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SASKATCHEWAN FORMULARY BULLETIN

Update to the 62nd Edition of the Saskatchewan Formulary

Product	DIN	Pre-Markup ($)
New Exception Drug Status (EDS) Listing Effective August 1, 2012:		
Xarelto tablet (rivaroxaban) (BAY)		
15mg tablet	02378604	2.8400
20mg tablet	02378612	2.8400

Inclusion:

At-risk patients with non-valvular atrial fibrillation who require rivaroxaban 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:

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 of 30-49 mL/min for 15 mg once daily dosing or ≥ 50 mL/min for 20 mg once daily dosing that is maintained for at least 3 months.
(b) At-risk patients with atrial fibrillation are defined as those with a $CHADS_2$ score of ≥ 1. Although the ROCKET-AF trial included patients with higher $CHADS_2$ scores (≥ 2), other landmark studies with the other newer oral anticoagulants demonstrated a therapeutic benefit in patients with a $CHADS_2$ score of 1. Prescribers may consider an antiplatelet regimen or oral anticoagulation for patients 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 2 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 rivaroxaban product monograph).

(f) Patients starting rivaroxaban should have ready access to appropriate medical services to manage a major bleeding event.

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

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