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Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

30th September 2022

Circular 027/22

RE: Reimbursement of Rivaroxaban 2.5 mg (Xarelto®) effective 1st October 2022

Dear Pharmacist,

The HSE has approved reimbursement for rivaroxaban 2.5 mg (Xarelto®) film coated tablets under Community Drug Schemes from 1st October 2022. This product is approved for reimbursement on the basis of managed access. Conditional reimbursement is for one of the two licensed indications in adults patients:

Rivaroxaban (Xarelto®) 2.5 mg, co-administered with acetylsalicylic acid (aspirin), for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.

Due to the potential budget impact associated with this medicine, PCRS is introducing a reimbursement application system to ensure appropriate patients have access to this treatment. A separate communication has been issued to the hospital system in this regard. The reimbursement application must be made by the physician responsible for the initiation of treatment due to the mandatory information required for reimbursement to be approved.

Approval can be confirmed through the 'Secure Scheme Checker' on the Pharmacy Suite under 'Patient Specific Arrangements'. Pharmacies can dispense and claim for rivaroxaban 2.5 mg (Xarelto®) electronically using the product GMS code, submitting in the normal manner with monthly claims. Claims submitted for patients who are not approved will not be paid. Please note that patients currently accessing the medicine through an early patient access programme will need online approval for ongoing reimbursement support from 1st October 2022.

Please see attached letter from Prof. Michael Barry, Clinical Lead of the HSE-Medicines Management Programme (MMP) outlining supporting information available and further details in relation to reimbursement of rivaroxaban 2.5 mg.

Yours faithfully,

Shaun Flanagan
Primary Care Eligibility & Reimbursement

Re: Rivaroxaban (Xarelto®) 2.5 mg reimbursement

30th September 2022

Dear Colleagues,

Rivaroxaban (Xarelto®) 2.5 mg film-coated tablets will be available for reimbursement under the Community Drug Schemes from 1st October 2022. Reimbursement of rivaroxaban (Xarelto®) 2.5 mg is approved for the following licensed indication only:

- Prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events, when co-administered with aspirin.

Due to the potential budget impact associated with this medicine, the HSE-Primary Care Reimbursement Service (PCRS) is introducing an online reimbursement application system for rivaroxaban (Xarelto®) 2.5 mg.

Prescribers will be required to apply for reimbursement approval on an individual patient basis, demonstrating that management of cardiovascular risk factors such as hyperlipidaemia, hypertension and diabetes mellitus have been optimised. Further information is outlined in the HSE-Managed Access Protocol for Rivaroxaban (Xarelto®) 2.5 mg available on the HSE-Medicines Management Programme's (MMP) website www.hse.ie/yourmedicines.

GPs and hospital prescribers, once user-registered with the PCRS, will be authorised to apply for reimbursement, through the Special Drug Request (SDR) section on the GP Application Suite or under "Services for Hospitals" on the PCRS website (www.pcrs.ie). The reimbursement application should be made by the prescriber responsible for the initiation of treatment.

Applications submitted will be reviewed by the MMP before a reimbursement recommendation is made. This recommendation will be communicated to the prescriber through the online reimbursement application system. Once a patient is approved for reimbursement there will be no expiry on the duration of this approval.

Incomplete applications will not be approved. In the case where additional clinical information is required, the application will be returned to the prescriber through the online reimbursement application system.

If you are applying for reimbursement approval for a patient who is in receipt of rivaroxaban 2.5 mg through the early access programme operated by Bayer Limited, please indicate this when completing the online application in the field entitled *Please provide any additional information in support of the application.*

I would like to remind you that there are four direct oral anticoagulants (DOACs) available with multiple indications and differing doses and frequencies of administration. Care must be taken when prescribing, transcribing, dispensing and administering all DOACs to ensure that the dose and frequency of administration are correct for the indication and for the individual being treated. To enhance safe and effective prescribing of DOACs we have published updated anticoagulation prescribing tips available on the MMP's website www.hse.ie/yourmedicines.

As per my previous communication from 05/10/2020, there remains no requirement to submit an online reimbursement application for apixaban, dabigatran, edoxaban and other strengths of rivaroxaban (i.e. other strengths excluding the 2.5 mg formulation) when prescribed for reimbursed licensed indications.

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,

Michael Barry.

Professor Michael Barry, **National Clinical Lead, HSE-Medicines Management Programme.**
www.hse.ie/yourmedicines