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

Health and Social Care Board

1	**Treatment & Condition** *(Title)* Edoxaban for treating and for preventing deep vein thrombosis and pulmonary embolism
2	**Associated appraisal body** *(NICE/SMC/Other)* ***&*** **Summary of ruling** *(to include indication, restrictions, other relevant information)* NICE technology appraisal guidance 354. Edoxaban (Lixiana, Daiichi Sankyo) is an anticoagulant that directly inhibits factor X (factor Xa), which is a key component in the formation of blood clots. Edoxaban has a marketing authorisation for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. It is administered orally. The recommended dosage of edoxaban is 60 mg once daily, or 30 mg once daily in specific patient groups (people with renal impairment, low body weight [60 kg or less], or concomitant use of potent permeability glycoprotein [P glycoprotein] inhibitors), following treatment with a parenteral anticoagulant for at least 5 days.
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). NICE have not estimated the percentage of patients who will get Edoxaban as a proportion of the population on NOACs • = 6.24% of 1737 incident cases There may also be prevalent cases on life-long warfarin switched to a NOAC. As edoxaban is an alternative to rivaroxaban, dabigatran etexilate and apixaban and the all four drugs are similarly priced, NICE does not anticipate a significant impact on resources as a result of implementing the guidance.
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)** Drug cost per patient depends on length of treatment. One year's treatment costs £767 which is similar to other NOACs. Prevalent cases: NICE estimate that between 28 and 50% patients being treated for this indication will go on to receive life long therapy. The cost for each patient will be in the region of £800 per annum irrespective of what NOAC is used.
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** It is not possible to estimate as the uptake of Edoxaban compared to other NOACs. Edoxaban is likely to be a replacement for other agents currently in use.
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. Most of the costs of implementing TA354 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 in Primary Care for 2015-16 is approximately £7m. Uptake is proceeding faster in some Trust and LCG areas. Cumulative recurrent funding of £525k has been provided to Secondary Care in 2014-15 and 2015-16. Further funding will be provided in 2016-17 to Secondary Care. The overall position on uptake by Trust and LCG 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** No implementation period anticipated.
7	**Commissioning arrangements** No specific commissioning arrangements are required
8	**Monitoring arrangements** The majority of costs are expected to be incurred in Primary Care – any spend will be monitored as part of primary care prescribing budget
9	**DHSSPS Legislative/Policy Caveats** *(NICE guidance only)* 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.