriate medical services to manage a major bleeding event.

SPECIAL SERVICES FEES

The number of Special Services fees that PharmaCare paid each month over the past year:

Apr 2012..... 1316	Dec 2011 2,112	Aug 2011 1,804
Mar 2012.....1439	Nov 2011 2,002	Jul 2011 1,838
Feb 2012.....1,502	Oct 2011..... 1,891	Jun 2011..... 1,921
Jan 2012.....1,409	Sep 2011 1,949	May 2011 ... 1,959

BENEFITS

Limited Coverage Drug Program Benefits

The following products are eligible benefits under the Limited Coverage Program—by Special Authority only—for Fair PharmaCare and Plans B, C, and F. For the Special Authority criteria, please visit the [Special Authority Information](#) page on the PharmaCare website at <http://www.health.gov.bc.ca/pharmacare>.

DIN	DRUG NAME	PLAN G	PLAN P
02312441	dabigatran (Pradax [®]) 110 mg capsule	No	No
02358808	dabigatran (Pradax [®]) 150 mg capsule	No	No

Non-Benefits

The following products have been reviewed and will not be added as benefits under PharmaCare.

DIN	DRUG NAME
02341174	buprenorphine (BuTrans®) 5 mcg/hr transdermal system
02341212	buprenorphine (BuTrans®) 10 mcg/hr transdermal system
02341220	buprenorphine (BuTrans®) 20 mcg/hr transdermal system
02360373	tapentadol (Nucynta™ CR) 50 mg extended-release tablets
02360381	tapentadol (Nucynta™ CR) 100 mg extended-release tablets
02360403	tapentadol (Nucynta™ CR) 150 mg extended-release tablets
02360411	tapentadol (Nucynta™ CR) 200 mg extended-release tablets
02360438	tapentadol (Nucynta™ CR) 250 mg extended-release tablets