

**South East London Integrated Medicines Optimisation Committee
(SEL IMOC, formerly the SEL Area Prescribing Committee)
Formulary recommendation**

Reference	122
Intervention:	Rivaroxaban for the treatment of left ventricular thrombus (LVT) in adults (off-label use) (Rivaroxaban is an anticoagulant)
Date of Decision	December 2020
Date of Issue:	January 2021
Recommendation:	RED – Prescribing and supply by hospital only
Further Information	<ul style="list-style-type: none"> • Rivaroxaban is accepted for use in South East London as a 2nd line anticoagulant treatment option for patients with left ventricular thrombus (LVT) in the following scenarios: <ul style="list-style-type: none"> (i) Post myocardial infarction + percutaneous intervention / in combination with dual antiplatelet therapy (DAPT – aspirin and clopidogrel). (ii) Secondary to dilated cardiomyopathy or left ventricular dysfunction • Warfarin remains the 1st line anticoagulant for the management of LVT. • Rivaroxaban may be considered as a 2nd line option for patients who cannot tolerate warfarin or for those in whom warfarin is not felt to be safe (determined by the initiating clinician). • The Trust thrombosis teams must be involved in any decision to use rivaroxaban for LVT. • Treatment with rivaroxaban would be stopped/switched if: <ul style="list-style-type: none"> - Treatment not tolerated - Thromboembolic event whilst on anticoagulation - Major bleeding risk or risk of bleed outweighs benefit of anticoagulation - Renal function declines to <30ml/min (would require discussion with the thrombosis team). • The usual treatment duration is 3 to 6 months, although a small proportion of patients may require longer term treatment. Cardiology will determine when treatment ends based on resolution of LVT on cardiac imaging. • As part of the risk management plan, local acute Trusts are required to ensure that there is robust governance in place at individual Trust level for the use of rivaroxaban in LVT. This includes the applicant developing agreed standardised criteria for use of rivaroxaban in this setting across SEL acute Trusts (detailed criteria for starting/stopping rivaroxaban and how outcomes will be monitored over time). The agreed standardised criteria should be approved through the individual Trust Drug and Therapeutics Committees and shared with the SEL IMOC for information. • Funding will need to be confirmed at individual Trust level as the complete treatment course for rivaroxaban in LVT will be prescribed and supplied by the hospital. • It should be noted that rivaroxaban is not licensed for use in this setting. Informed consent should be gained from the patient before treatment is started.
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> • The applicant estimates that 70 patients per annum for SEL, which equates to ~4 patients per 100,000 population, might be suitable for treatment. • Based on prevalence data, there are around 80,000 people in England admitted with MI per annum. Around 70% of these patients survive (56,000), and approximately 40% (22,000) go on to develop LVT. The majority of these will have warfarin, but approximately 20% (4,400) will require a DOAC. This equates to 8 patients per 100,000 population.

	<ul style="list-style-type: none"> Assuming between 4 – 8 patients per 100,000 population are treated for 6 months, this could result in a cost impact of between £1,080 to £2,176 per 100,000 population (or between £20K to 40K across SEL). Experts estimate around 25% of patients may require longer term treatment (1 -2 patients per 100,000 population).
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> Monitor use and report back to IMOC when required. Audit use upon request to ensure use is in line with this recommendation. <p>SEL CCG Borough Medicines Optimisation Teams:</p> <ul style="list-style-type: none"> Monitor exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	<p>References (from evidence evaluation)</p> <ol style="list-style-type: none"> G YH Lip (2019), Left ventricular thrombus after acute myocardial infarction, UpToDate,. Available at: https://www.uptodate.com/contents/left-ventricular-thrombus-after-acute-myocardial-infarction [last accessed 03/08/2020] F Habash et al (2017), Challenges in management of left ventricular thrombus, Therapeutic Advances in Cardiovascular Disease. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5933579/ [last accessed 05/08/2020] R Delewi et al (2012), Left ventricular thrombus formation after acute myocardial infarction, BMJ. Available at: https://heart.bmj.com/content/98/23/1743 [last accessed 05/08/2020] PT Vaitkus et al (1993), Embolic potential, prevention and management of mural thrombus complicating anterior myocardial infarction: a meta-analysis, Journal of the American College of Cardiology. Available at: https://pubmed.ncbi.nlm.nih.gov/8409034/ [last accessed 05/08/2020] NICE NG106 (2018) Chronic heart failure in adults: diagnosis and management. Available here. [last accessed 05/08/2020] NICE Pathways (2020) Preventing stroke in people with atrial fibrillation. Available at: http://pathways.nice.org.uk/pathways/atrial-fibrillation [last accessed 26/08/2020] NICE Pathways (2020) Anticoagulation treatment for venous thromboembolism. Available here. [last accessed 26/08/2020] WN Kernan (2014), Guidelines for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack, American Heart Association/American Stroke Association. Available here: [last accessed 05/08/2020] R Sedhom et al (2020), Use of Direct Oral Anticoagulants in the Treatment of Left Ventricular Thrombi, a Systematic Review. The American Journal of Medicine. AR Robinson et al (2020), Off-label Use of Direct Oral Anticoagulants Compared With Warfarin for Left Ventricular Thrombi. JAMA Cardiology. M Alizadeh et al (2019), The use of direct oral anti-coagulations (DOACs) compared to vitamin k antagonist in patients with left ventricular thrombus after acute myocardial infarction. European Heart Journal. A Yunis et al (2020), Direct Oral Anticoagulants are Effective Therapy in Treating Left Ventricular Thrombi. Journal of The American College of Cardiology H Iqbal et al (2020), Direct oral anticoagulants compared to vitamin K antagonist for the management of left ventricular thrombus. ESC Heart failure. British Heart Foundation (2020), England statistical factsheet. Available at: https://www.bhf.org.uk/what-we-do/our-research/heart-statistics [last accessed 23/09/2020] CP McCarthy et al (2018), Left Ventricular Thrombus after acute MI. JAMA Cardiology. Available here. [last accessed 23/09/2020] UKMI (2012) Prescribing outlook, National Developments. Available here (with sign in). [last accessed 23/09/2020]

NOTES:

- SEL IMOC recommendations and minutes are available publicly via the [website](#).
- 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.
- Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**