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

AntiCoagulation Europe (ACE) wish to make the following observations in response to Appraisal to the Consultation Document for the above technology

The Committee has acknowledged the challenges surrounding the current standard treatment practice of LMWH and VKA – warfarin.

Rivaroxaban offers an alternative treatment option for eligible patients presenting with a Pulmonary Embolism (PE) and /or a Deep Vein Thrombosis (DVT) Studies show that it is non - inferior to LMWH and the Committee has concluded that it is more effective than enoxaparin and VKA in preventing VT recurrences. From the patient's perspective, as an oral therapy, it is easier to administer than LMWH subcutaneous injections which are painful and cause bruising.

This single drug approach offers continuity and consistency in anticoagulation therapy. It will negate the need for patients to be weaned from LMWH onto dose adjusted warfarin which requires monitoring by frequent blood tests either in a primary or secondary care setting. As warfarin is affected by diet and interacts with many other drugs including 'over the counter' medicines – the adjustments required to stay with INR targets can be challenging and can cause anxiety for the individual.

With an aging working population, people who experience a DVT/PE will be required to take time off work to have their INR monitored and this can be demanding if they commute or travel for their work. Individuals with reduced mobility or who live remotely, can be greatly inconvenienced by having to make arrangements for transport/carers to help them attend GP or hospital anticoagulation clinics

Whilst the majority of patients may accept that checking INR levels is necessary in order to help them prevent further events; the need for continuous monitoring can have a detrimental impact with clinic visits being a constant reminder of the negative outcomes of a VTE episode. These regular visits reinforce their dependency on clinical intervention in order to 'check' they are getting the adequate protection they require.

The Committee has acknowledged the variations in the frequency of INR monitoring in clinical practice in the UK and have accepted that 6 visits in the first three months and 2/3 in the three months thereafter are reasonable. Stabilising on warfarin varies from individual to individual and some people despite frequent testing do not increase their TTR and could be tested far more frequently than the figures presented in the ACD[1]

We note that the Committee have requested further information from the manufacturer for patients where long –term anticoagulation is intended. Patients who may be considered for this treatment in the short term but who may benefit from a term exceeding the current duration period should not be

discriminated against if this treatment will provide safe and effective protection against potential further VTE episodes.

As NICE will be considering this treatment for use in the UK, The Scottish Medicines Consortium(SMC) decision to accept this treatment is an acknowledgement of it's approval for use on eligible patients.

Rivaroxaban being one of a range of new oral anticoagulants brings an innovative new treatment option to the existing standard practice. It will be of benefit to new and existing patients at risk of VTE by giving reassurance and effectiveness with a one dose approach which will be far simpler and straight forward to manage for patients and their healthcare professionals.

Anticoagulation Europe(ACE)

4 April 2012

[1] Rose P, James R, Chapman O, Marshall S. A real world evaluation to describe the characteristics, outcomes and resource use associated with patients being managed by a secondary care based anticoagulation service. Accepted for poster presentation at 14th Annual European Congress of ISPOR(International Society of Pharmacoeconomics and Outcomes Research)2011