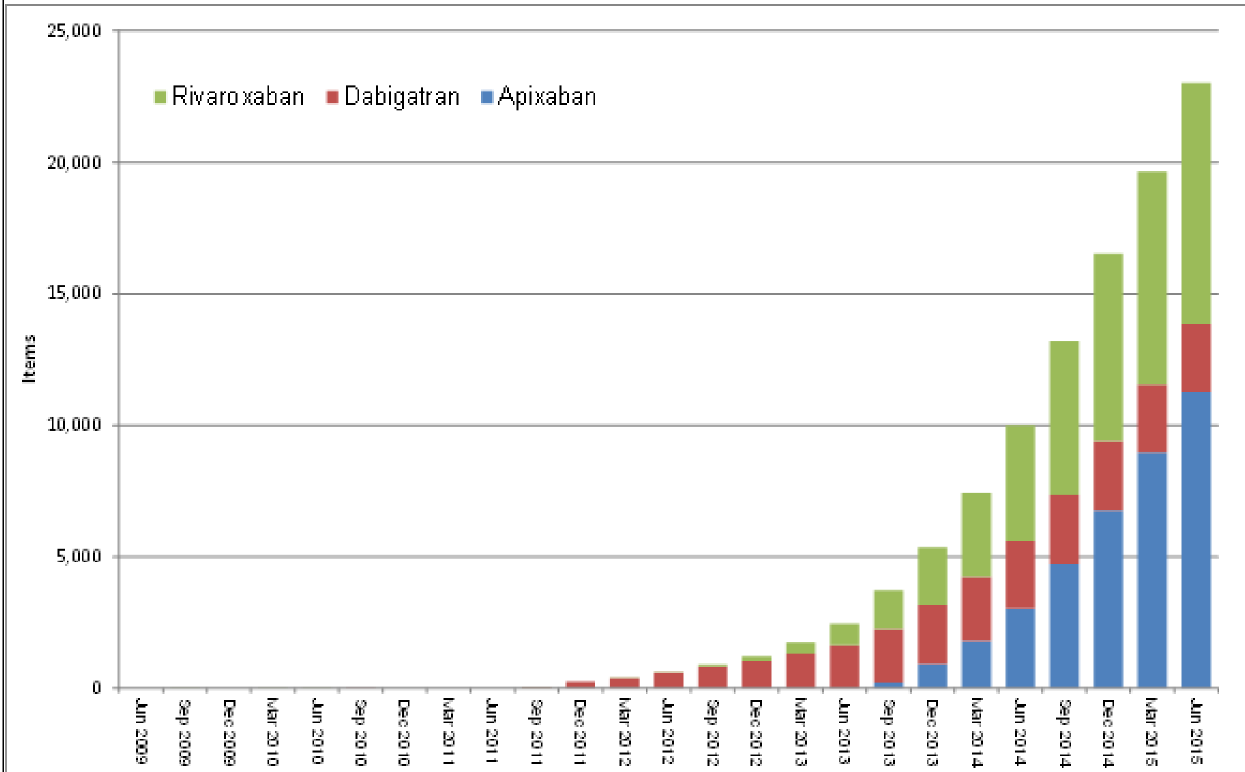
HSCB Service Notification for the managed entry of new medicines and technologies

Health and Social Care Board

1	**Treatment & Condition** Edoxaban for preventing stroke and systemic embolism in people with nonvalvular atrial fibrillation
2	**Associated appraisal body & Summary of ruling** NICE technology appraisal guidance 335. 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. It is administered orally. Edoxaban has a marketing authorisation for the 'prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age 75 years or older, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).' The summary of product characteristics states that the recommended dose is 60 mg once daily. The recommended dose is 30 mg once daily in people with one or more of the following clinical factors: moderate or severe renal impairment (creatinine clearance 15–50 ml/min); body weight of 60 kg or less; concomitant use of the P-glycoprotein inhibitors ciclosporin, dronedarone, erythromycin or ketoconazole. There was insufficient evidence to distinguish between the clinical and cost effectiveness of edoxaban and the newer oral anticoagulants recommended in previous appraisals (apixaban, dabigatran etexilate and rivaroxaban). Therefore, edoxaban could be recommended as a cost-effective treatment for non-valvular atrial fibrillation in people who have 1 or more risk factors for stroke.
3	**Number of people in Northern Ireland expected to take up service/therapy** Since 2006/7 there has been a 35% increase in numbers of cases of atrial fibrillation recorded on GP registers. In March 2015, 30,758 patients were recorded on GP registers as having Atrial Fibrillation.

Uptake of Rivaroxan, Dabigatran and Apixaban for the treatment of atrial fibrillation



4 Patient Access Scheme availability

Not applicable

5 Costs *(before PAS if applicable)*

The NICE Appraisal committee commented that ‘Edoxaban was more expensive and less effective than at least one of the alternative treatments. When all of the ERG's preferred values were used in the model the pairwise deterministic ICER for the comparison of edoxaban with warfarin was £16,008 per QALY gained, and the probabilistic ICER was £22,079 per QALY gained.

When additional alternative amendments were included to reconcile the model survival outputs with the trial data, and to reflect the changing age and sex distribution over time, this changed the deterministic pairwise ICER to between approximately £15,176 and £15,807, and the probabilistic ICER to between £21,728 and £23,634 per QALY gained’

5.1 Drug cost per patient per annum (for new and prevalent cases)

Edoxaban costs £58.80 for a 28‑tablet pack (60 mg or 30 mg) and the daily cost of treatment is £2.10 (excluding VAT). Annual cost per patient= £764.40

5.2	**Infrastructure costs per patient per annum** No additional costs anticipated as funding has already been made available for previous TA for the introduction of dabigatran, rivarobaxan and apixaban.
5.3	**Current in year costs** No additional costs
5.4	**Recurrent overall costs per annum** *(including additional costs)* The accompanying NICE costing template for TA 355 advises the following: Edoxaban provides another option for preventing stroke and systemic embolism in adults with non-valvular atrial fibrillation with one or more risk factors including congestive heart failure, hypertension, diabetes, prior stroke or transient ischaemic attack, or age 75 years or older. As Edoxaban is an alternative to rivaroxaban, dabigatran etexilate and apixaban and the four drugs are similarly priced, NICE does not anticipate a significant impact on resources as a result of implementing the guidance. 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. Costing templates for these NOACs identified a maximum spend of £4.5m per year in 5 years. However, in N.I, it is estimated that in 2015/16 approximately £9m will be spent in Primary Care on NOACs. It is estimated that a further £1m will be required by HSC Trusts. Given the growth profile, it is estimated that £12m will spent in primary care in 2016/17. The expenditure on NOACs is causing significant pressure on the budget for prescribing. Despite best efforts to deliver the Pharmaceutical Clinical Effectiveness Programme, it will be exceptionally challenging to achieve financial balance. 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** No opportunities for cost savings anticipated.
6	**Expected implementation period** There are no anticipated barriers to immediate implementation.

7	**Commissioning arrangements** The Medicines Management Commissioning team will continue to monitor the usage of all NOACS including Edoxaban.
8	**Monitoring arrangements** The prescribing trends for this budget will be monitored closely by practice prescribing advisers. The Medicines Management Commissioning team will track trends in the use of this drug.
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.