Basingstoke, Southampton and Winchester District Prescribing Committee

Shared Care Guideline: Enoxaparin in Pregnancy

Policy Number:		
Version:	3	
Authorisation Committees:	**District Prescribing Committee**	**Southampton Drugs Committee**
Date of Authorisation:	April 2012	
Ratification Committee (Category 1 documents):		
Date of Ratification (Category 1 documents):		
Signature of ratifying Committee Group/Chair (Category 1 documents):		
Lead Job Title of originator/author:	Christina Nurmahi Women & Newborn Care group pharmacist	
Name of responsible committee/individual:	Matthew Coleman Women & Newborn Care Group Clinical Lead	
Date issued:	April 2012 (original issued April 2008)	
Review date:	April 2015	
Target audience:	Maternity Services in UHS and local GPs	
Key words:	Enoxaparin, Clexane,	
Main areas affected:	Maternity Services in UHS and local GPs	
Consultation:	Women & Newborn Clinical Governance Steering Group	
Equality Impact Assessments completed and policy promotes Equity	23/09/11	
Number of pages:	5	
Type of document:	Level 2	

The Trust strives to ensure equality of opportunity for all, both as a major employer and as a provider of health care. This **Enoxaparin in Pregnancy** document has therefore been equality impact assessed by the Women & Newborn Clinical Governance Steering Group to ensure fairness and consistency for all those covered by it, regardless of their individual differences, and the results are shown in Appendix A.

Contents

Executive Summary

This shared care guideline has been produced to support the seamless transfer of prescribing and patient monitoring from secondary to primary care, and provides an information resource to support clinicians providing care to the patient. It does not replace discussion about sharing care on an individual patient basis.

This guideline was prepared using information available at the time of preparation, but users should always refer to the manufacturer's current edition of the Summary of Product Characteristics (SPC or "data sheet") for more details.

Shared Care Guideline: Enoxaparin in Pregnancy

1. Introduction

Enoxaparin is an 'amber' drug using our local traffic light system. This means that treatment will usually be initiated in secondary care and may be transferred to primary care if the initial response is good. The key principle of this guideline is that the GP is provided with information and given the opportunity to accept (or decline) prescribing responsibility before the transfer occurs.

1.2 Scope

These guidelines apply to all women prescribed enoxaparin (Clexane) in the antenatal and postnatal period in secondary care, and who may be transferred to primary care if the initial response is good.

1.3 Purpose

The purpose of these guidelines is to provide prescribing and monitoring information for enoxaparin for both secondary care staff and for GPs. The key principle is that the GP is provided with information and given the opportunity to accept (or decline) prescribing responsibility before the transfer occurs.

2. Related Trust Policies

- Venous Thromboembolism in Pregnancy: Diagnosis and Management Guidelines http://staffnet/TrustDocsMedia/DeptDivSpecific/DivC/WomenNewborn/Obstetrics/ObstetricClinicalGuidelines/VenousThromboembolisminPregnancy-Diagnosisan/VenousThromboembolisminPregnancy-DiagnosisandManagementGuidelines.doc

- Thromboprophylaxis and thrombophilia in Pregnancy Guidelines http://staffnet/TrustDocsMedia/DeptDivSpecific/DivC/WomenNewborn/Obstetrics/ObstetricClinicalGuidelines/ThromboprophylaxisandThrombophiliainPregnancy/ThromboprophylaxisandThrombophiliainPregnancyGuideline.doc

3. Roles and Responsibilities

Role of Consultant

To assess and initiate enoxaparin therapy in secondary care, including all relevant initial investigations and monitoring, and to notify the GP and keep him/her informed of any relevant information.

Role of GP

GP will continue prescribing of enoxaparin and fulfil any monitoring requirements as outlined in the guideline.

4 Implementation

No special requirements as ongoing practice

5 Process for Monitoring Compliance/Effectiveness

Element of Policy to be monitored (use relevant NHSLA criterion where appropriate)	**Lead**	**Tool/Method** (eg audit, review of minutes, records, training etc)	**Frequency**	**Who will undertake**	**Where results will be reported** (eg which group/committee)
Communication with GP, usually GP letters -- these should be correct, accurate and precise in their recommendations for anticoagulation through pregnancy and postnatally	Matthew Coleman and PAH ''thrombosis'' team	Audit and case note review especially communicating letters with GP's	Biannual	Joint obstetric and GP responsibility	Care group audit meetings

6 Arrangements for review of the policy

These guidelines will be reviewed every three years or as clinically indicated.

7 Appendices

- Appendix A – Equality Impact Assessment form
- Appendix B – Shared Care Guideline: Enoxaparin in Pregnancy

Appendix A - EQUALITY IMPACT ASSESMENT

EQUALITY IMPACT ASSESSMENT TOOL - To be completed for all new/revised policy, procedural and guideline documents.

Equality Impact Assessments (EQIAs) are a way of examining new procedural* documents to see whether they have the potential to affect any one group of people more or less favourably than another. Their purpose is to address actual or potential inequalities resulting from policy development. The duty to undertake EQIAs is a requirement of race, gender and disability legislation.

The word procedural is taken to mean ***all*** *procedural* documents i.e.: Policy, Procedure, and Guideline. (This does *not include Patient Information*)

Document Title	Shared Care Guideline: Enoxaparin in Pregnancy	**Version 3**
Is this a new or revised document?	Revised	
Area to which document relates Specify whether Trust-wide, Division, Care Group or Department.	Maternity in UHS and local GPs	
Name of person completing Assessment	Matthew Coleman, Consultant Obstetrician, Women & Newborn Care Group Clinical Lead	

STAGE 1 – INITIAL SCREENING

This stage establishes if the proposed change will have an impact from an **equality perspective** on any particular group(s) of people. See guidance notes on completion.

Does the document affect one group more or less favourably than another on the basis of <u>any</u> of the strands of diversity?	**Positive Impact** **Y/N/Neutral**	**Negative Impact** **Y/N/Neutral**	**Comments -** Give details of concerns and evidence in the boxes below	**Impact Level** N/L/M/H
Age	No			N
Disability	No			N
Gender	No			N
Sexual Orientation	No			N
Race & Ethnicity	No			N
Religion or Belief	No			N
Culture	No			N
Other e.g. Mental Health, Geographic factors, Economic factors...	No			N

Level of impact:

Taking into account the impact level for each group, circle one of the words in the boxes below to identify the overall impact level:

NONE	LOW	MEDIUM	HIGH

Significance

Is the positive / adverse impact significant enough to warrant a more detailed assessment (Stage 2) *A full assessment will usually be required if the level of impact is above 'LOW' as identified above.*

~~**YES /**~~ **NO** *(delete as applicable)*

If no give brief details of any action taken/information gathered to justify this decision:

Or give brief details of how the change will be monitored to assess the impact over a specified period of time:

IF NO POTENTIAL DISCRIMINATION HAS BEEN IDENTIFIED or THE IMPACT IS NOT SIGNIFICANT ENOUGH TO WARRANT A FULL IMPACT ASSESSMENT, PLEASE SIGN AND DATE BELOW.

(NOTE: A full impact assessment should be undertaken if initial screening demonstrates that there could be significant detrimental impact.)

I have assessed this document and found:

- No potential impact on any group
- The impact is not significant enough to warrant a full impact assessment

(delete as applicable)

SIGNATURE: **DATE:** 23/09/11

PRINT NAME: Matthew Coleman **POST HELD:** Women & Newborn Care Group Clinical Lead

THE COMPLETED EQIA MUST BE RETURNED TO THE TRUST POLICY ADMINISTRATOR ALONG WITH THE FINAL RATIFIED DOCUMENT

IF YOU HAVE IDENTIFIED ANY POTENTIAL IMPACT THAT REQUIRES FURTHER ASSESSMENT PLEASE CONTINUE TO COMPLETE STAGE 2 OF THE ASSESSMENT

APPENDIX B

Basingstoke,Winchester and Southampton District Prescribing Committee

Shared Care Guideline: **Enoxaparin in Pregnancy**

Name of patient treated under this guideline:

This shared care guideline has been produced to support the seamless transfer of prescribing and patient monitoring from secondary to primary care, and provides an information resource to support clinicians providing care to the patient. It does not replace discussion about sharing care on an individual patient basis.

This guideline was prepared using information available at the time of preparation, but users should always refer to the manufacturer's current edition of the Summary of Product Characteristics (SPC or "data sheet") for more details.

1.0 Status of Enoxaparin

Enoxaparin is an 'amber' drug using our local traffic light system. This means that treatment will usually be initiated in secondary care and may be transferred to primary care if the initial response is good. The key principle is that the GP is provided with information and given the opportunity to accept (or decline) prescribing responsibility before the transfer occurs.

2.0 Licensed Indications and Dose

- Enoxaparin is a low molecular weight heparin licensed for the prevention and treatment of deep-vein thrombosis and pulmonary embolism.
- It is also used in the management of venous thromboembolism in pregnancy.
- Enoxaparin is **not licensed** for use in pregnancy, as there are no adequate, well-controlled studies in pregnant women. However, significant national and local experience shows it to be a well-tolerated drug in pregnancy that does not cross the placenta. It is therefore the drug of choice locally, both for women who require therapeutic and prophylactic treatment before, during and after pregnancy.
- Prophylactic doses are prescribed in the following groups of patients (see table below for dosing guidelines):
  - Previous history of thrombosis
  - Positive family history of thrombosis or thrombophilia i.e. a 1st degree family member with a proven venous thrombosis (aged less than 50 years) or hereditary thrombophilia, unless relative had acquired cause for thrombosis (antiphospholipid syndrome, malignancy or other pro-thrombotic diagnosis)
  - Positive Antiphospholipid syndrome
  - Women on warfarin therapy

Early pregnancy weight	Prophylactic dose of enoxaparin
< 50kg	20mg daily
50-90kg	40mg daily
91-131kg	60mg daily
131-170kg	80mg daily
>170kg	0.6mg/kg/day

- The initial therapeutic treatment dose is 1mg/kg twice daily, based on early pregnancy weight (as per current RCOG guidelines).
- Enoxaparin is available in syringes of 20mg, 40mg, 60mg, 80mg and 100mg. The dose closest to the patient's weight should be employed (see table below for dosing guidelines).

Early pregnancy weight	Initial therapeutic dose of enoxaparin
< 50kg	40mg twice daily
50-69kg	60mg twice daily
70-89kg	80mg twice daily
>90kg	100mg twice daily

- Therapeutic anticoagulation would usually continue for at least **six months**. If the venous thromboembolism occurs early in pregnancy, the dose of enoxaparin may be reduced to prophylactic levels (typically 40mg once daily) approaching term. This must only be done under specific guidance from consultant hospital medical staff.
- Enoxaparin should usually be stopped or reduced at the time of delivery.
  - **Spontaneous labour** - the woman should be advised not to inject any further doses once she is in established labour or thinks she is in labour.
  - **Induction of labour** - the dose of enoxaparin should be reduced to its thromboprophylactic dose (i.e. usually 40mg once daily) on the day prior to induction of labour. Treatment doses (usually twice daily) may be restarted 6-12 hours following delivery.
  - **Elective caesarean section** – thromboprophylactic dose should be given on the day before the planned delivery. Dose should be omitted on the day of planned delivery. The thromboprophylactic dose may be restarted either 3 - 6 hours post caesarean (for those without epidural analgesic) or 4 hours after epidural removed. Treatment doses can usually be recommenced on the evening of the caesarean, if there are no surgical contra-indications.
- Post delivery, treatment with enoxaparin should be continued for 6-12 weeks, depending on whether the venous thromboembolism occurred early or late in pregnancy. This information will be communicated to the GP by the consultant.

3.0 Referral Criteria

Consultants in University Hospital Southampton NHS Foundation Trust and Hampshire Hospitals NHS Foundation Trust will consider enoxaparin as a therapy for pregnant women, under their care, presenting with venous thromboembolism or risk factors for venous thromboembolism.

4.0 Patient Selection

As indicated above.

5.0 Safety Issues

5.1 Contra-indications refer to most recent BNF and / or SPC (summary of product characteristics)

5.2 Cautions refer to most recent BNF and / or SPC

5.3 Common Side Effects refer to most recent BNF and / or SPC

5.4 Drug Interactions refer to most recent BNF and / or SPC

5.5 Pre-treatment Assessment

- Full blood count (including differential white blood cell count and platelets).
- Baseline clotting
- Check renal and liver function, and potassium level
- D-Dimer screen
- Doppler ultrasound (preferred) or X-ray venography
- Ventilation-perfusion lung scan, pulmonary angiography or magnetic resonance imaging, if chest x-ray is abnormal

(See UHS' 'Venous Thromboembolism in Pregnancy: Guidelines' for interpretation of results and subsequent management).

5.6 Routine Safety Monitoring

- Anti Xa levels – not usually indicated unless concerns about compliance, overdose, renal failure or if maternal weight is >100kg or <40kg. Levels taken four hours post injection (for 12 hourly administration) should achieve a peak of 0.4-1.0 units/ml.

Additional risks – long-term use may be associated with osteoporosis and bone fractures though the risk is lower for LMWHs when compared with unfractionated heparin. Heparin induced thrombocytopenia, haemorrhage or hyperkalaemia are also possible. Care should be used in women with long-term diabetes, chronic renal failure and metabolic acidosis. Routine platelet counts are not required as heparin induced thrombocytopenia (HIT) with LMWH is extremely rare in pregnancy. However, if the woman has had prior exposure to unfractionated heparin during this pregnancy then the platelet count should be checked on day 5. Blood should also be taken to confirm baseline levels. Should the platelet count fall by more than 30% of the baseline, enoxaparin should be discontinued and the patient referred to haematology at UHS on bleep 9145. Potassium levels need not be routinely measured unless there are pre-disposing factors for hyperkalaemia, such as diabetes mellitus or renal impairment.

6.0 Role of Consultant

- To assess the suitability of the patient to be commenced on enoxaparin.
- To carry out initial investigations and safety monitoring.
- To explain the possible side effects of the medication to the patient and any monitoring procedures
- To initiate therapy and maintain prescribing responsibility for the first month of treatment.
- To write to GP enclosing a copy of these shared care guideline requesting that a shared care agreement be initiated.
- To arrange for appropriate investigations during pregnancy and for the first month after birth.
- To keep the patient and GP informed of any abnormalities.
- To monitor the patient's response to enoxaparin therapy (e.g. anti Xa levels if needed)
- **To advise the GP on appropriate action with respect to any of the safety monitoring results. The prescriber should carry out the safety monitoring unless otherwise agreed in writing with the other party. When the safety monitoring is carried out other than by the prescriber, the prescriber must receive a copy of all the safety monitoring results**
- To decide when to stop therapy

7.0 Role of GP

- To ensure that all relevant staff within the practice are aware of the shared care guideline.
- To consider any side effects reported by the patient and discuss with the consultant if action is uncertain
- To carry out the safety monitoring and any other tests as agreed with the Consultant in writing. If the GP does not wish to undertake the safety monitoring then this must be agreed in writing with

the Consultant. **The GP must ensure under all circumstances that they receive copies of the safety monitoring before writing a prescription**

- To avoid the drug interactions indicated in current BNF.
- To provide prescriptions of the drug after the initial 1 month. To increase the dose, if necessary, after discussion with the consultant.
- To refer back to the consultant if any problems arise relating to enoxaparin therapy.

8.0 Role of Patient

- To self-administer enoxaparin; training will be provided by the haematology specialist nurse. A patient information leaflet to support the teaching of self-administration of enoxaparin will be provided.
- To report any side effects to the GP or consultant.
- To have blood tests carried out at agreed intervals. The patient must fully understand the need for safety monitoring whilst on enoxaparin
- To dispose of used syringes, etc appropriately. This will be explained by the specialist nurse who will also organise clinical waste collection with the appropriate council.

9.0 Further Information

University Hospital Southampton NHS Foundation Trust 023-80777222	
Women & Newborn Department	
Lead Consultant	Matthew Coleman (secretary) ext 4727
Lead Nurse	Chris Harris (haematology) ext 4047
Lead Pharmacist	Christina Nurmahi ext 6970 / bleep 9038
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Obstetrics & Gynaecology Department	
Lead Consultant	Martyn Pitman ext 5919 (01962 825162)
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Reviewed by: Matthew Coleman (Consultant, Obstetrics, UHS)
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