NHS Somerset

Shared Care Protocol

Enoxaparin for thrombo-prophylaxis in pregnant women and women post-natally at higher risk of venous thrombo-embolism (according to RCOG guidance)

This shared care protocol (SCP) sets out details for the sharing of care of pregnant women who are higher risk of venous thrombo-embolism VTE who require thrombo-prophylaxis with enoxaparin.
It should be read in conjunction with the Summary of Products Characteristics (SPC; available at www.medicines.org.uk)

As outlined in NHS Circular 1992 (Gen 11), when a consultant considers a patient's condition is stable he/she may seek the agreement of the patient's GP to "share" the patient's care. This document provides information on drug treatment for the shared commitment between the consultant and GP concerned. GPs are invited to participate. If the GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as is practical.

Introduction
Enoxaparin is one of several available low-molecular weight heparins (LMWHs) administered by sub-cutaneous injection. LMWHs are now widely used for a number of licensed and off-license indications including the prevention (thrombo-prophylaxis) and treatment of venous (and sometimes arterial) thromboses in selected patient groups.

Pregnancy predisposes women to venous thrombo-embolism (VTE), partly due to a change in the balance between clotting components in the blood. Additional risk factors for VTE during pregnancy include obesity, advanced maternal age, thrombophilia, previous VTE, sepsis such as urinary tract infection, and caesarean section. **VTE is now the commonest direct cause of maternal death in the United Kingdom.**

- The use of LMWH in pregnancy is widespread because warfarin is contraindicated in pregnancy.
- LMWH is known **not** to cross the human placenta and has not been associated with any risk of teratogenesis or fetal haemorrhage
- The Royal College of Obstetricians and Gynaecologists (RCOG) has produced guidance on thromboprophylaxis during pregnancy and the puerperium.

The Somerset Prescribing Forum have agreed that thrombo-prophylaxis in pregnancy and post natally using enoxaparin is **suitable for shared care** and the normal expectation is that GPs will take this on.

Licensed indication
Enoxaparin is not licensed in pregnancy but is used **off-label** for the prevention and treatment of venous thrombosis in pregnancy, and in the treatment of the anti-phospholipid syndrome. The use in pregnancy is supported by national and local guidelines (Somerset prescribing forum and drugs and therapeutic committees).

Target Patient Group
Prophylaxis of venous thrombo-embolic disease in women who meet the criteria:

- Pregnant or in puerperium
- Previous thromboembolic event.
- Thrombophilia
- Multiple current risk factors according to RCOG guideline:
  Thrombosis and Embolism during Pregnancy and the Puerperium, Reducing the Risk (Green-top 37)

Duration of treatment
Antenatally, prophylaxis will usually be from recognition/development of risk until delivery.

Postnatally, the majority of patients will need 7 days prophylaxis but a minority of higher risk patients will be recommended to have 42 days.

Exclusions:
Patients with the following conditions are excluded from this protocol:

- History of heparin induced thrombocytopenia (HIT)
- Severe renal impairment (calculated creatinine clearance <30ml/min)
- Mechanical prosthetic heart valves
- Significant hepatic impairment
- Active gastric or duodenal ulceration or oesophageal varices
- Haemophillia and other inherited bleeding disorders / major bleeding disorders
- Thrombocytopaenia (platelets less than 100 x 10^9/L)
- Recent cerebral haemorrhage
- Severe hypertension
- Recent neurosurgery or eye surgery
- Acute bacterial endocarditis
- Hypersensitivity to enoxaparin
- Children under 16 years

Initial Prescription
A decision is made for a patient to be started on enoxaparin by the patient's clinical team. This is discussed with the woman and she is given a patient information leaflet. The woman should be told that enoxaparin does not cross the placenta.

The patient is commenced on treatment with the support of the obstetric day unit. The patient is given a prescription for a **30 day** supply of the drug and advice or arrangements made for administering the enoxaparin.

The GP practice will be informed of the proposed treatment plan.

During the first **30 days** initiation and prescribing of enoxaparin will be the responsibility of the secondary care specialist in obstetrics, after this time the GP should accept responsibility for shared care in accordance with this protocol.

Administration
In most circumstances the patient or family member is advised on how to perform the administration of the drug. This is usually provided through the obstetric day unit. Rarely a referral is made to the district nurse.

Monitoring - None required

Dose

Administration is by **sub-cutaneous injection** given via a pre-filled syringe at the same time(s) each day.

Suggested thromboprophylactic doses for antenatal and postnatal LMWH

Weight (kg)	**Enoxaparin**
< 50	20 mg daily
50–90	40 mg daily
91–130	60 mg daily*
131–170	80 mg daily*
> 170	0.6 mg/kg/day*

* may be given in two divided doses

High prophylactic (intermediate) dose for women weighing 50–90 kg
40 mg 12-hourly

Treatment dose: 1 mg/kg/12 hourly antenatal;
1.5 mg/kg/daily postnatal

Renal Impairment: GFR < 30ml per min – maximum dose is 20mg once a day.

Low body weight: requires dose adjustment

Criteria for Continuing Therapy
Risk status should be regularly reassessed to determine the need to alter or stop therapy.

Labour / Induction of labour - this is the full responsibility of secondary care

Postpartum
- Prophylaxis is discontinued for delivery, but is resumed post-natally.
  This will be communicated to the GP.
- Postpartum prophylaxis, if appropriate, should begin as soon as safely possible after delivery.
- Caution should be taken for women with severe hypertension (particularly in the presence of pre-eclampsia because of the risk of intracranial haemorrhage). Consider delay and use of TED stockings.

Adverse effects
- Injection site reactions (common)
- Hyperkalaemia (rare)
- Haemorrhage (rare)
- Thrombocytopenia (rare)
- Osteoporosis (rare)
- Skin necrosis and hypersensitivity reactions (rare)

Drug Interactions
This is not a comprehensive list. Refer to the current BNF for further information
- Systemic salicylates
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- ACE inhibitors (increased risk of hyperkalaemia)
- Dextran
- Ticlopidine
- Systemic glucocortocoids
- Thrombolytics
- Anticoagulants

Pregnancy and lactation
There is no contraindication to breast feeding.

Cost: BNF 58 September, 2009
20mg pre-filled syringe (10 doses) = £30.30
40mg pre-filled syringe (10 doses) = £40.40

Shared Care Responsibilities

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them. This provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.

Consultant
- Initiate treatment with enoxaparin and provide the first **30 days** of treatment in the antenatal setting.
- Instruct patient or carer on administration (or arrange for district nurse to be involved).
- Ensure patient has a basic understanding of what the drug is, why it is being used, awareness of side effects and arrangements for further prescriptions.
- All patients will be under the ongoing care of a named consultant.
- The GP will receive notification that the patient has been initiated on enoxaparin and a shared care protocol if appropriate.
- Handover to the GP will be via a letter which will be given to the patient and also sent to the GP surgery.
- The consultant will support if problems occur using the contact details provided.
- The consultant will give directions in most cases as to when treatment should be discontinued.
- The consultant will advise the GP on the need or otherwise of prophylaxis post-partum and the required duration of prophylaxis and supply the first **10 days.**

General Practitioner
For patients initiated on enoxaparin the role of the GP will be:
- Accept referral from secondary care to take on continued prescribing of enoxaparin by agreement and in accordance with this clinical shared care protocol.
- Repeat prescribing of enoxaparin after initiation and stabilisation of therapy. GPs may want to consider prescribing in small batches rather than one prescription for the full amount.
- Reinforce educational points provided by the hospital.
- Repeat prescribing of enoxaparin after initiation and stabilisation of therapy.
- The GP is asked to inform the consultant of any changes in the patient's medical condition and/or prescribed medication, particularly rashes, bleeding, signs of thrombosis or embolism
- Keep records of all patients for whom enoxaparin has been prescribed (should include relevant details such as indication, concurrent conditions, dose, start date, expected duration, monitoring details, adverse incidents, consultants involved in treatment, any advice or actions).

Patient
The patient should:
- Undergo training and be willing to administer the enoxaparin injections on a regular basis at home.
- Be counselled to report any side effects or the Maternity team or to the GP.
- Be counseled to report any symptoms of VTE.

BACK-UP ADVICE AND SUPPORT

For further information please contact:

Department of Maternity,
Musgrove Park Hospital,
Taunton
TA1 5DA

Maternity Services
Women's Hospital,
Yeovil District Hospital
Higher Kingston,
Yeovil, Somerset,
BA21 4ATY

Contact details	Telephone	Bleep	Fax	E-mail address
Dr Sarah Allford **Consultant Haematologist** **Musgrove Park Hospital**	01823 342269	Radio-page via Hospital switchboard	01823 271023	sarah.allford@tst.nhs.uk
Mr John Macaulay **Consultant Obstetrician & Gynaecologist,** **Musgrove Park Hospital**	01823 342564		01823 343551	john.macaulay@tst.nhs.uk
Labour ward, MPH **Musgrove Park Hospital**	01823 343059		01823 343551	
Mr Leke Osoba **Consultant Obstetrician and Gynaecologist,** **Yeovil District Hospital**	01935 384628	Radio-page via Hospital switchboard	01935 384645	
Labour ward, YDH	01935 384350		01935 384305	
Medicines Information **Pharmacy Department,** **Musgrove Park Hospital**	01823 342253	3000	01823 286257	nigel.ankcorn@tst.nhs.uk

References:

- Summary of Product Characteristics:: Clexane® Sanofi Aventis
- Patient Information Leaflet: Clexane® Sanofi Aventis
- British National Formulary: Heparins
- Thromboprophylaxis during Pregnancy, Labour and after Vaginal Delivery. Musgrove Park Hospital, Maternity Guideline Index No: 1.43.01
- Thrombosis and Embolism during Pregnancy and the Puerperium, Reducing the Risk (Green-top 37), Royal College of Obstetricians and Gynaecologists, November 2009
- Low-molecular weight heparin. WeMeRec Bulletin, Welsh Medicines Resource Centre June 2007

This shared care protocol has been approved through the Somerset Prescribing Forum following liaison with Musgrove Park Hospital and Yeovil District Hospital Drug & Therapeutics Committees.

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Approved by the Somerset Prescribing Forum **26 January 2010**

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