

## New from NICE

### Technology appraisal. Apixaban for the prevention of stroke and systemic embolism in people with nonvalvular atrial fibrillation with one or more risk factor for stroke or systemic embolism. TA275. **Recommended.**

In 2012 NICE recommended the Factor Xa inhibitor rivaroxaban (Xarelto) and the direct thrombin inhibitor dabigatran etexilate (Pradaxa) as options for the prevention of stroke and systemic embolism in people with nonvalvular atrial fibrillation with one or more risk factors. It has now made the same recommendation for apixaban (Eliquis), also a Factor Xa inhibitor.

The list of risk factors for apixaban and rivaroxaban is similar (prior stroke or transient ischaemic attack, age 75 years or older, hypertension, diabetes and heart failure) but the use of dabigatran is limited to patients aged over 75, or over 65 if they have diabetes, coronary artery disease or hypertension.

Choosing between one of these anticoagulants and warfarin should be made after an informed discussion about their risks and benefits. For people who are taking warfarin the potential risks and benefits of switching to an alternative anticoagulant should take into account the quality of their control according to the proportion of time spent within the target INR range.

NICE's recommendation is based on the ARISTOTLE trial, a large randomised study comparing apixaban with warfarin. It concluded that apixaban was more effective than warfarin for reducing stroke and systemic embolism and was associated with a lower risk of bleeding. Patients recruited to this trial were broadly representative of the UK population and there was no evidence of differences in efficacy in various subgroups, including those with different levels of control with warfarin.

Treatment with apixaban costs about £800 per year. NICE concluded that it is cost effective compared with warfarin, with a cost per QALY below £20 000.

This latest recommendation begs the question of which of the three new anticoagulants offers best value

for money. NICE noted the 'considerable uncertainty' around their relative treatment effects and cost effectiveness and concluded there is currently insufficient evidence to distinguish between them.

### Technology appraisal. Ranibizumab for the treatment of diabetic macular oedema (rapid review of TA237) TA274. **Recommended.**

In November 2011, NICE did not recommend ranibizumab (Lucentis) for the treatment of visual impairment due to diabetic macular oedema as an effective use of NHS resources, criticising the manufacturer's economic model for not adequately reflecting clinical practice.

Manufacturer Novartis subsequently updated its economic model to demonstrate greater efficacy in patients with central retinal thickness of  $\geq 400\mu\text{m}$ . It also offered a price cut as part of a confidential Patient Access Scheme. NICE has now conducted a rapid review and recommended ranibizumab for this group of patients.

Using the revised model, NICE estimated that the cost per QALY compared with laser photocoagulation for treating all patients with diabetic macular oedema with ranibizumab would be approximately £43 000 – above the usual value-for-money threshold. However, in patients with worse vision – defined as a thicker central retina – the figure would be below £25 000, making treatment cost effective. Clinicians advised that patients treated with ranibizumab are likely to have had laser photocoagulation previously but NICE found no evidence about the merits of sequential treatment and made no recommendation on this indication.

NICE had intended its appraisal to include a comparison between ranibizumab and bevacizumab, which is being used in some trusts to treat diabetic macular oedema though it is not licensed for this indication. Novartis did not offer any evidence, stating there were insufficient data on the safety and effectiveness of bevacizumab. NICE agreed, noting that the issue is currently being considered by its Decision Support Unit.