# BNSSG Shared Care Guidance
Please complete all sections

## Section 1: Heading

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|---|---|
| **Drug** | Rivaroxaban (in combination with aspirin 75 mg daily) [1] |
| **Amber** *three months* | |
| **Indication** | Prevention of atherothrombotic events in people with coronary or peripheral artery disease who are at high risk of ischaemic events [1]<br><br>For this indication, Rivaroxaban should be prescribed in line with NICE TA 607 .<br><br>The NICE TA contains information about people at high risk of ischaemic events.<br><br>A Shared Decision Making tool is available here |

## Section 2: Treatment Schedule

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| **Usual dose and frequency of administration** *(Please indicate if this is licensed or unlicensed and any relevant dosing information)* | 2.5 mg twice daily [1] |
| **Route and formulation** | oral tablet |
| **Duration of treatment** | Ongoing, with plan to review ongoing risks and benefits after 2 years<br>The risks and benefits of continuing treatment with rivaroxaban should also be reviewed annually |

## Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

| **Baseline tests - where appropriate** |
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| Baseline creatinine clearance (CrCl) by initiating clinician<br>FBC<br>LFTs<br>Clotting Screen<br>Weight (as increased bleed risk if <60kg)<br>HAS-BLED score (this should be used as a guide to assess bleeding risk, address modifiable bleeding risk factors and to have an informed conversation with the patient about the risks and benefits of adding low dose rivaroxaban). |

**Subsequent tests - where appropriate** *(Please indicate who takes responsibility for taking bloods and interpreting results)*

| Test | Frequency | Who by | Action/management |
|---|---|---|---|
| Electrolytes (to calculate CrCl) | Annually or Every six months if the person is older than 75 years, or is frail.<br><br>At least every six months if the person has a CrCl between 30–60 ml/min.<br><br>At least every three months if the person has a CrCl between 15–30 ml/min[3*] | Primary Care | Use is not recommended in patients with CrCl < 15 ml/min. Review patients with CKD 5.<br><br>CrCl should be calculated rather than using eGFR to determine renal function when prescribing rivaroxaban.<br><br>CrCl is available on EMIS and can be calculated using the CrCl calculator available from: https://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation) |
| FBC | Annually if required[3*] | Primary Care | Bleeding risk highest within first year of treatment.<br><br>Consider co-morbidities and concurrent medication. |
| LFTs | Annually if required[3*] | Primary Care | Consider co-morbidities and concurrent medication. |
| Weight ( to calculate CrCl) | Annually if required or if weight has changed significantly. | Primary Care | |

- ***Renal and liver function tests should be performed more often if there is an intercurrent illness that may impact renal or liver function.**

## Section 4: Side Effects

*Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.*

**Side effects and management** [1]

| Side effect | Frequency/severity | Action/management |
|---|---|---|
| Skin and subcutaneous tissue disorders: pruritus, rash, ecchymosis, cutaneous and subcutaneous haemorrhage | Common | Discontinue rivaroxaban at first appearance of severe skin rash |
| Epistaxis, haemoptysis, gingival bleeding, haemorrhage (eye/gastrointestinal/post-procedural, urogenital tract) | Common | Discontinue rivaroxaban if clinically significant bleeding |

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| **Referral back to specialist** | Patients who have fully recovered bleeds/ concerns of bleeds but are high cardiovascular risk should be referred to the appropriate specialist |

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| | team to review risk versus benefit of treatment with rivaroxaban.<br><br>For Cardiology team- use Advice and Guidance to contact<br>For Vascular team- refer to vascular team |

**Section 5: Other Issues**

**(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)**

*Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)*

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| **Issues** [1] | Interactions:<br>See SPC for complete list.<br>Dual antiplatelet therapy has not been studied in combination with rivaroxaban 2.5 mg twice daily in patients with CAD/PAD. If this combination is prescribed, confirm combination is intentional with Specialist prior to continuing.<br><br>Contraindications:<br>• Hypersensitivity to the active substance or any of the excipients<br>• active clinically significant bleeding<br>• lesion or condition considered to be at significant risk of major bleeding<br>• Concomitant treatment with any other anticoagulants<br>• Creatinine clearance <15ml/min<br>• Concomitant treatment of CAD/PAD with aspirin in patients with previous **haemorrhagic** or lacunar stroke, or any stroke within a month<br>• Antiphospholipid syndrome: use of all Direct Oral Anticoagulants (DOACs) are contraindicated (link to MHRA DSU)<br>• Concomitant treatment of ACS with antiplatelet therapy in patients with a prior stroke or a transient ischaemic attack (TIA)<br>• Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C<br>• Pregnancy and breast-feeding<br><br>Cautions:<br>• Not recommended for use in patients with haemorrhagic risk (see SPC)<br>• Creatinine clearance 15-29mL/minute<br>• Medication interactions<br>• Weight < 60 kg<br>• Age > 75 years<br><br>Gastro-protection considerations:<br>• Refer to local guidance for information about prescribing and review of gastro-protection for people taking anticoagulants and antiplatelets. |
| **Reminder to ask patient about specific problems** | Prolonged nosebleeds (more than 10 minutes). Blood in vomit. Blood in sputum. Passing blood in your urine or stools. Passing black stools. Severe or spontaneous bruising. Unusual headaches. Tiredness, dizziness, paleness or weakness. For women, heavy or increased bleeding during your period or any other vaginal bleeding. |

**Section 6: Advice to the patient**

Advice for prescribing clinician to inform patient

1. Can be taken with or without food
2. Provide the patient with a new oral anticoagulant medications patient information leaflet

3. Counsel the patient using the leaflet highlighting in particular the side effects and when to seek immediate medical attention.
4. Provide patient with Anticoagulant Alert Card which they should keep on them at all times [2]
5. Monitor for signs of bleeding and anaemia [1]
6. OTC medicines should be checked with the Pharmacist prior to using.
7. Rivaroxaban has minor influence on the ability to drive and use machines. Adverse reactions like syncope (frequency: uncommon) and dizziness (frequency: common) have been reported. Patients experiencing these adverse reactions should not drive or use machines.

## Section 7: Generic principles of shared care for SECONDARY CARE

*Please do not amend.*

**Core responsibilities**

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

## Section 8: Generic principles of shared care for PRIMARY CARE

*Please do not amend.*

**Core responsibilities**

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

## Section 9: Contact Details

| Name | Organisation | Telephone Number | E mail address |
|---|---|---|---|
| Consultant Vascular Surgeons | North Bristol NHS Trust | Via switchboard (0117 950 5050) or 0117 4140766 | nbn-tr.bbwvascularnetwork@nhs.net |
| Consultant Interventional Cardiologists | North Bristol NHS Trust | Via switchboard | Andrew.Skyrme-Jones@nbt.nhs.uk<br>Amardeep.Dastidar@nbt.nhs.uk<br>Shahid.Aziz@nbt.nhs.uk<br>Philip.Boreham@nbt.nhs.uk |

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|---|---|---|---|
| Dr Tom Johnson<br>Consultant Cardiologist | University Hospitals Bristol and Weston NHS Foundation Trust | 0117 342 6573 | Tom.johnson@uhbw.nhs.uk |
| Cardiac Specialist Nurses | University Hospitals Bristol and Weston NHS Foundation Trust | | heartteam@uhbw.nhs.uk |

**Section 10: Document Details**

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|---|---|
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**Section 11: Collaboration**

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Dr Tom Johnson, Consultant Cardiologist, UHBW; Dr Andrew Skyrme-Jones, Consultant Cardiologist, NBT; Dr Christopher Twine, Consultant Vascular Surgeon, NBT; Dr Shaba Nabi, GP Prescribing Lead, BNSSG; Dr Phil Simons, Clinical Lead for Stroke, BNSSG; Sue Bacon , Lead Anticoagulation Nurse, NBT; Robert Brown, Cardiac Pharmacist NBT; Daniela Goddard, Lead Cardiac Pharmacist, UHBW

**Section 12: References**

Please list references

1. Bayer plc. Xarelto 2.5mg film-coated tablets. Electronic medicines compendium [updated 2020 Jan 17] Available from: https://www.medicines.org.uk/emc/product/3410/smpc (accessed 17/07/2020)

2. Joint Formulary Committee. British National Formulary [Internet]. London: British Medical Association and Royal Pharmaceutical Society of Great Britain; [updated 2020]. Available from: https://bnf.nice.org.uk/

3. Steffel, J., Verhamme, P., Potpara, T.S., *et al.* (2018) The 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation. *European Heart Journal* **39**(16), 1330-1393. Available from: 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation | European Heart Journal | Oxford Academic (oup.com) (table 2)