Title	**Rivaroxaban in DVT/PE in NHS Borders.**
Document Type	**Clinical guideline**
Issue no	***Clinical Governance Support Team Use***
Issue date	**June 2014 (updated)**
Review date	**June 2017**
Distribution	**NHS Borders clinical staff**
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Equality & Diversity Impact Assessed	

Rivaroxaban in DVT /PE in NHS Borders- Treatment Protocol

1.	**Drug** : Rivaroxaban 15mg and 20mg tablets
2	**NHS Borders formulary indication:** Treatment of dee*p vein thrombosis (DVT),* and treatment of pulmonary embolism (PE), and prevention of recurrent deep vein thrombosis (DVT) and PE in adults. **Treatment with rivaroxaban should not be commenced until diagnosis of DVT/PE has been confirmed**.
3.	**Dose**: - 15mg twice daily for 3 weeks followed by 20mg once daily. (eGFR >50mL/min) - 15mg twice daily for 3 weeks followed by 15mg once daily (eGFR 15-49mL/min)
4	**Duration of treatment** • For 3 months in DVT associated with surgery or other transient risk factor (eg COC, pregnancy, plaster cast) • For 6 months treatment of unprovoked proximal DVT. • For 3, 6 or 12 months (as clinically indicated) in PE • Young patients (under 40) with completely spontaneous thrombotic events (DVT/PE), recurrent thromboses or with family history of DVT/PE should have duration of anticoagulation considered on an individual basis and, if necessary, discussed with consultant haematologist.
5	**Cautions & contraindications** • All patients being considered for rivaroxaban should be assessed for "bleeding risk", including PMH of upper gastrointestinal haemorrhage or upper GI symptoms, and if risk is deemed to be high, alternative anticoagulation should be considered. Rivaroxaban is not indicated for treatment of DVT/PE in cancer patients (LMWH is the treatment of choice) • When rivaroxaban is commenced the need for concomitant aspirin, clopidogrel, NSAIDS or other anti-platelet agents / anti-coagulants should be reviewed by consultant/senior medical staff, and stopped where possible. • For patients at risk of ulcerative gastrointestinal disease prophylactic treatment with an oral PPI should be considered. • If an invasive procedure or surgical intervention is required, rivaroxaban should be stopped at least 24 hours before the intervention, if possible - based on the clinical judgement of the physician. If the procedure cannot be delayed the increased risk of bleeding should be assessed against the urgency of the intervention. • Rivaroxaban should be restarted after the invasive procedure or surgical intervention as soon as possible provided the clinical situation allows and adequate haemostasis has been established • Refer to product information for contraindications and further information.
6.	**Supply.** - On discharge from BGH, the patient will receive a supply to complete the 3 weeks treatment of 15mg twice daily. (Patient packs containing the 3 weeks treatment supply of 15mg twice daily + patient alert card are available from ward 4 and A& E, if required "out of hours", or from pharmacy between 8.50 and 1700 hours.). **- GP surgeries** will issue prescriptions for the remainder of the treatment course.
7.	**Drug Interactions** • Co-prescription of rivaroxaban with azole-antimycotics (eg ketoconazole, itraconazole, voriconazole and posiconazole), HIV protease inhibitors (eg Ritonavir) is contra-indicated. • Cautious use in renal impairment concomitantly with potent inhibitors of CYP3A4 (ie clarythromycin) • See cautions, above, re aspirin, clopidogrel, NSAIDs, anti-platelets/anticoagulants. • Refer to BNF & SPC for further interaction information
8.	**Patient counselling**. (Clinician responsible for counselling patient must document this in patients medical notes)

- Rivaroxaban patient alert card should be completed – addressograph added. Patient to complete “please notify section”.
- Ensure patient is aware of potential adverse reactions
- Ensure that patient understands the prescribed dose to take
- Patient to be aware that rivaroxaban should be taken with food.

9. Monitoring – patient safety:

- Patients should be advised not to take rivaroxaban on the evening before any diagnostic procedure (eg colonoscopy, endoscopy)
- Patients should be counselled on the symptoms and signs of bleeding prior to discharge from BGH and an information leaflet supplied. This is particularly important for the at risk patient groups highlighted above
- Monitor eGFR in patients with renal impairment
- Rivaroxaban is a black triangle new drug and any adverse events should be reported to the MHRA via the yellow card reporting system.

10. Management of bleeding.

- There is no specific antidote for rivaroxaban
- The use of activated charcoal to reduce absorption in case of rivaroxaban overdose may be considered.
- Should a bleeding complication arise in a patient receiving rivaroxaban, the next dose of rivaroxaban should be delayed or treatment discontinued as clinically appropriate - rivaroxaban has a half-life of approximately 5 to 13 hours
- Management should be individualised according to the severity and location of the haemorrhage. Appropriate symptomatic treatment could be used as needed, such as mechanical compression (e.g. for severe epistaxis), surgical haemostasis with bleeding control procedures, fluid replacement and haemodynamic support, blood products (packed red cells or fresh frozen plasma, depending on associated anaemia or coagulopathy) or platelets.
- If bleeding cannot be controlled by the above measures, on advice of consultant haematologist administration of a specific procoagulant reversal agent should be considered, such as prothrombin complex concentrate (PCC) activated prothrombin complex concentrate –APCC (Beriplex), or recombinant factor VIIa (r-FVIIa).

11. Switching from rivaroxaban to warfarin.

- Warfarin and rivaroxaban should be co-administered until INR ≥ 2.0. For the first 2 days of the conversion period, standard initial dosing of warfarin should be used followed by warfarin dosing guided by INR testing. While patients are on both rivaroxaban and warfarin the INR should not be tested earlier than 24 hours after the previous dose, but prior to the next dose of rivaroxaban. Once rivaroxaban is discontinued INR testing may be reliably done at least 24 hours after the last dose.

Switching from warfarin to rivaroxaban

- Discontinue warfarin and start rivaroxaban when INR is <2.0.

Switching from parenteral anticoagulants to rivaroxaban

- start rivaroxaban at time next dose of LMWH due: or at time of discontinuing heparin infusion

Switching from rivaroxaban to parenteral anticoagulants

- give first dose of parenteral anticoagulant at time next dose of rivaroxaban would be taken