

National Institute for Health and Clinical Excellence

**Rivaroxaban for the treatment of deep vein thrombosis and prevention
of recurrent deep vein thrombosis and pulmonary embolism**

Royal College of Nursing

Introduction

The Royal College of Nursing (RCN) was invited to review the Appraisal Consultation Document (ACD) for Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism.

Nurses caring for people with deep vein thrombosis and pulmonary embolism reviewed the documents on behalf of the RCN.

Appraisal Consultation Document – RCN Response

The Royal College of Nursing welcomes the opportunity to review this document. The RCN's response to the four questions on which comments were requested is set out below:

i) **Has the relevant evidence has been taken into account?**

The evidence review seems comprehensive.

ii) **Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**

We note that the Committee requested further information about the clinical and cost effectiveness of rivaroxaban for consideration at the next committee meeting. The RCN looks forward to receiving the

outcome of the committee's deliberation following the review of the new information provided by the manufacturers.

The fact that the new anticoagulant does not require monitoring is raised as a benefit; however this could be misrepresented because all medication requires patient consultation. There is concern about the twice daily initial dose and the switch to once a day dose. There has to be very clear pathway on how this is introduced. Patient education is vital with particular reference to the [NICE Medicine Adherence guideline \(CG76\)](#); otherwise there is a potential risk of increase in the incidence of pulmonary embolism.

Patients who develop DVT post surgery or have distal DVTs are on anticoagulation therapy for three months. There appears to be lack of information for this group of patients in the ACD.

Given the lack of evidence on the use of this drug for longer than twelve months, does this mean that patients need to be switched to warfarin after twelve months?

We are concerned about the increased risk of bleeding.

The cost of monitoring of the current oral anticoagulation appears to be higher.

This new oral anticoagulant appears to be less effective compared to LMWH in patients with cancer so there appears to be a need for exclusion criteria. However, this also raises some issues; for example, potential increase in medication error - if clinicians are expected to use several different anticoagulants, standardising practice could be an issue therefore introducing potential risk to patient safety.

We would ask that the summaries of the clinical and cost effectiveness of this appraisal be aligned to the clinical pathway followed by people

with deep vein thrombosis and pulmonary embolism. The views on resource impact and implications should be in line with established standard clinical practice.

iii) **Are the provisional recommendations sound and a suitable basis for guidance to the NHS?**

Nurses caring for people with this condition have reviewed the recommendations of the Appraisal Committee and do not have any other comments to add at this stage.

iv) **Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?**

None that we are aware of.

v) **Are there any equality-related issues that need special consideration that are not covered in the appraisal consultation document?**

We are not aware of any specific issue at this stage. We would ask that any guidance issued should show that an analysis of equality impact has been considered and that the guidance demonstrates an understanding of issues relating to all the protected characteristics where appropriate.