

<b>Version Control</b>		
<b>Version</b>	<b>Date Amended</b>	<b>Summary of amendments</b>
20190624 Subtherapeutic INR LES Final v7	April 2022	Open Exeter changed to FPPS. Termination and GMPI added Funding updated for 22-23
Administration of Enoxaparin to valve patients with a sub- therapeutic INR LES Specification Final v7 Revised June 2019 reviewed April 2022	May 2023	Fees amended
20190624 Subtherapeutic INR LES Final v7 2023- 24	July 2023	Updated claims information

## **ADMINISTRATION OF ENOXAPARIN TO MECHANICAL HEART VALVE PATIENTS WITH A SUBTHERAPUTIC INR LOCAL ENHANCED SERVICE SPECIFICATION**

### **Introduction**

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification for the administration of Enoxaparin to mechanical heart valve patients with a sub-therapeutic INR outlines the more specialised services to be provided.

The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services.

No part of the specification by commission, omission or implication defines or redefines essential or additional services.

### **Background**

Patients who require anticoagulation with vitamin K antagonists have increased risk of thrombus formation if their INR is sub-therapeutic. Patients with mechanical heart valves are at particular risk, and require immediate "bridging" therapy with either unfractionated heparin or low molecular weight heparin (LMWH), until their INR returns to within target therapeutic range. Enoxaparin is the LMWH of choice within CAVUHB, and is in the primary care formulary.

The most common method of managing the administration of LMWH for these patients was via the hospital emergency units, which was not providing timely care and was also inconvenient for the patient and exposed them to the risks associated with hospital admission.

### **Overall Aim**

This Local Enhanced Service (LES) is designed to provide a safe, effective and convenient service within primary care to mechanical heart valve patients with a sub-therapeutic INR.

## **Objectives**

The Objectives of this service are to:

- Minimise risk to patients who have sub-therapeutic INRs
- Provide an accessible Enoxaparin administration service within general practice for mechanical heart valve patients with a sub-therapeutic INR. The scope of the service does not include patients with cancer or those discharged from orthopaedics, or any other indications for low molecular weight heparin.
- Provide safe, effective and timely care.
- Promote and offer locally based services within the primary care setting which are convenient to the patient. It will provide care closer to home and avoid unnecessary hospital admissions.

## **Service Outline**

### **Geographic coverage/boundaries**

This local enhanced service (LES) is aimed at practices contracted by Cardiff and Vale UHB wishing to administer enoxaparin to mechanical heart valve patients with a sub-therapeutic INR on their own patient register as well as those wishing to provide a service to patients who are registered with other practices contracted by Cardiff and Vale UHB.

### **Location(s) of Service Delivery**

The service will be provided from the practice premises, including branch surgeries, health centres and outreach clinics as appropriate.

### **Referral criteria and sources**

The service will be available to mechanical heart valve patients with a sub-therapeutic INR.

Those wishing to provide a service to patients who are registered with other practices contracted by Cardiff and Vale UHB must already be providing a Warfarin initiation enhanced service and have in place auditable processes and written procedures to ensure timely responses to referrals and effective reporting back to the referring practice.

### **Exclusion criteria**

The service does not include patients using LMWH for cancer related conditions or those discharged from orthopaedics, or any other indications for LMWH.

### **Service Delivery**

This local enhanced service will fund practice to implement the care pathway attached at appendix A.

We recommend that INR checks for mechanical valve patients should be held early in the week and early in the day to maximise time available for dealing with issues.

Training: each practice must ensure that all staff involved in providing any aspect of care under this scheme has the necessary training and skills to do so.

No sub-contractors will provide any element of this Service unless agreed in writing by the UHB prior to the sub contractor starting work.

### **Client Group Served / Eligibility / Access Criteria**

The Service Provider must ensure that the service offered is accessible to all, sensitive and respecting all areas of Race, Economics, Gender, Age, Religion, Disability and Sexual Orientation. Appropriate arrangements should be made for non-English speaking patients and to provide the same high level of service to those requiring interpreter services.

### **Quality Targets and Continual Improvement**

The practice must ensure that they contribute to the wider patient safety agenda including, but not exclusively, the control of infection agenda and the identification, reporting and investigation of incidents and complaints. This must be reported within 72 hours of the information becoming known to the practitioner. This includes all emergency admissions or deaths of any patient covered by this service, where such admission or death is due to haemorrhage. This is in addition to a practitioner's statutory obligations. Please refer to the Primary Care Clinical Governance/incident reporting pages of the UHB intranet for the most up-to-date guidance on reporting requirements.

Participation in clinical audit and implementation of changes arising from audits should take place. The service should be able to demonstrate learning and improvement across the quality agenda and in response to local and/or national policy guidance.

It is the responsibility of the Practice to:

- Continually improve the quality of service delivery, e.g. in response to audit (undertaking and completing the audit cycle), user and staff feedback (complaints, compliments, suggestions) and incidents.
- Continually review and be aware of relevant new and emerging guidance and recommendations and take the appropriate steps to assess and improve services to achieve current best practice.
- Ensure that appropriate professional standards are maintained updated and validated through clinical supervision and provision of relevant training to support reflective practice and CPD.
- During the term of this specification fully co-operate in reviewing and improving/redesigning services at the request of the UHB, to include improving quality and performance monitoring.

#### **Details of Service Monitoring, Evaluation and Review**

The practice will be required to undertake an annual audit as agreed in advance with the UHB and provide the monitoring data to the UHB Primary Care team for annual review of the LES. This information will inform service planning and allow for identification and/or sharing of good practice and/or areas for improvement where the service outline has not been met. The audit should be updated regularly, and submitted to the Health Board after the end of the financial year, no later than **30<sup>th</sup> June**. (See Appendix B for audit sheet)

#### **Untoward Events**

It is a condition of participation in this Local Enhanced Service that (in addition to their statutory obligations) doctors / practices will give notification to the UHB via the significant events reporting process, of all emergency admissions or harm / potential harm to patients under this service, where such events may be due to administration/usage of the drug(s) in question or attributable to the relevant underlying medical condition. Notification should be given within 72 hours of the information becoming known to the doctor/practice and the standard incident reporting process/form should be used. (Please refer to the UHB intranet to link to the correct form and the most up-to-date guidance on reporting).

#### **Clinical and Corporate Governance**

Service Providers must ensure that they adhere to all relevant legislation and best practice.

#### **Accreditation**

UHBs are responsible for ensuring that enhanced services are delivered by professionals who are properly qualified to do the job and accreditation of the service should be based upon consideration of the enhanced service specification. This Local Enhanced Service has been classified as requiring **General Accreditation**.

An Enhanced Service that requires General Accreditation is defined as a named GP who has the necessary skills and experience to carry out a contracted specific service or procedure. It provides a means whereby **accredited persons will be responsible and accountable** for

the delivery of the enhanced service on behalf of the practice. This enhanced service does not have to be delivered by the accredited GP however where components of the service are delivered by somebody other than the accredited GP, the accredited GP is responsible for ensuring that the appropriate skills are available to deliver the service safely.

### Reimbursement

Each practice contracted to provide this service as detailed above will receive the following payment:

- **£117.90** per ambulant patient for **each new episode** of treatment with LMWH which is defined as:
  - A sub-therapeutic INR on Day 1
  - Completion of the pathway (appendix a) beyond “payment step” as indicated.
  - Stopping LMWH due to INR returning to therapeutic range or being advised to stop LMWH by Coagulation pharmacist or Consultant.
  - Recording relevant Read codes in patient records as follows:
    - *For all patients:* “INR below target range – enhanced service admin” (**#9k25.**)
    - *For those on pathway (GP or ART led):* “Bridging anti-coagulation therapy with low molecular weight heparin” (**#88A5000**)
    - *For those admitted at any point on pathway:* “Admit anticoagulation emergency” (**#8H2Y**)
- **£136.69** per housebound patient for each new episode of treatment with LMWH

If LMWH has to be restarted for a new episode, a new claim may be made. Please contact Primary Care Team if unclear about a new claim outside these circumstances.

**Please note the relevant Read Code must be used even when a claim is not being made. The annual audit must be submitted by 30<sup>th</sup> June.**

**Significant events which result in patient harm must be submitted to the UHB within 72 hours of event.**

**All claims to be submitted via Family Practitioner Payments System (FPPS) in accordance with NWSSP Primary Care Services claim guidance. Enhanced service claims must be submitted within 6 months from the end of the quarter in which the service was provided to ensure payment.**

Paycode **ZLLMWH** must be used for **Non Housebound** patients

Paycode **ZLENOD** must be used for **Housebound** patients

### Termination Period

Should the practice wish to cease providing the Enhanced Service, it will be required to provide 3 months’ notice in writing to the Health Board. Should the practice wish to suspend providing the Enhanced Service it should contact the Health Board for guidance prior to any action being taken.

If, for any reason, a practice terminates/suspends the Enhanced Service and, if claims have been made during the current financial year, any reporting/auditing requirements outlined in the specification must be submitted upon request.

### General Medical Practice Indemnity

This Enhanced Service is covered by the scheme for General Medical Practice Indemnity (GMPI) which falls under the GMS Contract Wales.

This scheme relates to potential or actual clinical negligence claims arising from incidents on or after 1 April 2019, and captures all General Medical Practice (GP practice) staff undertaking NHS ‘primary medical services’ as defined in The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019

The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019, sets out the scope of the scheme, namely “primary medical services” which are defined as health services provided under a contract, arrangement or agreement made under or by virtue of the following sections of the National Health Service Wales Act 2006:

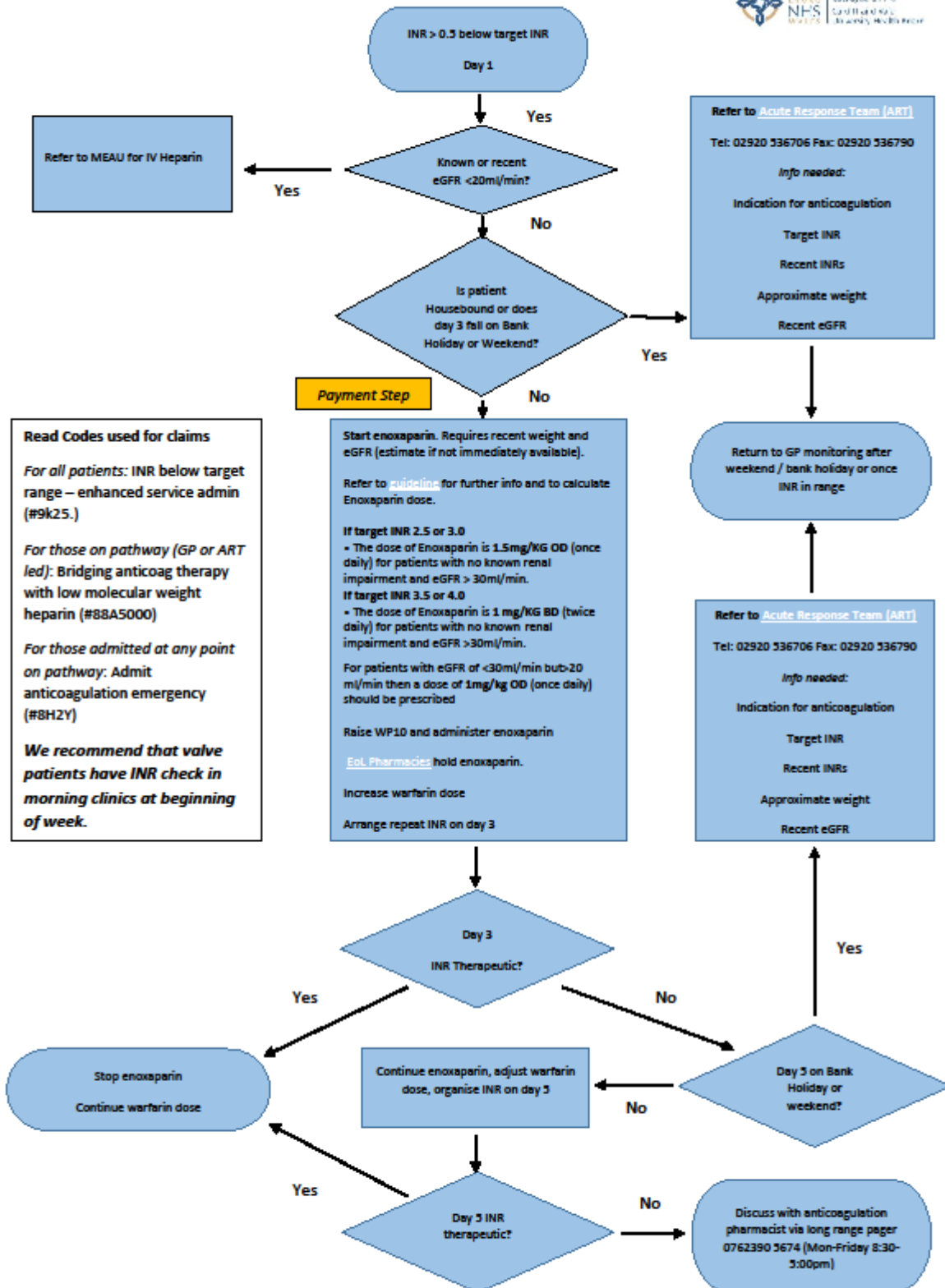
- (a) section 41(2) (primary medical services);
- (b) section 42(1) (general medical services contracts);
- (c) section 50 (arrangements by Local Health Boards for the provision of primary medical services).

The GMPI will include clinical negligence liabilities for NHS work arising from the activities of all GP practice staff, including: GP partners; salaried GPs; locum GPs, if on the All Wales Locum Register; Practice Pharmacists; Practice Nurses; Practice Healthcare assistants; and any other member of staff providing clinical services. GP trainees and trainee nursing students delivering general medical services will also be covered. The GMPI will also cover any healthcare professionals providing the delivery of NHS Primary Care through Primary Care cluster arrangements and any vicarious liability to practices where a cluster-based health professional is providing direct care to the practice’s registered patients.

GP Locums who are registered with and working to the terms of the All Wales Locum Register (AWLT) for Wales have access to the scheme for GMPI.

Appendix A (double click on pathway to open as PDF)

Enoxaparin Therapy for Mechanical Heart Valve Patient with Subtherapeutic INR



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