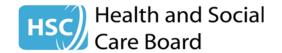
HSCB Service Notification for the managed entry of new medicines and technologies



1. Treatment & Condition

Rivaroxaban for preventing atherothrombotic events in people with coronary or peripheral artery disease.

2. Associated appraisal body & Summary of ruling

Technology appraisal guidance [TA607] Published date: 17 October 2019.

Rivaroxaban plus aspirin is recommended within its marketing authorisation, as an option for preventing atherothrombotic events in adults with coronary artery disease or symptomatic peripheral artery disease who are at high risk of ischaemic events.

For people with coronary artery disease, high risk of ischaemic events is defined as:

- aged 65 or over, or
- atherosclerosis in at least 2 vascular territories (such as coronary, cerebrovascular, or
- peripheral arteries), or
- 2 or more of the following risk factors:
 - > current smoking
 - diabetes
 - kidney dysfunction with an estimated glomerular filtration rate (eGFR) of less
 - ➤ than 60 ml/min (note that rivaroxaban is contraindicated if the eGFR is less than 15 ml/min)
 - heart failure
 - > previous non-lacunar ischaemic stroke.

Assess the person's risk of bleeding before considering rivaroxaban. Treatment should only be started after an informed discussion with them about the risks and benefits of rivaroxaban, weighing up the risk of atherothrombotic events against the risk of bleeding. The risks and benefits of continuing treatment with rivaroxaban should be regularly reviewed.

3. Number of people in Northern Ireland expected to take up service/therapy

It is estimated that 46,872 people in Northern Ireland meet the eligibility criteria, but NICE has used a planning assumption that only 2.9% of these will commence treatment with rivaroxaban. As it is close to the end of the 2019/20 financial year, it is assumed that up to 199 people in this financial year will treated with Rivaroxaban for preventing atherothrombotic events. This is expected to rise to 1,359 people in 2020/21 and beyond.

4. Patient Access Scheme Availability

(Yes/No)

There is no patient access scheme, commercial arrangement, or any other type of price discount applicable to rivaroxaban under NICE TA607.

5. Infrastructure Requirements

Any additional infrastructure costs associated with the introduction of new cardiac medications will be managed as part of the routine commissioning process. This TA assumes that patients on this treatment will be prescribed the medication in primary care.

6. Expected implementation period

There is no impediment to immediate implementation for new patients.

7. Commissioning arrangements

For those patients who commence treatment for this indication in secondary care, this regimen will be formally commissioned by the HSCB/PHA on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.

8. Monitoring arrangements

The HSCB cost per case process will generate quarterly reports on the number of applications.

9. DoH (NI) Legislative/Policy Caveats

This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.

The Rural Needs Act NI 2016 has been considered and this guidance, which is purely of a technical nature, is not regarded as galling within the scope of the act.