


Prescribing Clinical Network

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath), Crawley CCG and Horsham & Mid-Sussex CCG

Application for change in colour classification

Low Molecular Weight Heparins (LMWH) for Venous Thromboembolism (VTE) treatment in patients unable to take oral anticoagulant (excluding obstetrics)

GREEN - Non-Specialist Drugs GPs (or non-medical prescribers in primary care) are able to take full responsibility for initiation and continuation of prescribing		
BLUE - Specialist Input WITHOUT Formal Shared Care Agreement Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement		
AMBER - Specialist Initiation WITH Shared Care Guidelines Prescribing initiated and stabilised by specialist but has potential to transfer to primary care under a formal shared care agreement		
RED - Specialist ONLY drugs Treatment initiated and continued by specialist clinicians		
BLACK – NOT recommended Not recommended for use in any health setting across Surrey and NW Sussex health economy		
Medicine details		
Name	Dalteparin (Fragmin), Enoxaparin (Arovia, Clexane, Enoxaparin BECAT, Inhixa), Tinzaparin (innohep)	
Manufacturer	See SPC	
Licensed indication	Dalteparin - Treatment of venous thromboembolism (VTE) presenting clinically as deep vein thrombosis (DVT), pulmonary embolism (PE) or both. Enoxaparin - Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery. Tinzaparin – Treatment of venous thrombosis and thromboembolic disease including deep vein thrombosis and pulmonary embolus in adults.	
Formulation	Subcutaneous injection	
Usual dosage	See individual SPC	
Traffic Light Status	Current status	Proposed status
	Amber Star - information sheet provided, initial supply of 1month made by provider  20160526_colour classification guideline	BLUE - Specialist Input WITHOUT Formal Shared Care Agreement Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement

Reason for requested change

Current situation:

The above listed drugs were awarded the traffic light status of AMBER STAR by the PCN (now APC) in February 2015 for a **more limited indication than product license** – namely, VTE treatment in patients unable to take oral anticoagulants (excluding obstetrics).

A shared care information sheet for LMWH for this indication was approved at the same time, which is now overdue for review by the APC.

The primary care prescriber responsibilities listed within the current Amber Star information sheet are:

1. Subsequent prescribing of LMWH at the dose recommended and of sharps bins for disposal.
2. When initiating new medications, ensure that they do not interact with LMWH.
3. Monitoring of platelets, renal function and body weight as instructed by the specialist (minimum yearly).
4. Adjust the dose or stop treatment as advised by the specialist or immediately if an urgent need to stop treatment arises. Reasons for dose adjustment include a change in the patient's weight or renal impairment with creatinine clearance <30mL/minute. If HIT is suspected, LMWH should be stopped and the specialist informed immediately.
5. Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment.
6. Refer back to specialist if the patient's condition deteriorates.
7. Report adverse events to the specialist and CSM.

The above listed responsibilities are all either basic medical/prescribing care which should be used whenever prescribing/treatment occurs and/or are described within the SPC or the BNF, therefore there is no need for another, separate information sheet.

Current prescribing within APC CCG's area (from ePACT):

Data from ePACT will not differentiate between the various and different indications for use, therefore it is not supplied.

Proposed changes to the traffic light system:

There is a need for a specialist assessment or recommendation to enable patient selection and initiation of treatment, but:

- Monitoring of efficacy can be undertaken in primary care without specialist support
- Monitoring of toxicity can be undertaken in primary care without specialist support
- may require specific monitoring and possibly dose titration before transfer
- no ongoing requirement for specialist support but opportunity for advice

Also to be noted;

- The Amber Star Information sheet is a duplication of selected information available from BNF, however there is some information from the BNF that is not included in the information sheet e.g. monitoring of potassium. It is not known whether this is a deliberate omission or that the information on the BNF is more current.
- Information may become out of date whenever a new SPC or edition of BNF is issued.

Consequently it seems appropriate that these drugs should be re-classified as BLUE without information sheet.

The primary care prescriber responsibilities listed in the Amber Star information sheet are a combination of the judicious use of the drug SPC, BNF and professional knowledge, and (if unsure) seeking further advice from the specialist.

There does not appear to be a clear case to continue to have a separate information sheet for this indication, as all required information should be included in the treatment plan from the specialist.

Key Considerations

Cost implications to the local health economy

Colour change in PAD only - no cost implications anticipated

Impact to current prescriber or medication initiator

Initial prescription (and supply) of the LMWH to occur within secondary care by a specialist, as per local guidance.

Primary care can take over prescribing upon receipt of an agreed treatment plan, which should include details of drug dosage, possible side effects, blood tests and action to take if problems arise.

If further advice is required, primary care prescribers should use the contact details supplied on the communication letter from the specialist.

Impact to proposed prescriber or medication initiator

See above

Impact to patients

Colour change on PAD only – patients should not experience transfer of care issues if treatment plans are communicated effectively.

Additional comments

It is to be noted that the monitoring requirements considered by the BNF are different from that recommended in the current (and out of date) document, further illustrating the danger of having a separate source of information, that goes out of date almost as soon as it is published for use.

Proposals for APC consideration

All proposed drugs to change from AMBER Star to BLUE (with no information sheet).

Initial prescription (and supply) of the LMWH to occur within secondary care by a specialist, as per local guidance.

Proposed recommendation - Specialist prescribes the initial 1st month of drug treatment.

Primary care can take over prescribing **upon receipt of an agreed treatment plan from the specialist**, which must include details of drug dosage, possible side effects, and action to take if problems arise, as per local guidance.

Identified lead for development of necessary documents e.g. shared care agreement

Name:

Designation:

Organisation:

Estimated date of preparation:

Prepared by:

Georgina Randall, Senior Pharmacy Technician, Pharmaceutical Commissioning, Surrey Downs Medicine Management Team (Hosted Service)

Declaration of Interest:

Nil to declare

Date: 19/06/2019

Reviewed by:

Liz Clark, Lead Commissioning Pharmacist, Surrey Downs Clinical Commissioning Group (Hosted Service)

Declaration of Interest:

Nil to declare

Date: 28/08/19

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1	19/06/2019			Out for review
v.2				

DRAFT