Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	3rd June 2014
Appraisal & Details	**Rivaroxaban (Xarelto®▼) for acute coronary syndromes.** The Northern (NHS) Treatment Advisory Group considered an appraisal of rivaroxaban (Xarelto®▼, Bayer) for the prevention of atherothrombotic events in adults after an acute ACS with elevated cardiac biomarkers.
Recommendation	**The Northern (NHS) Treatment Advisory Group does not recommend Rivaroxaban (Xarelto®▼) for acute coronary syndromes.** The group was concerned with the quality of the clinical evidence (i.e. license based on one clinical trial with no active comparator and vital status missing for 8.4% of trial participants).
Clinical evidence summary	The group considered the evidence from the phase III double blind placebo controlled trial that looked at adding rivaroxaban 2.5mg to either aspirin on its own or with clopidogrel. The group noted that adding rivaroxaban 2.5mg to current therapy reduced the rate of the primary composite outcome of cardiovascular death, non-fatal MI or stroke compared to placebo. The NNT for 2 years to prevent one event was 63. However the group was concerned about the applicability of this to the local population. Due to trial exclusion criteria, patients were likely to be at lower risk of bleeding than is typical. The mean age of participants was 62 years and only one third were over 65, contrasting with a mean age of 71 for patients with acute MI in England. There are no data available on combining rivaroxaban with other drugs used in ACS such as ticagrelor or prasugrel.
Safety	Major bleeding (drop in haemoglobin of at least 5g/dL) was significantly more common with rivaroxaban 2.5 mg than placebo, as were bleeding requiring medical attention and intracranial haemorrhage but there was no difference in the incidence of fatal bleeding. The NNH for two years to cause one additional major bleed was 84, and the NNH for two years to cause one bleed requiring medical attention was 19. There was no difference in the incidence of non-bleeding adverse events.
Patient Perspective	Since anticoagulants have not routinely been added to therapy post-ACS, the patient impact of rivaroxaban is difficult to predict. Safety concerns, particularly the risk of bleeding, are likely to be a major factor. Counselling will be required on the appropriate management of any bleeding events. The problem of polypharmacy should also be considered, since the target population are likely to already be receiving several medicines.
Cost analysis summary	Rivaroxaban is administered at a dose of 2.5 mg twice daily for ACS. A cost for the 2.5mg formulation is not currently available. It is estimated that addition of rivaroxaban (at an estimated cost of £2.10 per tablet) for 25-100% of eligible people would cost an additional £58,000-£232,000 per 100,000 people per year.
Financial impact **PbR: In-tariff**	The potential financial impact of adding rivaroxaban to all patients with ACS on aspirin and clopidogrel treatment would be high. The financial impact of this recommendation is expected to be nil.