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

Health and Social Care Board

1	**Treatment & Condition** *(Title)* Rivaroxaban for preventing adverse outcomes after acute management of acute coronary syndrome
2	**Associated appraisal body** *(NICE/SMC/Other)* ***&*** **Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE Technology Appraisal Guidance 335 (March 2015) Rivaroxaban is recommended as an option within its marketing authorisation, in combination with aspirin plus clopidogrel or aspirin alone, for preventing atherothrombotic events in people who have had an acute coronary syndrome with elevated cardiac biomarkers. Clinicians should carefully assess the person's risk of bleeding before treatment with rivaroxaban is started. The decision to start treatment should be made after an informed discussion between the clinician and the patients about the benefits and risks of rivaroxaban in combination with aspirin plus clopidogrel or aspirin alone. A decision on continuation of treatment should be taken no later than 12 months after starting treatment. Clinicians should regularly reassess the relative benefits and risks of continuing treatment with rivaroxaban and discuss them with patient. While patients will commence treatment in secondary care the majority of the costs will be incurred in primary care. Based on TA236 – Ticagrelor for Acute Coronary Syndromes, which is a drug used for the same patient group, it is estimated that 88% of the total drug cost would be in primary care.
3	**Number of people in Northern Ireland expected to take up service/therapy** *(including new cases per year)* *NICE assumptions, based on the manufacturer's estimates, on uptake of treatment options for patients with STEMI or NSTEMI eligible for treatment for secondary prevention of atherothombotic events* **Treatment interventions available** / **Current** / **Future** Aspirin + ticagrelor / 0.5% / 0.5% Aspirin + prasugrel / 0.5% / 0.5% Aspirin + clopidogrel / 99% / 85% Aspirin + clopidogrel + rivaroxaban / n/a / 14% In the TA NICE acknowledged that the use of aspirin plus clopidogrel was already falling in the UK, with local protocols being applied as to the choice of other drugs

	for this indication. These assumptions were discussed with the Regional Cardiology Implementation Group. The broad consensus was that current practice in NI is already considerably different than the TA assumptions. There is a recently agreed regional protocol for the use of aspirin plus ticagrelor in STEMI, so prasugrel is not used for that indication. It was advised that in NI the patient groups covered by this TA were possibly already 50% on aspirin and ticagrelor and 50% aspirin and clopidogrel. In this scenario it was felt that rivaroxaban would not be used in routine practice in NI for this patient group.
4	**Patient Access Scheme availability** Not applicable
5	**Costs** *(before PAS if applicable)* The NICE TA states 'there is no change expected in the number of people currently having aspirin plus prasugrel or aspirin plus ticagrelor.' NICE expected that only the people currently treated with aspirin with or without clopidogrel would switch to rivaroxaban, in combination with aspirin with or without clopidogrel, upon the implementation of the guidance. In their submission, the manufacturer expected the market share of rivaroxaban to increase from 0% to 5% in year one (in 2015/16) and rise to 14% by 2017/18 (year 3) *and this is assumed to be the steady state (recurring position).* Under NICE standard assumptions, the gross drug cost of treating 14% of this cohort of patients by 2017/18 is estimated at £283k However, based on local clinical advice, a much higher proportion of the eligible patient cohort are already receiving aspirin and ticagrelor and the likelihood of any significant use of rivaroxaban as a treatment option is low.
5.1	**Drug cost per patient per annum (for new and prevalent cases)** Rivaroxaban 2.mg b.d. for 12 months =£764.40 Uptake in Northern Ireland is expected to be minimal.
5.2	**Infrastructure costs per patient per annum** If rivaroxaban was to be used there could in theory be additional costs in primary care associated with more frequent monitoring of patients. However, as uptake is expected to be minimal, infrastructure costs are assumed to be zero.
5.3	**Current in year costs** Uptake in Northern Ireland is expected to be minimal.

5.4	**Recurrent overall costs per annum** *(including additional costs)* At the present time there is no indication that the implementation of NICE TA335 should increase costs. This is the same patient group i.e. STEMI, NSTEMI and unstable angina which was addressed in NICE TA 236 - Ticagrelor for Acute Coronary Syndromes. The implementation of NICE TA236 was supported by an allocation of £1.4m of which £120k was to support implementation in secondary care. The original allocation assumed capitation usage while actual usage more closely matches PCI activity which is delivered in three Trusts. Funding will be adjusted to reflect actual costs. There will be on-going monitoring of Rivaroxaban as part of monitoring of uptake of a new oral anti-coagulants (NOACs)
5.5	**Opportunities for cost savings and how these will be secured** Not applicable
6	**Expected implementation period** Immediate
7	**Commissioning arrangements** There is no additional resource required.
8	**Monitoring arrangements** There will be on-going monitoring of Rivaroxaban as part of monitoring of uptake of new oral anti-coagulants (NOACs).
9	**DHSSPS 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.