Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte
Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50
An Bóthar Thuaidh
Fionnghlas
Baile Átha Cliath 11

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Primary Care Reimbursement Service
Exit 5, M50
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Dublin 11

Tel: (01) 864 7100
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Circular No 05/14

31 January 2014

Re: Dabigatran, Rivaroxaban and Apixaban

Dear Doctor,

The HSE approved reimbursement for dabigatran, rivaroxaban and apixaban some time ago for their further indication(s) in circumstances where one of the products is used as a second line therapy when warfarin may not be appropriate. The HSE has been operating a paper based reimbursement approval system since.

Warfarin remains the recommended first line agent reimbursed (including for newly diagnosed patients). Dabigatran, Rivaroxaban and Apixaban should be reserved for:

a. Existing patients on warfarin with poor INR control despite adhering to monitoring and lifestyle requirements to optimise warfarin therapy
b. Existing patients who require regular periodic treatment with medicines that are known to interact with warfarin
c. Patients with a documented allergy to warfarin.

The HSE, under the guidance of the Medicines Management Programme, has improved the patient specific applications for reimbursement to incorporate certain safety alerts. This form will be available online from 1 February 2014 at www.pcrs.ie (online services). A letter from Professor Barry is included with this communication outlining the importance of this patient safety initiative.

In addition, from 1 February 2014, online applications will be possible. The online application system has a number of advantages:

1. The prescriber will have been enabled to consider relevant clinical information as they submit the patient specific application for reimbursement approval.
2. The prescriber will receive immediate confirmation at the point of submission that the application has been approved with a reference number provided. Note: This will only occur where no safety alerts have been triggered.
3. The patient can be provided with their individual reference number of submission of application on their behalf

It is envisaged that the paper based reimbursement approval service will be phased out over the coming months.

A separate communication has been issued to the hospital system including the request to ensure that where this treatment has been initiated as an Inpatient / Outpatient that the application for reimbursement approval should emanate from the hospital setting.

Where a GP is initiating therapy as the Prescriber responsible for the management of the patient's anticoagulation and the patient is not validly registered under one of the HSE's reimbursement schemes, the prescriber may encounter a message, 'approval deferred'. If this happens, the prescriber can be assured that their input to the process has been completed. However, patients can only receive reimbursement support if they have registered for one of the relevant schemes. The patient's approval letter for reimbursement of a New Oral Anticoagulant will clarify that reimbursement support is dependent on registration under one of the community drug schemes. Patients will be asked to address this eligibility matter further with the HSE.

It is envisaged that the paper based reimbursement approval service will be phased out over the coming months. All applications received from 1 February 14 should have the patient safety alerts completed. A copy has been included for ease of reference.

Yours faithfully,

Patrick Burke
Primary care Reimbursement service

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Clinical Strategy and Programmes Directorate
Dr Steevens' Hospital
Dublin 8

30th January 2014

Re: Oral Anticoagulant HSE Reimbursement Form

Dear Colleagues

I am writing to inform you of changes we have introduced to the reimbursement approval form for new oral anticoagulant (NOAC) drugs which appears on the HSE website. These changes are designed to support us as clinicians in our use of NOACs. The Medicines Management Programme (MMP) is in agreement with HSE advice that warfarin is the oral anticoagulant of choice, not least because of resource use issues as NOACs already account for expenditure in excess of € 10million per annum.

The changes to the NOAC reimbursement form are designed to ensure that when NOAC drugs are used that we consider whether the drugs are indicated for the particular condition e.g. using the CHADS or CHADS-VASc score for patients with atrial fibrillation. We also include the HAS-BLED scoring system to help indicate those patients who are at greater risk of bleeding where some caution and regular review may be required. Although designed to assess bleeding risk in patients with atrial fibrillation the HAS-BLED scoring system provides a simple, user friendly way to assess bleeding risk.

The revised reimbursement form also facilitates calculation of the GFR using the Cockcroft – Gault Equation. This is preferable to using the eGFR which may appear on a biochemistry profile. The MMP advises that the NOACs are best avoided in patients with a calculated GFR less than 30 ml/min.

Where any entry (CHADS, CHADS-VASc, HAS-BLED,GFR) triggers a safety alert on the application form the application will be approved but ongoing audit reports will be produced for review by the MMP team.

My thanks to you all for your ongoing support in addition to the many helpful comments and suggestions which help shape the development of the new Medicines Management Programme.

With best wishes

Michael Barry.

Prof Michael Barry
National Clinical Lead, Medicines Management Programme
National Medicines Information Centre
St. James's Hospital
Dublin 8

Preferred Drugs
THE RIGHT CHOICE, RIGHT NOW.
MEDICINES MANAGEMENT PROGRAMME

Application Form for Individual Patient Reimbursement of a New Oral Anticoagulant by PCRS

All Sections must be completed in block capitals by the Prescriber responsible for Anticoagulation
All contact details must be provided so that formal decision notification can be issued
Form must be returned to the Primary Care Reimbursement Service, Exit 5, M50, Finglas, Dublin 11

Patient Name	
Patient Date of Birth	

Patient Identifier (at least one must be provided)	GMS Number (Medical Card/Doctor Visit)	
	DPS Number (Drugs Payment Scheme)	
	LTI Number (Long Term Illness)	
	PPS Number	
Patient Address	Line 1	
	Line 2	
	Town or City	
	County	

Physician Responsbile for Management of Anticoagulation	Physician Name	
	Medical Council Number	
	Department/Speciality	
	Landline	
	Mobile	
	Email	
Hospital or Practice Details	Name	
	Address Line 1	
	Address Line 2	
	Town or City	
	County	

New Drug Request

Apixaban 2.5Mg Tabs	Drug dosage		Duration of therapy	
Apixaban 5Mg Tabs	Drug dosage		Duration of therapy	
Dabigatran Etexilate 110Mg Caps	Drug dosage		Duration of therapy	
Dabigatran Etexilate 150Mg Caps	Drug dosage		Duration of therapy	
Rivaroxaban 10Mg Tabs	Drug dosage		Duration of therapy	
Rivaroxaban 15Mg Tabs	Drug dosage		Duration of therapy	
Rivaroxaban 20Mg Tabs	Drug dosage		Duration of therapy	

CLINICAL INFORMATION				
Is the clinical indication for the new oral anticoagulant (NOAC) atrial fibrillation	Yes		No	
If yes to the above, is it	Valvular		Non-valvular	

Note: Only Warfarin is indicated for valvular atrial fibrillation

Is the clinical indication for the new oral anticoagulant (NOAC) prevention or treatment of deep vein thrombosis	Yes		No	
Is the clinical indication for the new oral anticoagulant (NOAC) prevention or treatment of pulmonary embolism	Yes		No	

If the reason claimed is poor INR control secondary to unmanageable drug interaction(s) due to the ongoing prescription of (an)other essential medicine(s) please provide details of that medicine(s)	
Medicine	

If the reason claimed is allergy to warfarin please provide specific details including date of reporting to Irish Medicines Board

To assist you in determining whether a New Oral Anticoagulant is the appropiate treatment for your patient, please complete the following:

**(NB the following section is required if clinical indication is atrial fibrillation)*

CHADS SCORING SYSTEM		CHADS-VASC SCORING SYSTEM	
PARAMETER	SCORE	PARAMETER	SCORE
cardiac failure/LV dysfunction	**1**	**cardiac failure/LV dysfunction**	**1**
hypertension	**1**	**hypertension**	**1**
age ≥ 75 years	**1**	**age ≥ 75 years**	**2**
diabetes	**1**	**diabetes**	**1**
stroke/TIA/thromboembolism	**2**	**stroke/TIA/thromboembolism**	**2**
		peripheral vascular disease/prior myocardial infarction,aortic plaque	**1**
		age 65 – 74 years	**1**
		sex category i.e. female	**1**
CHADS score =		CHADS-VASc score =	

HAS-BLED SCORING SYSTEM (To be completed for all applications)	
PARAMETER	SCORE
hypertension (systolic BP>160 mmHg)	**1**
abnormal renal function, dialysis or creatinine >200 µmol/l	**1**
abnormal liver function, bilirubin>2 & transaminases>3x (ULN)	**1**
stroke	**1**
bleeding history/predisposition to bleeding	**1**
labile INRs i.e. unstable/high INRs or time in therapeutic range < 60%	**1**
drugs e.g. antiplatelet agents, NSAIDs	**1**
alcohol abuse	**1**
HAS-BLED score =	

A HAS-BLED score ≥ 3 out of 9 indicates 'high risk so caution is needed'

What is the calculated glomerular filtration rate (GFR) ml/min ? (1)	

(1) Use the Cockcroft-Gault eqn to estimate the GFR = (140-age years) x (Weight kg) x constant [1.23 for males & 1.04 for females]/serum creatinine µmol/l.

Summary Final Check:		
Is CHADS score >= 2 ?	Yes/No	
Is HAS-BLED score < 3?	Yes/No	
Is Calculated GFR > 30 ml/min	Yes/No	

If No to any of the above, reconsider the use of NOAC