

NORFOLK AND WAVENEY STP THERAPEUTICS ADVISORY GROUP (TAG)

SHARED CARE AGREEMENT (SCA) FRAMEWORK

Shared care guidelines for Low Molecular Weight Heparin (LMWH)

Monitoring level	Level Amber 2 – Prescribe the drug and perform a more intense level of monitoring, e.g. quarterly
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Generic and Proprietary/Brand Name

Low Molecular Weight Heparin (LMWH) preparations covered by this SCA are:

- Enoxaparin sodium* (Inhixa®)
- Dalteparin sodium (Fragmin®)
- Tinzaparin sodium (Innohep®)

Enoxaparin sodium is a biologic medicine and should always be prescribed by brand name. Please refer to the Specialist Pharmacy Services (SPS) publication '[Example medicines to prescribe by brand name in primary care](#)' for further information.

Indication for Shared Care

If an individual requires more than a few days anticoagulation treatment they are generally switched to oral therapy with warfarin or another oral anticoagulant (apixaban, edoxaban, rivaroxaban or dabigatran).

However, there are certain situations where long-term use of heparin may be indicated:

- Medium to long-term thromboprophylaxis for patients in whom oral anticoagulation is contraindicated or inappropriate
- Treatment of Venous Thromboembolism (VTE) for patients in whom oral anticoagulation is contraindicated or inappropriate (e.g. in those taking interacting drugs, certain patients with cancer, poor compliance).

Patient Information

The manufacturer's Patient Information Leaflet for the LMWH product prescribed will be used as the basis for counselling patients. This is available as a package insert or otherwise via <https://www.medicines.org.uk/emc>. Training for subcutaneous administration will be given to patients and can be arranged at the hospital (if necessary).

Specialist Contact Details

Haematology Department Contacts – Norfolk & Norwich University Hospital (01603 286286)

Anticoagulant practitioners: via the NNUH switchboard extension 3809 *or* **On Call Haematologist** via the NNUH switchboard extension 6744

Haematology Department Contacts – The James Paget University Hospital (Tel 01493 452452)

On Call Haematologist: Through the JPUH switch board

Anticoagulant Nurses: Tel: 01493 453213, or Bleep 1473 via switchboard

Haematology Department Contacts – The Queen Elizabeth Hospital (Tel 01553 613613)

On call Haematologist: Through the QEH switch board

Clinical Nurse Specialist: Tel: 01553 613355

GENERAL PRINCIPLES FOR SHARED CARE PRESCRIBING

- Shared Care is only appropriate if it provides the optimum solution for the patient.
- GPs are **invited** to participate. If GPs are not confident to undertake these roles, 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.
- **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable if they are unwilling to do so.**
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP and when the patient's condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring.
- **The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.**

Background to Treatment

Heparin potentiates the action of anti-thrombin accelerating inactivation of thrombin and other activated coagulation factors, especially Xa.

LMWHs have a longer duration of action than unfractionated heparin and do not require routine anticoagulant monitoring.

LMWHs are at least as effective as unfractionated heparin in the treatment and prophylaxis of VTE, with a lower or equivalent haemorrhagic risk. They have a lower incidence of heparin-induced thrombocytopenia (HIT) (see **side effects** below) and less risk of osteoporosis.

LMWHs have replaced unfractionated heparin for most indications.

Licensed Use

Please refer to the manufacturer's Summary of Product Characteristics (SPCs) for up-to-date information via <https://www.medicines.org.uk/emc>

- Prophylaxis of VTE - medical and surgical
- Treatment of VTE

Also, the treatment of unstable angina and non-Q-wave Myocardial Infarction (MI) / acute ST elevation MI / thrombus prophylaxis in haemodialysis.

Criteria for Patient Selection

Patients requiring therapeutic or prophylactic anticoagulation and:

1. Oral anticoagulation is contraindicated / ineffective (e.g. in those taking interacting drugs, certain patients with cancer)
2. Have poor compliance/life style e.g. alcoholism and drug addiction
3. Have high risk of bleeding e.g. existing thrombocytopenia / certain patients with cancer e.g. receiving myelosuppressive treatment

Form and strength of preparation

See BNF – LMWHs are available in pre-filled syringes, vials or ampoules.

Please note that LMWHs differ due to their manufacturing process, molecular weights, specific anti Xa activities, units and dosage. This results in differences in pharmacokinetics and associated biological activities (e.g. anti-IIa activity, and platelet

interactions). Special attention and compliance with the instructions for use specific to each proprietary medicinal product are therefore required.

Side Effects

Please refer to the manufacturer's Summary of Product Characteristics (SPCs) for up-to-date information via <https://www.medicines.org.uk/emc>

• Haemorrhage:

Common: such as haematoma, ecchymosis other than at injection site, wound haematoma, haematuria, epistaxis and gastro-intestinal haemorrhage

Uncommon: Intracranial haemorrhage; retroperitoneal haemorrhage

• Local skin reactions/injection site reactions – generally itchy, erythematous lesions

• **Heparin-Induced Thrombocytopenia (HIT):**

An immune mediated process where antibodies bind to platelets in the presence of heparin and cause aggregation (thrombosis) and thrombocytopenia. Signs of heparin-induced thrombocytopenia include a 30% reduction of platelet count, thrombosis, or skin allergy. If heparin-induced thrombocytopenia is strongly suspected or confirmed, the heparin should be stopped and an alternative anticoagulant should be given.

• Thrombocytosis (platelet count increased > 400g/l) – For Enoxaparin sodium reported as very common in treatment of patients with DVT, with or without PE

• Hepatic enzymes increase (transaminases levels > 3 times the upper reference limit)

• Hypersensitivity reactions (including urticaria, angioedema, and anaphylaxis (rare))

• Hyperkalaemia secondary to hypoaldosteronism - see also Contraindications &

Precautions

• Alopecia on prolonged use

• Osteoporosis following long-term therapy (> 3 months)

• Priapism (rare)

Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Drug Interactions

Please refer to [BNF](#) and [SPCs](#)

• Anti-platelet drugs – risk of bleeding increased

• Nitrates – increase excretion of LMWH – reduced anticoagulant effect

• NSAIDs – possible increased risk of bleeding

• ACE inhibitors and Angiotensin-II Receptor Antagonists – increased risk of hyperkalaemia.

Cautions and Contraindications

Contraindications:

Hypersensitivity/allergy to heparin including HIT.

Each patient must be assessed on an individual basis for risks (bleeding) and benefits (anti-thrombotic effect) of LMWH.

The risks of clinically significant bleeding with LMWH (as with all anticoagulants) are increased if the person has:

an inherited bleeding disorder; thrombocytopenia; recent cerebral haemorrhage; severe liver disease; renal failure; after major trauma or recent surgery - especially to eye (excluding cataract) or nervous system; severe hypertension; active or recent gastric or duodenal ulcer; acute bacterial endocarditis.

Precautions:

Thrombocytopenia: There is a risk of HIT associated with LMWH (a drop in platelets associated with thrombosis; see earlier under **side effects**).

HIT should be suspected if there is a sudden worsening of thrombotic problems, new skin lesions or symptoms of an allergic reaction after the injection. A reasonable level of suspicion is therefore important. The commonest time for HIT to occur is between 5 and 21 days following the beginning of therapy.

Patients should be warned to look for evidence of recurrence of thrombosis or bleeding and to report this immediately. If there is concern regarding HIT the FBC should be checked.

Platelet counts should be measured just before treatment with LMWH. Routine monitoring of platelet counts whilst on LMWH to detect HIT is indicated if the patient has had exposure to unfractionated heparin or after cardiac bypass. Routine platelet count monitoring in other situations is not required. If the patient develops symptoms of HIT, stop LMWH and seek advice from the On-Call Haematologist.

Renal Failure: LMWH is renally excreted, and caution must be taken in patients with severe renal failure as the risk of bleeding may be increased. A dose reduction and anti-Factor Xa monitoring may be required for these patients. See '**Indication for referral back to specialist**' section.

Consideration should be given to dose reduction and factor Xa monitoring for patients with Creatinine Clearance <30mL/min.

(See also **indication for referral back to specialist**)

Hyperkalaemia: Inhibition of aldosterone secretion by unfractionated or low molecular weight heparin can result in hyperkalaemia; patients with diabetes mellitus, chronic renal failure, acidosis, raised plasma potassium or those taking potassium-sparing drugs seem to be more susceptible. The risk appears to increase with duration of therapy. Plasma-potassium concentration should be measured in patients at risk of hyperkalaemia before starting the heparin and monitored regularly thereafter, particularly if treatment will be for longer than 7 days.

Initiation of therapy – by whom

- **Treatment dose:** by the hospital
- **Prophylactic dose:** GP in discussion with hospital or hospital

Initial dose and method of administration and supply

Please refer to [BNF](#) and [SPCs](#)

Route: Subcutaneous injection

Frequency of administration: Generally, once daily or twice daily depending on the LMWH being used. In severe thrombocytopenia, it may be given twice daily.

Maintenance Dose and Administration

Please refer to [BNF](#) and [SPCs](#)

Duration of therapy / How the treatment will be reviewed and if appropriate, stopped

Treatment: Generally, for 6 weeks to 6 months but may be longer if symptoms or precipitating cause persist. Duration will be indicated on individual patient plan.

Prophylaxis: Duration will be indicated on individual patient plan.

Initial monitoring / baseline assessment – by Specialist

All patients will have baseline platelet count, renal function and potassium level.

Specialist monitoring responsibilities

Anticoagulation:

LMWH does not prolong the activated Partial Thromboplastin Time (aPTT) (unless in overdosage) and can only be monitored by measuring the anti-Xa activity. This is not a routinely available assay.

No routine anticoagulant monitoring is required. Very occasionally monitoring may be indicated - this will be clearly outlined in the individualised patient plan and if necessary, will be arranged by the hospital.

Platelet count:

It is recommended that platelet counts be measured before the initiation of therapy.

Osteoporosis:

Bone density measurement is not generally indicated where the sole risk factor is LMWH.

For patients on treatment doses the NNUH recommend:

Patients are reweighed every 3 months to check if the dose is still appropriate, *and* that the need to remain on LMWH is confirmed with the initiator (generally the hospital specialist) *and* if there is concern regarding renal function, that this is checked.

GP / Community Team or other Primary Care monitoring responsibilities

- Indications for monitoring of FBC during LMWH treatment; post cardiac surgery, patient at high risk of bleeding (to detect anaemia), or known significant thrombocytopenia ($<80 \times 10^9/L$).
- Renal function and potassium should be checked 3-monthly in patients deemed at risk of developing renal impairment or hyperkalaemia. **Consideration should be given to dose reduction and factor Xa monitoring for patients with Creatinine Clearance $<30\text{mL}/\text{min}$.**

(See also indication for referral back to specialist)

- Creatinine Clearance $<30\text{mL}/\text{min}$ contact initiating specialist.

Consultant / Specialist prescribing responsibilities

- For patients on treatment regimen - initiation of LMWH and production of individual management plan for duration and dosage.
- To provide advice regarding the indications for prophylactic LMWH.

GP prescribing responsibilities

Following advice from hospital consultant:

- To start prophylactic prescriptions (unless there are contraindications)
- To continue the prescription for treatment and prophylaxis as and when necessary.

Indications for referral back to Specialist

Patient reports problems such as bleeding, suspicion of thrombosis or reactions.

Significant bleeding: Stop LMWH – seek advice from anticoagulant practitioners or On Call Haematologist

Life Threatening Haemorrhage: *Stop LMWH.* Admit via hospital

Suspected HIT: 30 to 50% drop in platelet count (usually platelets are $> 20 \times 10^9/L$ in HIT) or worsening thrombosis – *Stop LMWH* and seek advice from On Call Haematologist

Localised skin reactions: Consider change to another brand (N.B. note different dosages)

Development of renal failure (defined as Creatinine Clearance $<30\text{mL/min}$): assessment of risks and benefits of the patient staying on therapeutic anticoagulation is required; including consideration of the indication for anticoagulation, the cause of renal impairment (including the potential for reversibility), and the clinical state of the patient.

Additional information

[British Journal of Haematology | Wiley Online](#)

BCSH guidance Diagnosis and Management of Heparin Induced Thrombocytopenia: Third Edition- British Journal of Haematology, 2024, 204, 459-475

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Date of Approval	October 2025
Reviewed by	Norfolk & Waveney Therapeutic Advisory Group
Last review date	August 2021
Date of next review	August 2027

Document history:

Version	Date	Author/Editor	Status	Comment
1.	January 2004	Dr Jennie Wimperis, NNUH in consultation with Dr Jane Keidan (QEH) and Dr Shalal Sadullah (JPUH)	Superseded	Therapeutics Advisory Group (TAG) approved
2.	November 2007 to March 2008	Dr Jennie Wimperis, NNUH in consultation with Dr Natasha Curtin (QEH) and Dr Shalal Sadullah (JPUH).	Superseded	Patient criteria and prescribing responsibility reviewed and clarified. Hospital authors and contacts updated. V2 published March 2008.
3.0	July 2014	To be confirmed / Editor – Fiona Marshall, TAG Lead Pharmacist, NEL CSU Anglia.	Draft	Interim version whilst negotiations over provision of treatment and prevention of thromboembolism in line with national guidance are ongoing. Updated regarding general principles of shared care, formatting, ownership, authors, dosages and indications. Checked against current information regarding interactions, ADRs, side-effects, contraindications and precautions. Info regarding risk of hyperkalaemia and monitoring requirements inserted.
3.1	August 2014	Dr Jennie Wimperis, NNUH / Editor – Fiona Marshall, TAG Lead Pharmacist, NEL CSU Anglia.	Draft	Support for suggested changes plus further recommendations for changes received from Dr Jennie Wimperis (NNUH); relating to dosing in renal failure, overweight and low weight patients, monitoring requirements and indications for referral back to the specialist, dosage near delivery in pregnancy, References to use of NOACs added.

				Reference and link to BCSH guidance added to additional information.
3.2	September 2014	Dr Jennie Wimperis, NNUH / Editor – Fiona Marshall, TAG Lead Pharmacist, NEL CSU Anglia.	Current	Changes noted and supported by the TAG September 2014. Details confirmed with local specialists after the TAG meeting.
4.0	May – Sept 17	TBC, NNUH, Dr Shalal Sadullah, JPUH, and Dr Martin Lewis, QEH / Editor – Fiona Marshall, TAG Lead Pharmacist, NEL CSU Anglia	Draft	Updated in line with current BNF and manufacturers' SPCs. Suggested amendments in Red font . For consideration by local specialists. No comments received May to August 2017. Supported for continued use by the TAG September 2017 in the interim.
5.0	Aug 2021	Jen Carroll, TAG Lead Technician	Superseded	Discussed at August 2021 TAG meeting. Review dates extended for a year from meeting due to covid pressures
6.1	September 2025	Medicines Optimisation Team (NC)	Final	Inhixia replacing Clextane as cost-effective brand of Enoxaparin. SCA updated onto new ICS template. Appendix 1 dosing information removed. Criteria for referral back to the specialist defined as Creatinine Clearance <30mL/min. References to pregnancy removed. References in additional information section updated. Reference to the SPS publication 'Example medicines to prescribe by brand name in primary care' added.