Patient Group Direction

Hospital: Bristol Royal Infirmary
Department: UHBristol Thrombosis Service
University Hospitals Bristol NHS Foundation Trust.

This Patient Group Direction (PGD) has been written in accordance with the guidance detailed in HSC 2000/026 and relevant legislation. It provides authorisation for the supply or administration of the medicines detailed, only for treatment of the conditions specified by authorised staff. A record of named, authorised staff must be maintained by the department manager. Any suspected adverse drug reactions must be reported to a doctor or pharmacist.

Title: Oral anticoagulation treatment with rivaroxaban tablets for the treatment of newly diagnosed Deep Vein Thrombosis (DVT) and Pulmonary Embolism

Medicine: Rivaroxaban **(Xarelto®)** tablets

Clinical situation: Proven newly diagnosed DVT and PE

Rivaroxaban is a ▼Please report all suspected reactions (including those not to be considered serious through the Yellow Card Scheme.

Clinical Condition or Situation

Definition of clinical condition / situation and eligibility for inclusion:

Adults with proven newly diagnosed DVT and PE

Exclusion criteria and circumstances in which advice must be sought from doctor (including interacting, concurrent medication*)*:

1) Contraindications
Exclude patients from treatment using this PGD where any of the following apply:

- Patients 18 years of age or less
- Known hypersensitivity to rivaroxaban or any excipients of rivaroxaban tablets
- Clinically significant active bleeding
- Pregnancy and breastfeeding
- Hepatic disease associated with coagulopathy and clinically relevant bleeding risk
- Active or recent gastric or duodenal ulceration
- Ischemic stroke within past six weeks

- Known renal impairment CrCl<15ml/minute
- Severe hypertension (systolic BP>200, diastolic BP>110mm Hg)
- Major trauma
- Recent eye or neurosurgery (within one month)
- Recent intracranial or intracerebral haemorrhage
- Presence of malignant neoplasm at high risk of bleeding
- Recent brain or spinal injury
- Known or suspected oesophageal varices
- Arteriovenous malformation
- Vasculkar aneurysms, or major intraspinal or intracerebral vascular abnormalities

2) Relative contraindications

Refer to a doctor before supplying rivaroxaban via this PGD in the following circumstances:

- CrCl 15ml/minute to 49ml/minute see dosing guidance under treatment **
- Known or suspected cognitive impairment
- Bronchiectasis or history of pulmonary bleeding

3) Drug Interactions

- Drugs that inhibit CYP3A4 and P-glycoprotein e.g. rifampicin, ketoconazole, phenytoin, carbamazepine, phenobarbital, St John's Wort and ritonavir- causes increased rivaroxaban exposure and as a result an increased risk of bleeding**-do not use these combinations**

- Dronedarone

- Concomitant use of Non-steroidal anti-inflammatory drugs / platelet aggregation inhibitors- increased bleeding risk if treated concomitantly **–do not use combinations**

- Anticoagulants e.g. enoxaparin, low molecular weight heparins- increased bleeding risk

This is not a complete list of drug interactions. Please

refer to the British National Formulary (BNF) Appendix 1 or the Summary of Product Characteristics (SPC) for full information on drug interactions http://www.medicines.org.uk/emc

Action following refusal of exclusion: Refer to supervising doctor. Document refusal/action taken in patient's record.

Authorised Staff

Class of health professional who are authorised: Registered nurses working for the UHBristol NHS Foundation Trust Thrombosis service.

Nurses using medicines under the terms of a PGD must be sure of their competence to do so and act in accordance with the Nursing and Midwifery Council (NMC) Code (NMC, 2008) and Standards for Medicines management (NMC 2008). Nurses must also be familiar with NMC 'Record keeping: Guidelines for nurse and midwives (NMC 2009).

Additional required qualifications, training, experience and competences:

- Has undertaken appropriate training and successfully completed the competencies to undertake the clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD
- Has undertaken appropriate training for working under PGDs for the supply and administration of medicines
- Has undertaken training appropriate to this PGD
- Demonstrable knowledge of the drug

rivaroxaban

Requirements for ongoing training/ education:	The practitioner must be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development

Treatment

Name and legal status of medicine for administration and/ or supply:	Rivaroxaban (Xarelto®) tablets Prescription Only Medicine (POM)
Appropriate dose, frequency of administration and maximum total dosage:	**For a CrCl >50ml/min** The recommended dose for the initial treatment of acute DVT and PE is 15mg TWICE daily for the first THREE weeks followed by 20mg ONCE daily for the continued treatment and prevention of recurrent DVT or PE **For moderate (CrCl 30-49ml/min) or severe (15-29ml/min)** The recommended dose for the initial treatment of acute DVT or PE is 15mg TWICE daily for the first THREE weeks followed by 20mg ONCE daily for the continued treatment and prevention of recurrent DVT or PE ** A reduction of the dose from 20mg once daily to 15mg once daily should be considered if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT

	Maximum total daily dosage Days 1 to 21 maximum daily dose =30mg Days 22 and onwards maximum daily dose =20mg
Quantity to be supplied:	Rivaroxaban is Amber according to the BNSSG formulary and so the patient must be supplied with one month's treatment before prescribing is continued by primary care. Please refer to the Shared Care Protocol at the following link for further information: http://www.bnssgformulary.nhs.uk/includes/documents/Rivaroxaban%20for%20DVT%20August%2012%20updated%20dec%2012sm%20(2).pdf
Quantity to be administered:	Not applicable
Pharmaceutical form, strength and route of administration:	Rivaroxaban 15mg and 20mg tablets For oral administration
Minimum or maximum period over which the medicine must be administered:	Specialist to supply the first 21 days of twice daily treatment, and to start the once daily treatment. GP to prescribe the ongoing daily treatment. Specialist to advise on length of ongoing treatment (usually 3, 6, or 12 months). Note: Experience with rivaroxaban for this indication for more than 12 months is limited.
Patient advice and relevant warnings:	• If a dose is missed during the 15mg twice daily treatment phase, the patient should take immediately to ensure intake of 30mg per day. In this case the two 15mg tablets can be taken at once. The patient should then continue with the regular 15mg twice daily intake as recommended on the following day.

- Report any unexplained bleeding or bruising
- Always carry your 'Patient Alert Card'
- Advise your anticoagulant practitioner of any changes to your general health or medications.
- Women of childbearing age should take suitable contraceptive precautions.
- Advise any healthcare professional treating you that you take rivaroxaban.

Potential adverse reactions and their management:

The most common adverse effects for rivaroxaban are:

Blood and lymphatic system disorders:
Anaemia

Nervous System Disorders:
Dizziness, headache, syncope

Eye Disorders:
Eye haemorrhage

Cardiac Disorders:
Tachycardia

Vascular Disorders:
Hypotension, haematoma

Respiratory, Thoracic and Mediastinal disorders:
Epistaxis

Gastrointestinal Disorders:
GIT haemorrhage, GI and abdominal pains, dyspepsia, nausea, diarrhoea,

Skin and subcutaneous tissue disorders:
Pruritis, rash, ecchymososis

Renal and urinary Disorders:
Urogenital Tract Haemorrhage

General disorders and administration site conditions:
Peripheral oedema, decreased strength and energy

Investigations:
Increases in transaminases

This is not a complete list of adverse effects associated with rivaroxaban. For more information please refer to the BNF or the SPC via the following link: www.medicines.org.uk

Rivaroxaban is currently a black triangle medicine and so is monitored intensively by the Commission on Human Medicines (CHM). All suspected reactions (including those not considered to be serious) should be reported through the yellow card scheme. Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF or via the following link http://yellowcard.mhra.gov.uk

Details of any follow up action and the circumstances:

- Any adverse reaction to be documented in patient notes. Refer to a doctor in the event of any suspected side effects of a serious nature.
- Ensure primary care is aware of their responsibilities when prescribing to patients after one month of treatment

Management

Records required for audit purposes:

All notes are coded to facilitate internal audit of medicines given by PGD
The record of a drug supplied or administered using a PGD must include:

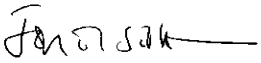
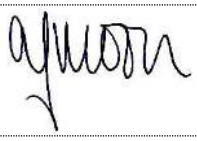
- Patient Name
- Patient identifier
- The date on which PGD supply or administration was made
- The name of the authorised healthcare professional

It must be possible to reconcile incoming stock and out-goings on a patient by patient basis

Supply Record supply in the patient notes together with the signature and name of the professional authorised to use the PGD

PGD document prepared by:	Signature	Date
	Dr Amanda Clark	Consultant Haematologist
	Rachel Heneker,	Thrombosis Specialist Nurse
	Emma Kinnaird,	Thrombosis Specialist Nurse
	Helen Charleton	Pharmacist

Implementation date: 01/12/2012
Revised: 04/12/2012
Review date: 01/09/2014
Expiry date: 01/12/2014

Authorised by:	Signature	Date
Lead Doctor, Division of Medicine: Dr John Smithson		16/11/2012
Chief Nurse: Alison Moon		16/11/2012
Director of Pharmacy: Stephen Brown		16/11/2012

This section is to be completed by each individual who has been authorised to act in accordance with the PGD document. By signing this declaration the individual confirms that they have received appropriate training, understands all aspects of the treatment detailed and will follow the schedule.

(One copy to be retained by the individual and one by the manager)

Name:	Qualifications:
Signature:	Date:
Name:	Qualifications:
Signature:	Date:
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