

SHARED CARE GUIDELINE

Enoxaparin Pre-Filled Syringes for patients within Barking, Havering and Redbridge University Hospitals NHS Trust

Document control

Guideline written by: Inaul Hussain, Lead Pharmacist Anticoagulation, BHRUT

Date approved by NEL Formulary & Pathways Group: 25/04/2023

Date ratified by NEL Integrated Medicines Optimisation & Prescribing Committee: 23/05/2023

Review date: 05/2024

Review date extended: October 2026

1. Background

The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between consultant and the primary care prescriber.

The primary care prescriber must reply in writing to the request for shared care within two weeks to acknowledge receipt and their decision to participate. Specialist teams can contact their local ICB Pharmacy and Medicines Optimisation Team if no response is received from the patient's GP.

The responsibility for prescribing and monitoring must be documented clearly in the patient's hospital and the primary care prescriber notes.

Shared care should only be considered when the patient's clinical condition is stable or predictable.

2. Indications

Low molecular weight heparins are widely used for a number of licensed and unlicensed indications including the prevention and treatment of venous (and sometimes arterial) thromboses in selected patient groups.

Enoxaparin under this guideline may be used for:

(Refer to appendix 1 for dosages)

Licensed indications:

- Prophylaxis of venous thromboembolic disease (VTE), especially in surgical patients – moderate and high risk
- Prophylaxis of VTE in medical patients
- Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) in uncomplicated patients with low risk of recurrence
- Treatment of DVT in patients with risk factors such as obesity, cancer, recurrent VTE, or proximal thrombosis
- Treatment of PE in patients with risk factors such as obesity, symptomatic pulmonary embolism, cancer, or recurrent VTE
- Extended treatment of DVT and PE and prevention of its recurrence in patients with active cancer

Unlicensed/off-label indications:

- Prophylaxis and treatment of VTE in pregnancy and postpartum
- Treatment of portal vein thrombosis under the direction of a hepatology specialist
- Patients unable to take warfarin and in whom a direct oral anticoagulant (DOAC) is not appropriate or contraindicated.

	<ul style="list-style-type: none"> • Patients in whom it has not been possible to stabilise on oral anticoagulant therapy and in whom a DOAC is not appropriate or contraindicated (for example: a patient with a replacement metal mitral heart valve and a sub-therapeutic INR and 'bridging' therapy is required). • IV drug users (where warfarin is generally considered inappropriate) and in whom a DOAC is not appropriate or contraindicated. 	
3. Locally agreed off-label use	<ul style="list-style-type: none"> • Any other indications as agreed with haematology or as per the BNF and SPC 	
4. Contraindications and cautions Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.	Contraindications: Refer to the current <u>BNF</u> and Summary of Product Characteristics https://www.medicines.org.uk/emc/ for complete and up to date information. Cautions: Refer to the current <u>BNF</u> and Summary of Product Characteristics https://www.medicines.org.uk/emc/ for complete and up to date information.	
5. Initiation and ongoing dose regime Note - <ul style="list-style-type: none"> •Transfer of monitoring and prescribing to primary care is normally after the patient's dose has been optimised and with satisfactory investigation results for at least 4 weeks •The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability. •All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician •Termination of treatment will be the responsibility of the specialist. 	Initial prescribing: <ul style="list-style-type: none"> • Initial prescribing by the hospital specialist for the first 4 weeks of treatment. • The decision is made for a patient to be commenced on enoxaparin by the patient's clinical team. This is discussed with the patient and he or she is given a drug information sheet, detailing side effects and monitoring requirements. • Baseline investigations are requested and, if satisfactory, the patient is commenced on treatment. • The patient is given a prescription for a 28 days supply of the drug. • 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. • Arrangements are made for monitoring of heparin induced thrombocytopenia (HIT), hyperkalaemia and anti-Xa if appropriate (see section 9). • The patient's GP will be informed of the proposed treatment plan and monitoring arrangements. See Hospital Clinician's referral letter/EPRO. Maintenance dose (following initial stabilisation): <ul style="list-style-type: none"> • Maintenance prescribing will be handed over to the GP with specified dose and duration of treatment. Conditions requiring dose adjustment: <ul style="list-style-type: none"> • 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). 	
6. Pharmaceutical aspects	Route of administration:	By subcutaneous injection
	Formulation:	Solution for injection pre-filled syringes

	<p>Administration details:</p>	<p>Dose should be calculated on the patient's current weight (in pregnancy use early pregnancy booking weight) and renal function.</p> <p>Patients/carers will be taught how to self-administer/administer the LMWH. The hospital team will provide training on the administration of injections and provide initial sharps bin for the safe disposal of the syringes. If the patient is unable to self-administer, the patient will be referred to the community district nurse team and the GP notified accordingly.</p> <p>Enoxaparin should be given by deep subcutaneous injection into the lower abdomen when the patient is lying down. The whole length of the needle should be introduced vertically into the skin fold held between the thumb and index finger. Do not release the skin fold until you have withdrawn the needle to minimise irritation to the patient. Do not rub the injection site after administration. Use a different injection site every day and do not inject near any bruising.</p>
	<p>Other important information:</p>	<p>Total dose may need to be made up with two syringes.</p>
<p>7. Significant medicine interactions</p> <p>For a comprehensive list consult the BNF or Summary of Product Characteristics. SPC</p>	<p>Interactions:</p> <p>Drugs affecting haemostasis (e.g. antiplatelets, anticoagulants, NSAIDs, systemic glucocorticoids, thrombolytics) should be discontinued before LMWH is initiated unless their use is essential. If the combination cannot be avoided, LMWH should be used with careful clinical and laboratory monitoring.</p> <p>Refer to the current BNF and Summary of Product Characteristics https://www.medicines.org.uk/emc/ for complete and up to date information.</p>	
<p>8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist</p>	<p>Baseline investigations:</p> <ul style="list-style-type: none"> • FBC, serum creatinine & urea, LFTs, coagulation screen and weight (kg) • Post-operative patients and cardiopulmonary bypass patients who have been exposed to heparin in the previous 100 d and are receiving any type of heparin should have a platelet count determined 24 h after starting heparin • Consider serum potassium 7-10 days after treatment initiation for patients at high risk of hyperkalaemia, particularly if it is to be continued for longer than 7 days. <p>Initial monitoring:</p> <ul style="list-style-type: none"> • Monitoring at baseline and during initiation is the responsibility of the specialist, only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to the GP. <p>Ongoing monitoring:</p> <p><i>Ongoing monitoring to be undertaken by primary care only if specified by the specialists.</i></p> <ul style="list-style-type: none"> • Platelet monitoring is most relevant between days 5–14, when HIT risk is highest and early detection is critical. • From Day 15 onwards there is no need for routine monitoring unless clinical condition changes or is likely to change in which case check U&E as necessary. 	

	<ul style="list-style-type: none"> Beyond day 15, routine monitoring is typically not necessary unless there are clinical concerns (e.g. new thrombocytopenia, thrombosis, or other signs suggestive of HIT). 	
9. Ongoing monitoring requirements to be undertaken by primary care See section 10 for further guidance on management of adverse effects/ responding to monitoring results.	Monitoring When monitoring is indicated (as per specialist)	Frequency
	Full blood count. Special caution is necessary in rapidly developing thrombocytopenia and severe thrombocytopenia ($75 \times 10^9/L$) or a drop in baseline platelets of more than 30%; contact the hospital clinician for advice in this instance	Every 6 months
	Serum creatinine or eGFR and weight. The dose of enoxaparin should be reviewed when these results are available. The enoxaparin dose should be recalculated using the Cockcroft-Gault equation	Every 6 months (or CrCl <15ml/min – refer)
	Serum Potassium – Low molecular weight heparins (LMWH's) can cause hyperkalaemia due to suppression of aldosterone secretion. Patients at higher risk of this include those with diabetes mellitus, chronic renal failure, pre-existing metabolic acidosis, raised plasma potassium or those taking potassium-sparing drugs.	Every 6 months (in at-risk patients)
10. Adverse effects and managements Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme www.mhra.gov.uk/yellowcard	Result	Action for GP
	Hyperkalaemia: LMWH can cause hypoaldosteronism, which may result in hyperkalaemia. Potassium should be monitored before and during treatment, particularly in patients at risk of high potassium e.g. renal impairment, ACE inhibitors, angiotensin II receptor blockers, potassium sparing diuretics etc.	Monitor plasma potassium regularly. Stop if symptomatic hyperkalaemia develops. Discuss with initiating physician/haematology. Please refer to ukkidney.org <u>clinical practice guidelines -treatment of acute hyperkalaemia in adults.</u>
	Any active bleeding	Discuss with initiating physician/haematology
	Heparin-induced thrombocytopenia (HIT) is a rare side-effect of heparin including LMWH. Should thrombocytopenia occur, it usually appears between the 5 th and the 21 st day following the beginning of enoxaparin sodium treatment. The risk of HIT is higher in postoperative patients and mainly	Referral to haematology for review

	<p>after cardiac surgery and in patients with cancer.</p> <p>HIT should be suspected if platelet count falls by more than 30% from baseline alongside clinical suspicion of a new thrombotic event.</p>	
	Injection site reactions	Usually mild and should not cause discontinuation of therapy. If severe, seek advice from haematologist.
	Osteoporosis	Bone density measurement is not generally indicated for relatively short-term treatment (up to 3 months). This would be arranged by the hospital if appropriate.
	This only lists the key important ADRs – for comprehensive information on cautions, contra-indications and interactions please refer to the current BNF and Summary of Product Characteristics https://www.medicines.org.uk/emc/	
<p>11. Advice to patients and carers</p> <p>The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.</p>	<p>The patient should be advised to report any of the following signs or symptoms to their GP without delay:</p> <ul style="list-style-type: none"> • Report any adverse effects to their GP and/or specialist • Ensure they have a clear understanding of their treatment • Report any changes in disease symptoms to GP and/or specialist • Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy • Take/administer the medication as prescribed • Undertake any monitoring as requested by the GP and/or specialist 	
<p>12. Pregnancy, paternal exposure and breast feeding</p> <p>It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review but the ongoing responsibility for providing this advice rests with both the GP and the specialist.</p>	<p><u>Pregnancy:</u></p> <p>Enoxaparin is not known to be harmful, low molecular weight heparins do not cross the placenta.</p> <p><u>Breastfeeding:</u></p> <p>Enoxaparin can be used during breastfeeding. Although limited published evidence of safety, low levels anticipated in milk due to the drug's properties and not absorbed from the infant's GI tract. Used in full-term neonates from birth.</p>	
<p>13. Specialist contact information</p>	<p>Documented in letter from specialist care to the primary care prescriber. This is the initiating clinician in liaison with haematology</p> <p>Name: <i>[insert name]</i></p> <p>Role and specialty: <i>[insert role and specialty]</i></p> <p>Daytime telephone number: <i>[insert daytime telephone number]</i></p> <p>Email address: <i>[insert email address]</i></p> <p>Alternative contact: <i>[insert contact information, e.g. for clinic or specialist nurse]</i></p> <p>Out of hours contact details: <i>[insert contact information, e.g. for duty doctor]</i></p>	
<p>14. Additional information</p>	<p>Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed.</p> <p>Enoxaparin is a biological medicine where biosimilars are available. Therefore, enoxaparin must be prescribed by brand name and the brand name specified on the prescription should be dispensed in order to avoid inadvertent switching (this will be communicated at the point of initiation). In exceptional circumstances, (e.g. during an emergency or supply shortage), it may be appropriate to</p>	

	administer an alternative brand as the risk of missing a dose is far greater than the risk of interchanging brands.
15. References	<ul style="list-style-type: none"> • British National Formulary Online, accessed 26/08/222 • Electronic Medicines Compendium (EMC), accessed 26/08/2022 • The Renal Association, Clinical Practice Guidelines, Treatment of Acute Hyperkalaemia in Adults, accessed 26/08/2022 • <i>Guidelines on the diagnosis and management of heparin- induced thrombocytopenia...</i> (October 2012). Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1111/bjh.12059 (Accessed: April 8, 2023).
16. To be read in conjunction with the following documents	<ul style="list-style-type: none"> • NHSE policy- Responsibility for prescribing between Primary & Secondary/Tertiary Care
17. Local arrangements for referral Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.	<p>Hospital specialist to GP</p> <ul style="list-style-type: none"> • Write to inform GP (and/or substance misuse team if appropriate) when therapy has been initiated, supply a copy of the shared care guideline and request agreement to shared care. • Inform GP of baseline test results and intended duration of treatment. • Continue to prescribe and monitor the patient until GP has confirmed date for transfer of care. • Advise GP of any medication changes and any specific monitoring requirements. <p>GP to Hospital specialist</p> <ul style="list-style-type: none"> • Reply to request for shared care within two weeks to acknowledge receipt and decision to participate. • Contact the hospital specialist as soon as possible if concerns over prescribing, treatment efficacy, intolerance or disease progression. • Inform hospital specialist of relevant changes in concomitant medication.

APPENDIX 1 - DOSAGES

Licensed indications:

- Prophylaxis of venous thromboembolic disease, especially in surgical patients – moderate and high risk -**see table 1**

- Prophylaxis of venous thromboembolic disease in medical patients – **see table 1**

The recommended dose for the thromboprophylaxis of venous thromboembolism (VTE) is shown in table 1.

Table 1. Prophylactic enoxaparin dosing

Actual Body Weight (kg)	Dose	Dose if CrCl < 30mL/min
< 50	20mg SC OD	Discuss*
50 – 100	40mg SC OD	20mg SC OD
101 – 150	40mg SC BD	40mg SC OD
> 150	60mg SC BD	60mg SC OD
*Patients < 50kg with CrCl < 30mL/min should be discussed with Haematology registrar/ consultant.		

- Treatment of deep-vein thrombosis and pulmonary embolism in uncomplicated patients with low risk of recurrence -**see table 2**
- Treatment of deep-vein thrombosis in patients with risk factors such as obesity, cancer, recurrent VTE, or proximal thrombosis –**as per haematology**
- Treatment of pulmonary embolism in patients with risk factors such as obesity, symptomatic pulmonary embolism, cancer, or recurrent VTE –**as per haematology**
- Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer –**as per haematology**

The recommended dose of enoxaparin for the treatment of acute VTE is 1.5mg/kg subcutaneously (SC) ONCE a day rounded to the nearest whole syringe. See table 2. For high-risk patients, for example patients who have a symptomatic PE, cancer, recurrent VTE or proximal (vena iliaca) thrombosis consider discussing with haematology with regards to treating at an increased dose of 1mg/kg SC TWICE a day.

Table 2. Treatment enoxaparin dosing of acute VTE

Actual Body Weight (kg)	Standard dose	Severe renal impairment (Creatinine Clearance < 30mls/min)
40 – 46	60mg SC OD	1mg/kg SC OD*
47 – 59	80mg SC OD	1mg/kg SC OD*
60 – 74	100mg SC OD	1mg/kg SC OD*
75 – 89	120mg SC OD	1mg/kg SC OD*
90 – 110	150mg SC OD	1mg/kg SC OD*
111 – 130	180mg (100mg + 80mg) SC OD	1mg/kg SC OD*
> 130 (Obese)	0.75mg/kg SC BD**	1mg/kg SC OD*
For dosing in underweight patients please seek advice from haematology registrar/consultant		
**If total dose exceeds 150mg BD then discuss with haematology		
*Dose band to the nearest 10mg for ease of administration		

Note patients with end-stage renal disease should be discussed with haematology registrar/consultant or consultant nephrologist.

APPENDIX 1 - DOSAGES

Unlicensed/off-label indications:

- Prophylaxis and treatment of venous thromboembolism in pregnancy and postpartum – **see below**

Enoxaparin dosing in pregnancy and the puerperium

PROPHYLACTIC DOSE:

Booking Weight (kg)	Enoxaparin dose
<50	20mg daily
50 - 90	40mg daily
91 - 130	60mg daily
131 - 170	80mg daily
>170	0.6mg/kg/day*
High (intermediate) prophylactic dose (weight between 50 – 90kg)	40mg twice daily

TREATMENT DOSE: 1mg / kg TWICE daily (dose banded)

Booking Weight (kg)	Enoxaparin dose
<50	40mg TWICE daily
50 – 69	60mg TWICE daily
70 – 89	80mg TWICE daily
90 – 109	100mg TWICE daily
110 - 125	120mg TWICE daily
> 125	Discuss with haematologist

- Treatment of portal vein thrombosis under the direction of a hepatology specialist – **see table 2**
- Patients unable to take warfarin and in whom a direct oral anticoagulant (DOAC) is not appropriate or contraindicated. – **see table 2/as per haematology**
- Patients in whom it has not been possible to stabilise on oral anticoagulant therapy and in whom a DOAC is not appropriate or contraindicated (for example: a patient with a replacement metal mitral heart valve and a sub-therapeutic INR and ‘bridging’ therapy is required). – **see table 2/as per haematology**
- IV drug users (where warfarin is generally considered inappropriate) and in whom a DOAC is not appropriate or contraindicated. – **see table 2/as per haematology**

ENOXAPARIN SHARED CARE PROFORMA

Send this referral to GP for ongoing prescription of enoxaparin according to the BHRUT Enoxaparin Shared Care Protocol

- Hospital to provide initial 28-day supply of enoxaparin and to complete heparin induced thrombocytopenia (HIT) monitoring if required.
- GP to continue prescribing and carry out further monitoring as specified by specialist.

Name:

DOB:

Hosp No:

Consultant:

Please affix addressograph

- Patient's medical care remains with the hospital consultant who initiated enoxaparin.

1) REFERRING CONSULTANT Referring consultant _____ QH [] KGH [] Consultant contact number _____ Next consultant/nurse clinic appointment _____	2) REFERRING NURSE Referring nurse _____ QH [] KGH [] Nurse contact number _____ GP/practice receiving referral _____
2) INDICATION FOR ENOXAPARIN a) Thromboprophylaxis: In pregnancy Cancer b) Deep vein thrombosis / Pulmonary embolism: In pregnancy Injectable IVDU Cancer Other – give details _____	
3) TREATMENT INFORMATION Patient's weight _____ (kg) Dose of enoxaparin _____ mg ONCE/TWICE daily (delete as appropriate) Date started _____ Intended dose changes (if applicable): Dose to change to _____ mg ONCE/TWICE daily (delete as appropriate) on (date) _____ Proposed duration of treatment: 3 months 6 months LIFELONG DURATION OF PREGNANCY AND 6 WEEKS POSTPARTUM Enoxaparin to be administered by: Patient or carer District Nurse (fax this form along with DN referral)	
4) MONITORING REQUIREMENTS Baseline results: Creatinine: _____ (µmol/L) CrCl: _____ mL/min / eGFR _____ (mls/min/1.73m ²) Platelets: _____ (x10 ⁹ /L) Potassium: _____ mmol/L Other: _____	
Form completed by: Signature: _____ Print name: _____ Designation: _____ Contact No (bleep/ext): _____ Date: _____ Received at GP practice by: _____ Time: _____ Date: _____ Shared Care Accepted Yes [] No [] .If no, please state reason: _____	