NHS
Fylde and Wyre
Clinical Commissioning Group

Rivaroxaban (Xarelto®▼) 10mg tablets

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and extended prevention of recurrent DVT and PE in adults

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed to fund the prescribing of Rivaroxaban (Xarelto®) 10mg tablets for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and extended prevention of recurrent DVT and PE in adults:

- Short duration of therapy (at least 3 months) should be considered in patients with DVT or PE provoked by major transient risk factors (i.e. recent major surgery or trauma). Longer duration of therapy should be considered in patients with provoked DVT or PE not related to major transient risk factors, unprovoked DVT or PE, or a history of recurrent DVT or PE

This medicine is classified as AMBER 0 for this indication

Summary of evidence:

- In the Phase III EINSTEIN CHOICE study, rivaroxaban 20 mg and 10 mg once daily were superior to acetylsalicylic acid (ASA) 100 mg once daily for the extended treatment of recurrent venous thromboembolism (VTE) with no significant differences in bleeding rates. Patients treated with rivaroxaban 20 mg and 10 mg had comparable efficacy and safety outcome rates. Both rivaroxaban groups had a favourable net clinical benefit over the ASA group with comparable results for the two rivaroxaban groups. Following completion of at least 6 months of treatment for deep vein thrombosis (DVT) or pulmonary embolism (PE), rivaroxaban 10 mg provides an additional option for extended treatment to the approved rivaroxaban 20 mg dose.
- The primary efficacy outcome of symptomatic recurrent fatal or nonfatal venous thromboembolism occurred in 17 of 1107 patients (1.5%) receiving 20 mg of rivaroxaban and in 13 of 1127 patients (1.2%) receiving 10 mg of rivaroxaban, as compared with 50 of 1131 patients (4.4%) receiving aspirin.
- Rates of major bleeding were 0.5% in the group receiving 20 mg of rivaroxaban, 0.4% in the group receiving 10 mg of rivaroxaban, and 0.3% in the aspirin group; the rates of clinically relevant nonmajor bleeding were 2.7%, 2.0%, and 1.8%, respectively.
- A Cochrane review on the Secondary prevention of recurrent venous thromboembolism after initial oral anticoagulation therapy in patients with *unprovoked* venous thromboembolism (2017) found that the evidence is currently insufficient to permit definitive conclusions concerning the effectiveness and safety of extended thromboprophylaxis in prevention of recurrent VTE after initial oral anticoagulation therapy among participants with unprovoked VTE.

- A subset of patients with unprovoked thromboembolism in the EINSTEIN CHOICE study was included in this review however some outcome data was not made available for the analysis; the Cochrane review intends to update its findings when these become available. Cochrane concludes that additional good quality large-scale randomised controlled trials are required before firm conclusions can be reached.

For details around the evidence, cost effectiveness and for an explanation of the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/