Shared Care Protocol between Doncaster and Bassetlaw Hospitals NHS Foundation Trust and NHS Doncaster and Bassetlaw for the prescription and supply of Dalteparin (Fragmin®)

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1. Quick Reference Guide to the Doncaster and Bassetlaw Shared Care Protocol for Dalteparin

	Treatment of VTE	Prophylaxis of VTE
Patients included	Certain cancer patients, injectable drug users, those unstable on or with a contra-indication to oral anticoagulants, pregnant women with VTE	High-risk surgical patients, those with a history of thrombosis associated with central venous access*, certain cancer patients, pregnant women at high-risk of VTE & for management of the antiphospholipid syndrome (recurrent miscarriage/ adverse pregnancy outcome)
Dosage & duration of therapy (see below for doses in renal impairment)	**Pregnant women*:** dose based on early booking weight and should not change: Under 50kg: 5,000 units **twice** daily 50-64kg: 7,500 units am & 5,000 units pm 65-79kg: 7,500 units **twice** daily 80-94kg: 10,000 units am & 7,500 units pm 95-119kg: 10,000 units **twice** daily 120-149kg: 12,500 units **twice** daily 150kg or more: 15,000 units **twice** daily Continued throughout pregnancy & for at least 6 weeks post-partum as advised by Haem/Obs clinic **All other patients:** dose based on weight (see below for dosing in renal impairment): Under 46kg: 7,500 units once daily 46-56kg: 10,000 units once daily 57-68kg: 12,500 units once daily 69-82kg: 15,000 units once daily 83-119kg: 18,000 units once daily 120-149kg: 12,500 units **twice** daily 150kg or more: 15,000 units **twice** daily After **4 weeks treatment**, dose is reduced to: Under 57kg: 7,500 units once daily 57-68kg: 10,000 units once daily 69-82kg: 12,500 units once daily 83-100kg: 15,000 units once daily 101-120kg: 18,000 units once daily Over 120kg: discuss with Haematologist – unless a dose change is indicated on the shared care form Continue for at least 3 months if 1st event; long-term if recurrent idiopathic event; consider using long-term if ongoing risk factor	**In pregnancy for those at high risk:** dose based on early pregnancy bodyweight and should not change: under 46kg: 2500 units once daily 46-119kg: 5000 units once daily 120-150kg: 7500 units once daily 150kg or more: 5000units **twice** daily Continued throughout pregnancy and for 6 weeks postpa May be stopped at term in antiphospholipid syndrome ass with recurrent miscarriages. **All other patients:** Dose based on weight: Under 46kg: 2,500 units once daily 46-119kg: 5,000 units once daily 120-149kg: 7,500 units once daily 150kg or more: 5,000 units **twice** daily High risk surgical patients may receive extended prophylaxis post-discharge (e.g. fractured neck of femur patients receive a 30 day course post-operatively).
Renal impairment	If **eGFR less than 30 mls/min/1.73m^2**: Dalteparin is contraindicated	If **eGFR less than 20 mls/min/1.73m^2:** dose at 2,500 units once daily Monitor as advised by DBHFT
Hospital supply	First 28 days of treatment	First 28 days (high-risk surgical patients receive the full course from hospital)
Secondary care monitoring	Baseline FBC, coag screen (for treatment doses only), LFT, accurate body weight. Repeat FBC within 24hrs and weekly for 2 weeks ONLY if the patient has had exp to heparin/ LMWH or cardiopulmonary bypass surgery within the last 100 days. Regular potassium leve patients risk of hyperkalaemia (*i.e. those with diabetes mellitus, chronic renal failure, acidosis, raised potassium levels, on potassium-sparing drugs or potass supplements or on long-term dalteparin treatment.	
Primary care monitoring	Patients weight – adjust dalteparin dose as above if weight alters. Monitor renal function – dose may need adjusting if renal function deteriorates. In high-risk surgical patients: repeat FBC weekly for 2 weeks ONLY if the patient has had exposure to heparin/ LMWH or cardiopulmonary bypass surgery within the last 100 days (details to be faxed at discharge). **No HIT monitoring is required for other patients on treatment or prophylaxis.**	
Administ-ration of dalteparin	Patients or carers will be taught to administer where possible; otherwise referral for administration by the Community Nursing team will be made	

Note that only the pre-filled syringes for dalteparin should be prescribed under the terms of this protocol GPs will not be asked to initiate therapy; requests will be made via the Dalteparin SC Proforma (Appendix 2)

Contents

2. Background and supporting information

The use of low molecular weight heparins (LMWH) to prevent and treat venous thromboembolism (VTE) has increased significantly in recent years. The availability of LMWHs has permitted the treatment of VTE on an outpatient basis, and the recent NICE guidelines concerning the prevention of VTE have led to an increase in the use of prophylactic LMWH. LMWHs are now widely used for a number of licensed and unlicensed indications.

Purpose of the shared care protocol

This shared care arrangement has been developed to facilitate the prescribing and supply of LMWHs in the community and to provide a reference source for those involved in prescribing, supplying and monitoring patients who need LMWH, for treatment or prevention of VTE.

Exclusions from the shared care protocol

Patients with the following conditions are excluded from this protocol:

- History of Heparin Induced Thrombocytopenia (HIT)
- Significant hepatic impairment
- Active gastric or duodenal ulceration or oesophageal varices
- Haemophilia and other inherited bleeding disorders / major bleeding disorders
- Thrombocytopenia with platelets less than $75x10^9$/L
- Recent cerebral haemorrhage
- Severe hypertension (i.e. 230/120mmHg or higher)
- Recent neurosurgery or eye surgery
- Acute bacterial endocarditis
- Hypersensitivity to heparin, dalteparin, other low molecular weight heparins
- Peri-procedural bridging anticoagulation
- Children under 16 years

Administration of dalteparin

In most circumstances the patient or carer is advised on how to perform the administration of dalteparin. If this is not possible a referral is made to the district nurse to administer the injection.

Clinic Review

The medical team initiating treatment or prophylaxis is responsible, where required, for ensuring that the patient attends for regular disease review at intervals determined by their clinical status. This would normally be carried out by that medical team. If Haematology input is desired, the GP or medical team must make a referral to DBHFT Haematology

Contacts

If any problems or concerns arise please contact the relevant specialist:

Consultant initiating dalteparin treatment (contact details on referral form / clinic letters)

Dr Ruth Medlock (Consultant Haematologist) (01302) 644022

3. Dalteparin for treatment of VTE disease

The categories of patient suitable for Primary care continuation of prescription of dalteparin for treatment of VTE disease are follows**:**

- Cancer patients undergoing cancer therapies or with metastatic malignancy
- Injectable drug users
- Patients in whom it has not been possible to stabilise on oral anticoagulant therapy
- Patients with a contra-indication to oral anticoagulants
- Pregnant patients with VTE disease

Such patients who are referred to Primary care providers under the shared care arrangements will have been prescribed dalteparin for more than 28 days by a secondary care specialist. Monitoring for heparin induced thrombocytopenia (HIT) will have been completed before referral to primary care or arrangements should have been made for this to be completed (see below).

Initial prescription & monitoring

A decision is made for a patient to be commenced on dalteparin by the patient's DBHFT clinical team following discussion with the patient. Baseline investigations will be undertaken and, if satisfactory, the patient will be commenced on treatment. At discharge, the patient will be given a prescription for a 28 day supply of the drug. Arrangements will be made for monitoring for heparin induced thrombocytopenia as appropriate. The patient's GP will be informed of the proposed management plan and monitoring arrangements.

Referral method from secondary to primary care for continuation of supply

A formal referral to the patient's GP will be made from the DBHFT medical team initiating dalteparin treatment using the Dalteparin Shared Care Proforma (Appendix 2). HIT monitoring should be completed prior to discharge, or the patient should be given a form to attend for monitoring (the prescriber is responsible for reviewing and acting on abnormal results).

At the point of transfer, a medical and medication history will be provided to the GP, including:

- Consultant and contact details
- Indication for dalteparin, dose prescribed & proposed duration of treatment, including intended dose changes if applicable
- Patients weight, baseline creatinine, platelet and potassium results
- Date treatment started
- Other relevant clinical information, including concurrent medication
- Interval before patient next due to be seen by DBHFT for disease review
- Any specific instructions for the practice, e.g. for continued monitoring of potassium

Treatment should only be discontinued prematurely by the GP after discussion with the responsible hospital clinician, unless there are exceptional circumstances. Treatment discontinuation must be confirmed by letter from the GP to the hospital clinician and patient and/or carer.

Primary care monitoring

Once the patient has been accepted by their primary care provider the responsibility for re-prescribing the drug and further monitoring of renal function , if appropriate, will pass to the patient's practice (see "Responsibilities of the Practice"). This will be communicated via the dalteparin shared care proforma. It is advised that this monitoring is done regularly, according to clinical judgment, and action taken as appropriate. **Since the dose of dalteparin for treatment of VTE is calculated based on weight, non-pregnant patients on long-term treatment or prophylaxis should be accurately re-weighed** (at a frequency determined by clinical judgement e.g. more often if rapid weight loss) **and the dosage of dalteparin adjusted accordingly** see quick reference guide).

4. Dalteparin for prophylaxis of VTE disease

The patients who may be discharged from secondary care on thromboprophylaxis with dalteparin are:

- High risk surgical patients requiring extended prophylaxis according to NICE and DBHFT guidelines
- Those with a history of thrombosis associated with central venous access lines
- Pregnant women requiring prophylaxis
- Cancer patients undergoing cancer therapies or with metastatic malignancies

4.1 Patients discharged with extended courses of prophylactic dalteparin (e.g. fractured neck of femur patients receiving a 30 day course post-operatively):

Initial prescription & monitoring

These patients will be given the supply of prophylactic dalteparin required to complete the course by the DBHFT clinical team responsible for their care. Arrangements will be made for monitoring for heparin induced thrombocytopenia, where appropriate. The patient's GP will be informed of the proposed management plan and monitoring arrangements.

Referral method from secondary to primary care for continuation of supply

A formal referral to the patient's GP will be made from the DBHFT medical team initiating dalteparin treatment, once HIT monitoring is complete, using the Dalteparin Shared Care Proforma (Appendix 2). A full history of the patient will be provided, including:

- Name of responsible consultant and contact details
- Indication for dalteparin, dose prescribed & proposed duration of treatment, including intended dose changes if applicable
- Date treatment started
- Other relevant clinical information, including concurrent medication
- Baseline creatinine, platelet and potassium results
- Interval before patient next due to be seen by DBHFT for disease review
- Any specific instructions for the practice, e.g. for continued monitoring of potassium

Treatment should only be discontinued by the GP after discussion with the responsible hospital clinician, unless there are exceptional circumstances. Treatment discontinuation must be confirmed by letter from the GP to the hospital clinician and patient and/or carer.

Primary Care monitoring

Once the patient has been accepted by their primary care provider the responsibility for re-prescribing the drug and further monitoring of renal function (if appropriate, see "Responsibilities of the Practice"), will pass to the patient's practice. This will be communicated via the dalteparin transfer form. It is advised that this monitoring is done regularly, according to clinical judgment.

5. Summary of Responsibilities

Responsibilities of the Hospital

- Initiate treatment with dalteparin and provide the first 28 days of treatment, or the whole course for high-risk surgical patients needing extended thromboprophylaxis post-operatively
- Instruct patient or carer on administration (or arrange for district nurse to administer where this is not possible)
- Ensure patient has been given adequate written and verbal information about what dalteparin is, why it is being used, awareness of side effects, what to do if the side-effects occur and what the arrangements are for further prescriptions
- Monitor for heparin-induced thrombocytopenia and/or hyperkalaemia for the first 14 days of treatment
- Make formal referral to Primary care provider using the Dalteparin Shared care Proforma (Appendix 2)

- Keep the patient under clinical review by the Consultant initiating dalteparin, assessing need for ongoing dalteparin treatment for up to 6 months or arranging referral to consultant haematologist to assess need for longer-term treatment
- Provide advice and support if problems occur during treatment
- Give written direction to the GP as to when treatment should be discontinued
- Conduct annual audit / review as deemed appropriate

Responsibilities of the Practice

- Accept referral from secondary care to take on continued prescribing of dalteparin under this shared care agreement after initial 28 days (or sooner if agreed). Be aware that there are a number of different preparations of dalteparin injection; **only the pre-filled syringes** should be prescribed under the terms of this shared care protocol
- Reinforce educational points provided by the hospital
- .
- If patient develops thrombocytopenia, skin reaction or new thrombosis within 14 days of starting therapy, HIT should be considered. Refer as an emergency to the hospital for assessment and treatment.
- **Re-weigh non-pregnant patients on long-term dalteparin at a frequency according to clinical judgement** e.g. more often if rapid weight loss (e.g. cancer patients) **and change weight-adjusted doses as appropriate** (see quick reference guide).
- Monitor renal function and seek advice if deterioration becomes evident.
- Keep records or a register (using appropriate read codes) of all patients for whom dalteparin has been prescribed. Records 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.
- Discontinue treatment if the patient experiences severe side effects and the relevant contact at the hospital is not available
- Confirmation letter to patient and/or carer if treatment is discontinued
- Conduct audit / annual review as deemed appropriate

Reviewed by: Mr Lee Wilson – Formulary Pharmacist DBFHFT August 2017
Approved by: Doncaster & Bassetlaw Area Prescribing Committee August 2017

6. References

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2. Thrombosis and Embolism during Pregnancy and the Puerperium, Reducing the Risk: Royal College of Obstetricians and Gynaecologists Green Top Guideline No. 37a, November 2009. http://www.rcog.org.uk/files/rcog-corp/GTG37aReducingRiskThrombosis.pdf

3. Prevention of Venous Thromboembolism: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). William H. Geerts, David Bergqvist, Graham F. Pineo, John A. Heit, Charles M. Samama, Michael R. Lassen, and Clifford W. Colwell. Chest June 2008 133:381S-453 http://chestjournal.chestpubs.org/content/133/6_suppl/454S.abstract

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6. Low molecular weight heparin for intravenous drug users with deep vein thrombosis. Michael Russell and Deborah Dawson. http://emj.bmj.com/content/21/6/711.1.full

7. Summary of Product Characteristics Fragmin®: http://www.medicines.org.uk/EMC/searchresults.aspx?term=dalteparin+sodium&searchtype=QuickSearch

8. All Wales Medicines Strategy group. Prescribing of Low Molecular Weight Heparin in Wales http://www.wales.nhs.uk/sites3/Documents/371/Published%20to%20website%20v1.5.pdf

9. DBHFT VTE Guidelines http://www.dbh.nhs.uk/freedom_of_information/information_classes/Patient_Polices/Treatments_and_Investigations.aspx

10. NICE Clinical Guideline 92: Venous thromboembolism - reducing the risk. (January 2010) http://www.nice.org.uk/cg92

11. DH 2010. EFA2010/001 Medical patient weighing scales

Appendix 1: Dosing Tables for Dalteparin Dosing

- **Prophylaxis for Medical and Surgical Patients**

eGFR >20ml/min/1.73m^2	eGFR <20ml/min/1.73m^2*
5000units EVE	2500units EVE

*this lower dose should also be used in all those with evidence of acute kidney injury (oliguria over 12 hours or doubling of serum creatinine) - including obese patients

- **Treatment in Routine Patients**

Weight (kg)	Daily Dose
<46	7,500units OD
46-56	10,000units OD
57-68	12,500units OD
69-82	15,000units OD
>83	18,000units OD

- **Treatment in Pregnant Patients (unlicensed)**

Weight (kg)	Overall dose
<50	5,000units BD
50-64	7,500units AM & 5000units EVE
65-79	7,500units BD
80-94	10,000 units AM & 7,500units EVE
>95	10,000 units BD

- **Prophylaxis in Extremes of Body Weight (unlicensed)**

Weight (kg)	Dose
<46	2,500units EVE
≥120 - <150	7,500units EVE
≥150	5,000units BD

- **Treatment in Extremes of Body Weight (unlicensed)**

Consider using an increased treatment dose of dalteparin in patients weighing over 120kg (only in those with a calculated eGFR >30ml/min/1.73m^2) using the table below:

Weight (kg)	Dose
≥120 - <150	12,500units BD†
≥150	15,000units BD†

†for these patients, peak factor Xa level testing should be considered if the treatment continues for more than 5 days

APPENDIX 2

DALTEPARIN SHARED CARE PROFORMA

Send this referral to GP for ongoing prescription of dalteparin according to the Doncaster Dalteparin Shared Care Protocol

Not to be used for surgical patients being discharged on extended prophylaxis

Name:

DoB:

Hosp No.:

Consultant:

Please affix addressograph

- Hospital to provide initial 28 day supply of dalteparin and to complete heparin induced thrombocytopenia (HIT) monitoring* (repeat FBC weekly for 2 weeks) which is **ONLY** necessary if the patient has had exposure to heparin/ LMWH or cardiopulmonary bypass surgery within the last 100 days
- GP to continue prescribing and carry out further monitoring, as appropriate.
- Patient's medical care remains with the hospital consultant who initiated dalteparin.

1) REFERRING CONSULTANT

Referring consultant_____ DRI [ ] BDGH [ ]

Consultant contact number_____

Next consultant clinic appointment _____ GP/practice receiving referral_____

2) INDICATION FOR DALTEPARIN

a) Thromboprophylaxis: In pregnancy Central line Cancer

b) Deep vein thrombosis/ Pulmonary embolism: In pregnancy Injectable IVDU Cancer

Other – give details

3) TREATMENT INFORMATION

Patient's weight_____ (kg) Dose of dalteparin_____ units ONCE/TWICE daily (delete as appropriate)

Date started _____

Intended dose changes (if applicable)**:**

Dose to change to _____ units ONCE/TWICE daily (delete as appropriate) on (date) _____

Proposed duration of treatment:

3 months 6 months LIFELONG DURATION OF PREGNANCY

Dalteparin to be administered by: Patient or carer District Nurse (fax this form along with DN referral)

4) MONITORING REQUIREMENTS

Baseline results:

Creatinine:_____(µmol/L) eGFR_____(mls/min/1.73m^2) Platelets:_____(x10^9/L)

Form completed by:

Signature: _____ Print name: _____

Designation: _____ Contact No (bleep/ext.): _____ Date: _____

Received at GP practice by: _____ Time: _____ Date: _____