South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference	**132**
Intervention:	**Rivaroxaban 1mg/ml granules for oral suspension and 2.5mg, 15mg and 20mg tablets for treatment of venous thromboembolism (VTE) in paediatrics (aged less than 18 years old)** (Rivaroxaban is an anticoagulant)
Date of Decision	**March 2022**
Date of Issue:	**April 2022 – time limited approval to December 2022**
Recommendation:	**RED – suitable for prescribing and supply by hospital only**
Further Information	• Rivaroxaban is accepted for use in SEL as an **alternative first line option** alongside current anticoagulant treatments (warfarin or low molecular weight heparin) for the treatment of venous thromboembolism (VTE) in paediatrics (aged less than 18 years old) where patients meet the following criteria: - A confirmed diagnosis of VTE has been made - Age range from term neonate* (at least 37 weeks of gestation and at least 10 days of oral feeding) to < 18 years old. **Current weight of at least 2.6kg in term neonates* - At least 5 days of parenteral anticoagulation treatment has been completed - Baseline blood tests (FBC, LFTs, renal function and baseline clotting screen) have been taken in the last 28 days and results are available. • For all children aged less than 18 years old ***(except those less than 2 years old with catheter-related thrombosis – see below for this cohort)*** the recommended treatment is for 6 weeks to 3 months. This can be extended for up to 12 months using clinical discretion on an individual patient basis. • For all children aged less than 2 years **with catheter-related thrombosis** the recommended treatment is for at least 1 month. This can be extended for up to 3 months using clinical discretion on an individual patient basis. • Rivaroxaban 1mg/ml granules for oral suspension and rivaroxaban 15mg tablets are the only rivaroxaban preparations licensed for the treatment of VTE. The use of rivaroxaban 2.5mg and 20mg tablet is **off-label**. • The dose range for rivaroxaban in this setting is 0.8mg three times a day to 20mg once a day depending on the weight of the child. Weight and rivaroxaban dose should be monitored and reviewed regularly to ensure therapeutic dose is maintained. • Parents/carers and/or children should be counselled on the appropriate administration, interactions, management of missed doses and monitoring requirements as described in the product information. • Rivaroxaban 1mg/ml granules for oral suspension has specific dose administration instructions and once reconstituted, the suspension has an expiry of 14 days. Appropriate counselling and adequate supply is recommended. • This approval is **time limited to 9 months** to enable experience of use with rivaroxaban in this patient cohort. A report summarising outcomes with rivaroxaban over this period will be presented back to the Committee after 9 months. This report will be coordinated across all Trusts in SEL using rivaroxaban in this setting by the formulary applicants and will include: - Total number of patients initiated on treatment, separated into the number from within SEL and outside SEL. - Total number of patients who have had 3 months treatment vs. extended treatment & the specific indications - For any patients currently prescribed 3 months treatment at the time of the report, what is the anticipated duration of treatment - Total number of patients attending the Trust for other treatments/prescriptions

	- Adverse effects and/or medicine safety incidents - Any feedback from parents/patients regarding the provision of rivaroxaban prescriptions and monitoring in this setting
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	• It is estimated there will be approximately 65 patients per annum eligible for treatment with rivaroxaban for the management of VTE with the majority from SEL. • Assuming 75% of patients are ≥30kg, the average cost for each 3 month course is £135.50. If 20% of patients need 12 months as opposed to 3 months treatment, this equates to approximately £14,000 costs per annum in SE London (~ £737 per 100,000 population). • If warfarin suspension was required in 50% of patients based on an average dose of 3mg, the average cost per 3 month course is £136. If 20% of patients needed treatment for 12 months, this equates to £13,500 per annum costs in SE London (~ £700per 100,000 population). • Based on these estimates, overall drug costs for implementing rivaroxaban could be cost neutral.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor and audit usage of rivaroxaban as agreed and report back to the Committee in 9 months (data to be collated and presented no later than **December 2022**)
	SEL borough Medicines Optimisation teams: • Monitor ePACT2 data • Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care
Evidence reviewed	**References (from evidence review)** 1. Xarelto (rivaroxaban) – Public Assessment Report (variation), European Medicines Agency, November 2020. 2. Chalmers E, Gansen V, Liesner R et al. Guidelines on the investigation, management and prevention of venous thrombosis in children. British Journal of Haematology 2011 154 p196 to 207. 3. Xarelto, Summary or Product Characteristics. [online] Available here (accessed 26/11/2021). 4. Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism (TA261) NICE, July 2012. 5. Male C, Lensing A, Palumbo J et al. Rivaroxaban compared with standard anticoagulants for the treatment of acute venous thromboembolism in children: a randomised controlled phase 3 trial. Lancet Haematology 2020 7 (10) E18-E27. 6. Rivaroxaban (Xarelto®) 3875. All Wales Medicines Strategy Group December 2021. [Online] Available here (accessed 14/12/2021).

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.
b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS