



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte  
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Circular No. 026/11

4 November 2011

**Re: Direct Thrombin Inhibitors associated with certain Elective Orthopaedic Surgical Procedures – Dabigatran Etexilate and Rivaroxaban**

Pradaxa Caps. 75 mg. 10 (5 Day Dose)	60612
Pradaxa Caps. 75 mg. 60 (30 Day Dose)	60628
Pradaxa Caps. 110 mg. 10 (5 Day Dose)	60659
Pradaxa Caps. 110 mg. 60 (30 Day Dose)	60684
Xarelto Tabs. 10 mg. 30	53342

Dear Pharmacist,

The HSE wishes to bring to your attention that the above currently marketed direct thrombin inhibitor and the direct factor Xa inhibitor medicinal products were included on the List of GMS Reimbursable Items in 2008 on the basis of their original indications i.e. the prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.

Following a recent economic evaluation the HSE is assessing the availability of resources in 2012 to consider long term treatment with Pradaxa 150mg for the prevention of stroke in patients with Atrial Fibrillation. This is a complicated process with long term implications.

**Pending the outcome of these deliberations the HSE wishes to clarify the current reimbursement position around Pradaxa (and any other new oral anticoagulants).**

An economic evaluation in 2008 demonstrated that the reimbursement of both agents for the prevention of venous thromboembolism (VTE) in adult patients who have undergone *elective hip replacement surgery* or *elective knee replacement surgery* was cost effective for that indication.

We are aware that clinicians are considering whether to initiate patients on stroke prevention treatment by using the strengths already reimbursable under Schemes, which would entail treatment durations beyond those that follow elective surgery. **It is important to note that, with immediate effect, apart from the specified elective surgical indications the HSE will not reimburse such direct thrombin inhibitors.**

Therefore, GMS prescriptions should only be accepted and Pradaxa/Xarelto will only be reimbursed when submitted on a standard GMS prescription form. **Pharmacists will only be reimbursed for one month's supply under the GMS and Community Drug Schemes** and should be vigilant in this regard when accepting prescriptions.

Doctors have been informed that a maximum of one month's supply only for a direct thrombin inhibitor can be prescribed.

The HSE will continue to update you in relation to these matters.

Yours faithfully,

Patrick Burke  
Primary Care Reimbursement Service