Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Final Appraisal Recommendation

Advice No: 1721 – December 2021

Rivaroxaban (Xarelto®) 1 mg/mL granules for oral suspension and 15 mg and 20 mg film-coated tablets

Licence extension for paediatric use submission by Bayer plc

Recommendation of AWMSG

Rivaroxaban (Xarelto®) granules for oral suspension and film-coated tablets are recommended as an option for use within NHS Wales, for the treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in term neonates, infants and toddlers, children, and adolescents aged less than 18 years after at least 5 days of initial parenteral anticoagulation treatment.

Additional note(s):

- See NICE guidance for rivaroxaban (Xarelto®) for treating pulmonary embolism and preventing recurrent venous thromboembolism (TA287; originally published June 2013) and NICE guidance for rivaroxaban (Xarelto®) for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism (TA261; originally published July 2012).

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3875), which includes the All Wales Therapeutics and Toxicology Centre (AWTTC) assessment, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.

This recommendation has been ratified by Welsh Government and will be considered for review every three years.