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

Health and Social Care Board

1	**Treatment & Condition** Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism
2	**Associated appraisal body & Summary of ruling** NICE technology appraisal guidance 327 Dabigatran etexilate is recommended, within its marketing authorisation, as an option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults.
3	**Number of people in Northern Ireland expected to take up service/therapy** (including new cases per year) • Estimate 1737 incident cases of DVT/PE per year (using age specific incidents rates applied to NI population) • From NICE TA 327 estimate 52% of DVT/PE get NOACS (remaining 48% warfarin) and that 12% of DVT/PEs prescribed NOACs will get dabigatran = 6.24% • 6.24% of 1737 incident cases **= 108 patients/year expected to start on Dabigatran** There may also be prevalent cases on life-long warfarin switched to Dabigatran; however Rivaroxaban is expected to be a more favourable option due to better tolerance in renal function and no need for LMWH cover during initiation period.
4	**Patient Access Scheme availability** Not applicable
5	**Costs** (before PAS if applicable)
5.1	**Drug cost per patient per annum (for new and prevalent cases)** **New case** – cost per patient depends on the duration of treatment. Treatment with dabigitran requires an initial 9 days treatment with low molecular weight heparin. The cost of this has not been included in these calculations as this is required irrespective of whether warfarin or NOAC is used for treatment. The duration of treatment varies and can be 3 months, 6 months, 12 months or lifelong use. Costs are as follows: • £200 per patient for 3 months of treatment • £402 per patient for 6 months treatment and

- £802 for 12 months of treatment (taken from NICE TA 327 costing report)

Prevalent cases NICE estimate that around 50% cases will go on to have lifelong treatment which they report costs £802 per patient per annum (taken from NICE TA 327 costing report)

5.2 **Infrastructure costs per patient per annum**

Renal function at baseline and at least annual monitoring (U&E blood testing)
Cost of U&E <£10 per test = £20 annually per patient.

5.3 **Current in year costs**

In year costs will be approximately £38k

5.4 **Recurrent overall costs per annum** (including additional costs)

The cost of treating new patients depends on the duration of their treatment. For the purposes of this calculation it is estimated that 30% patients will be treated for 6 months or less and that 70% patients will be treated for at least 12 months in their first year.

Recurrent costs are likely to increase annually as at least 50% of patients are expected to require lifelong treatment (based on NICE TA 327) and there will be new incident cases each year which will then add to the prevalent pool of patients.

	Year 1	Year 2	Year 3	Year 4	Year 5
New cases	108	108	108	108	108
Cost of treating 30% patients for 6 months	35.52 x £402 = £14,279.04				
Cost of treating 70% patients for 12 months at £802 per patient per year	75.99 x £802 = £60,855.76				
Total cost of all new patients	£75,134.80	£75,134.80	£75,134.80	£75,134.80	£75,134.80
Cases progressing to lifelong treatment (assumed to be 50% of cases)	0	54.2	162.6	216.8	271

	Cost (£802 pp per year)	£0.00	£43,468.40	£130,405.20	£173,873.60	£217,342.00
	Total Costs	**£75,134.80**	**£118,602.80**	**£205,540.00**	**£249,008.40**	**£292,476.80**

Most of the costs of implementing TA327 and other new oral anti –coagulants (NOACs) fall to Primary Care. Approximately 1/12 (the first month's supply) of total costs will fall to Secondary Care.

Growth in this medication is proceeding faster than expected and may create a pressure in Primary Care and Secondary Care.

Expenditure on all NOACs for 2014-15 is approximately £3.5m. Uptake is proceeding faster in some Trust and LCG areas.

Funding of £225k has been provided to Secondary Care in 2014/15. Actual spend in Secondary Care is estimated at £300k.

Further funding of £175k has been earmarked for Secondary Care for 2015/16.

The overall position on uptake by Trust will continue to be reviewed and monitored.

5.5 Opportunities for cost savings and how these will be secured

Potential savings from no requirement for INR monitoring.
The costs of INR monitoring are difficult to quantify as there are several different delivery contexts including GP practice, domiciliary, INR clinic. NICE TA362 (Rivaroxaban for DVT/VTE) estimates the cost of first year of INR monitoring as £302 (Initial visit £22 plus 14 visits) and subsequent annual costs to be up to £240 (12 visits costing £20 per visit). However this must be offset against the need for monitoring of renal function at least twice annually in patients taking NOACs.

Potential savings from reduction in recurrent VTE.
The evidence presented in NICE TA 327 suggests equivalence of warfarin and dabigatran in preventing VTE, so there are unlikely to be significant reductions.

6 Expected implementation period

To commence 1st April 2015 – no implementation period anticipated

7 Commissioning arrangements

None

8 Monitoring arrangements

Majority of costs expected to be incurred in Primary Care – spend will be monitored as

	part of primary care prescribing budget
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.