Appendix A

Local Enhanced Service (LES) for 'Anti-coagulation monitoring'

Service Level Agreement

PRACTICE –

Contents:

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification 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.

1. Financial Information

This agreement is to cover the 19 months commencing 1 September 2011.

- The costs of Reagent strips will not be borne by the Practice. The process for supply may change as the service develops.
- The Practice retains the responsibility for the purchase, ongoing maintenance and quality control of the Coagucheck XS Plus equipment, and associated training arrangements for service provision.
- The Practice will use a decision support software package as agreed with the CHP. The cost of software provision will be the responsibility of the CHP**. (If there is a requirement for the system to change in the future this will be agreed between the Practice and the CHP).**
- An element of the Practice's total annual budget as defined in the "Abstract" dated 1 April 2011 will be retained by the CHP until the Practice's Anticoagulation Service as detailed within the Amended Clinical Details is being delivered.

- If this service is offered at the latest by 30 September 2012 or 3 months after the contact agreement has been issued to the Practice, this element will be paid, in full, in monthly payments in arrears.
- Where the above timescales cannot be met due to any fault of the CHP, the arrangement around the level of funding retained will be revisited.

Payment Verification

Practices entering into this contract must participate fully in the audit process determined by the CHP using the ESCRO reporting tool as defined in the "Abstract" dated 1 April 2011.

PAYMENT WILL ONLY BE MADE UPON RECEIPT OF THIS SIGNED CONTRACT

2. Signature Sheet

This document constitutes the agreement between the practice and the PCO in regards to this national enhanced service.

PRACTICE

Signature on behalf of the Practice:

Signature	Name	Date

Signature on behalf of the PCO:

Signature	Name	Date

3. Service Aims

Through this Local Enhanced Service, Practices are expected to provide a Point of Care anti-coagulation monitoring service designed to be one in which:

(i) therapy should normally be initiated for recognised indications for specified lengths of time

(ii) maintenance of patients should be properly controlled

(iii) the service to the patient is convenient

(iv) the INR and dosing history be made available to primary and secondary care clinicians via SCI Store.

(iv) the need for continuation of therapy is reviewed regularly

(v) the therapy is discontinued when appropriate

The practice achieves an average 'time in therapeutic range' (measured by standardised fashion: i.e. Rosendaal method).
of 70% or greater for patients on long term therapy (i.e. those beyond 22 weeks of therapy).

The practice maintains an audit trail pertaining to machines, reagents and the staff involved in all aspects of service provision to facilitate investigation of adverse events or quality assurance failures.

4. Criteria

The below details the criteria to be met in delivering this service.

- Development and maintenance of a register. Practices should be able to produce an up-to-date register of all anti-coagulation monitoring service patients, indicating patient name, date of birth, the indication for, and length of, treatment including the target INR.
- To ensure that systematic call and recall of patients on this register is taking place.
- To work together with other professionals when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained
- When appropriate to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist.
- To ensure that all newly diagnosed patients (and/or their carers and support staff when appropriate) receive appropriate management of, and prevention of, secondary complications of their condition including the provision of a patient-held record.
- To prepare with the patient an individual management plan, which gives the diagnosis, planned duration and therapeutic range to be obtained.
- To ensure that at initial diagnosis and at least annually thereafter an appropriate review of the patient's health is carried out including checks for potential complications and, as necessary, a review of the patient's own monitoring records. To ensure that all clinical information related to the LES is recorded in the patient's own GP held lifelong record, including the completion of the "significant event" record that the patient is on warfarin.

- To maintain adequate records of the performance and result of the service provided, incorporating appropriate known information, as appropriate. This may include the number of bleeding episodes requiring hospital admission and deaths caused by anti-coagulants
- To carry out clinical audit of the care of patients against the above criteria, including untoward incidents. This should also review the success of the practice in maintaining its patients within the designated INR range as part of quality assurance
- Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so
- All practices involved in this scheme should perform an annual review which could include:
  (a) information on the number of patients being monitored, the indications of anticoagulation, ie DVT etc, and the duration of treatment
  (b) brief details as to arrangements for each of the aspects highlighted above
  (c) details of any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance as agreed with the CHP from time to time.
  (d) details of any near-patient testing equipment used and arrangements for internal and external quality assurance
  (e) details of training and education relevant to the anti-coagulation monitoring service received by practitioners and staff
  (f) details of the standards used for the control of anti-coagulation

5. Audit

0.25% of patients per year on warfarin suffer fatal haemorrhage. This national figure equates to 10 patients/yr in NHS Highland. In addition approximately 40 patients per year will suffer major life threatening haemorrhage. Another significant number will suffer the effects of under anticoagulation (i.e. stroke, DVT, pulmonary embolus) which may be fatal. Furthermore deaths arising from failure to implement thromboprophylaxis are 10x greater than those due to MRSA.

Patients on anticoagulation have a target INR which reflects the degree of ‘thinning’ of their blood. There is clear evidence (Level A) that the risks associated with anticoagulation correlate with the time out with this target. The time in the target range is an extremely valuable tool for monitoring effectiveness of a service.

Recent audit figures for NHS Highland suggest that long term patients are 72% of the time in range. This is comparable with the national average for the UK Trusts/Boards which participate in audit – the act of participating in audit is indicative of a commitment to a quality service and therefore our performance is possibly better than the national average of all services.

Practices will be expected to work with the CHP to develop a standardised* mechanism to monitor % time in Target Range. Significant variance from the national average should be regarded as highly significant, and be subject to urgent review.

6. Quality Assurance

Practices will be expected to enrol in the National External Quality Assurance Scheme (NEQAS) as part of the overall quality assurance of the service. This programme aims to

promote high standards of performance and practice, achieved with the UK NEQAS aim of education, and provision of independent, objective and impartial information.

Along with quality assurance samples, NEQAS will supply internal quality control checks which they will circulate to all participants on a quarterly basis.

There may be an opportunity for Quality Assurance support to be provided locally.

7. Untoward events

It is a condition of participation in this LES that practitioners will give notification to the CHP clinical governance lead of all emergency admissions or deaths of any patient covered under this service, where such admission or death is or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition. This must be reported within 72 hours of the information becoming known to the practitioner. This is in addition to a practitioner's statutory obligations.

Any INR result greater than or equal to 6 will be reported as above, and a significant event review carried out.

8. Accreditation

Those doctors who had previously provided services similar to this enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

9. Dispute Resolution

Every attempt will be made to resolve any dispute informally between the Practice and the PCO. Failing that, the Dispute Procedure contained within the sections 464 to 474 of the Scottish General Medical Services Contract 2004 will apply.

10. Variation and Termination of Contract

Any variation to the terms and conditions contained herein requires to be agreed between the Practice and the CHP.

This 2 year SLA is coming in to force just as new alternative therapy may be introduced. While it is expected that use of new products in this field will be limited and gradual, significant change in the use of Warfarin would be seen as grounds for review/variation of the SLA.

Any termination of services, or any part of the services covered by this contract, requires to be agreed between the Practice and the CHP before any termination takes place.

Annex

Warfarin prescribing guidelines

National

http://www.bcshguidelines.com/documents/warfarin_4th_ed.pdf

http://www.bcshguidelines.com/documents/WarfarinandentalSurgery_bjh_264_2007.pdf

http://www.bcshguidelines.com/documents/safety_indicators_oral_anti_coag_bjh_2007.pdf

Reversal of over anticoagulation: document attached adopted as the 'Scottish' protocol and our local version is in sync with

Practices will need to keep supplies of i.v. Vit K.

Local

http://guidelines.nhshighland.scot.nhs.uk/haematology/anticoag/docs/how%20to%20initiate%20warfarin%20treatment.doc

http://intranet.nhsh.scot.nhs.uk/Org/DHS/SSU/Medical_DiagnosticsDivision/Laboratories/Raigmore/BloodSciences/Haematology/Documents/IDL%20-%20warfarin%20%20intranet%20link%20for%20guidance.doc

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http://guidelines.nhshighland.scot.nhs.uk/haematology/anticoag/index.htm