



17<sup>th</sup> June 2014

**Dabigatran (Pradaxa®) for the treatment and prevention of recurrent Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE) in adults.**

**The New Therapies Subgroup (NTS) discussed the above drug at a meeting on the 17<sup>th</sup> June 2014. The recommendation of this subgroup is as follows:\***

The New Therapies Subgroup of the GMMMG considered the use of dabigatran for the treatment and prevention of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE) in adults.

**The group does not recommend the routine use of dabigatran for the above indication; however it may be suitable for use in patients who are not suitable for LMWH plus warfarin or for rivaroxaban.**

The group noted that dabigatran was found to be non-inferior to warfarin but superior to placebo. The need for parenteral anticoagulation prior to giving dabigatran for 5-10 days initially was felt to be a disadvantage compared to rivaroxaban which is also licensed for this indication.

According to set criteria dabigatran for the above indication was deemed to be a low priority for funding

Review date: June 2016

\* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

## **Further information / commissioning implications for CCGs**

Spend on newer oral anticoagulants is currently shows a high degree of variation across GM CCGs. The NICE costing template for rivaroxaban in PE and VTE [TA287] has been used to give a starting point for considering potential increased costs of dabigatran prescribing in VTE but it is acknowledged that dabigatran has a slightly cheaper list price and also that CCG rebate schemes are in place which reduce the costings shown. Note that the levels of rebate are commercially sensitive.

### Recommendation / Future commissioning implications

NOACs are already recommended for use in line with NICE guidance for AF and VTE where there is an existing positive Technology Appraisal. NICE intends to issue a Technology Appraisal guidance for use of dabigatran etexilate in deep vein thrombosis and pulmonary embolism in October 2014 [ID483].

### Formulary and Interface considerations

Dabigatran is already included in the GMMMG formulary with a reference to the NICE clinical guideline on venous thromboembolism [CG144]. NOACs have a green RAG rating.

### Summary of impact

Patterns of usage are already variable and may suggest variable local commissioning arrangements. Use in VTE prevention is thought to be low in all CCGs apart from Bolton and as the drug is a low priority for funding, this recommendation is unlikely to have significant impact.