National Enhanced Service (NES) for 'Anti-coagulation monitoring'

Service Level Agreement

PRACTICE –MEDICAL PRACTICE

Contents:

1. Financial Details

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.

This agreement is to cover the 12 months commencing 1 April 2005.

On agreeing a service plan with the PCO for the 12 months commencing 1 April 2005 practices who monitor patients "in house" will receive payment at level 3 of the nationally agreed rates, per patient, per year (even if not monitored for the whole of that year) ie

Level 3 – Practice-funded phlebotomist or pharmacist etc, practice sample, laboratory test, practice dosing	£117.21

Where a patient is monitored at the Raigmore clinic the practice will receive payment at level 1 of the nationally agreed rates, per patient, per year ie

Level 1 – laboratory outreach sampling, test and dose	£10.65

In addition to the above fees, where sampling requires a domiciliary Visit to a housebound patient on behalf of the practice, and not by a member of staff employed by an NHS body to provide community health services, an additional fee would be paid for each separate address visited on that day	£5.33

Claims for Payment

An estimated annual number of patients will be agreed with the Practice as part of this Service Level Agreement

Payment of quarter of the annual fee will be made on quarterly basis, based on this estimated number.

Any in year changes in activity will be calculated/negotiated at the end of the financial year and payments amended accordingly.

Estimated Activity from Data Collection Exercise

Annual Number of Patients Monitored "in house" -	Annual Fees
Annual Number of Patients Monitored at Raigmore Clinic –	

Actual activity should be submitted to the PCO on a quarterly basis, being careful not to duplicate patients over all 4 quarters.

Payment Verification

Practices entering into this contract must participate fully in the verification process determined by the PCO and LMC. Practices should ensure that they keep proper records to ensure a full and proper audit trail.

It is anticipated that Practice computer systems will be utilised to enable this condition to be met.

Practices must be able and willing to evidence service delivery if required/requested by the PCO.

Annual Review of Contract

This contract will be reviewed annually, and will be in line with the annual review of the GMS Contract set out in the NHS (General Medical Services Contracts)(Scotland) Regulations, or other legislation as appropriate.

Practices will be expected to return to the PCO their end of year evaluation/results, in order to confirm compliance with the contract.

PAYMENT WILL ONLY BE MADE UPON RECEIPT OF THIS SIGNED CONTRACT, INCLUDING DETAILS OF PRACTICE PLANS AS INDICATED

2. Signature Sheet

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

PRACTICE…… MEDICAL PRACTICE……..

Signature on behalf of the Practice:

Signature	Name	Date

Signature on behalf of the PCO:

Signature	Name	Date

3. Service Aims

An anti-coagulation monitoring service is designed to be one in which:

(i) therapy should normally be initiated in secondary care, for recognized indications for specified lengths of time

(ii) maintenance of patients should be properly controlled

(iii) the service to the patient is convenient

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

(v) the therapy is discontinued when appropriate

4. Criteria

The National Enhanced Service Specification details the following criteria:

The following pages contain some further guidance from the PCO on expected processes, outcomes and deliverables based on this process. On aspiring to this service practices are required to submit plans under each of these items to the PCO.

(i) the development and maintenance of a register

(ii) call and recall

(iii) professional links

(iv) referral policies

(v) education and newly diagnosed patients

(vi) individual management plans

(vii) clinical procedures

(viii) record-keeping

(ix) audit

(x) training

(xi) review

Criteria One : Register

Details

- the 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.

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Two: call and recall

Details

- To ensure that systematic call and recall of patients on this register is taking place either in a hospital or general practice setting

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Three: professional links

Details

- To work together with other professionals when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Four : referral policies

Details

- When appropriate to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist.

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Five : education and newly diagnosed patients

Details

- 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 patient-held booklet

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Six : individual management plans

Details

- To prepare with the patient an individual management plan, which gives the diagnosis, planned duration and therapeutic range to be obtained

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Seven : Clinical procedures

Details

- To ensure that at initial diagnosis and at least annually 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 NES 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.

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Eight: Record-Keeping

Details

- 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

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Nine: Audit

Details

- 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

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Ten: Training

Details

- 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

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

Criteria Eleven: Review

Details

- 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
  (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

Practice Plans for Year 05/06
(please detail below your practice's plans for this criteria)

Practice Evaluation at end of Year / results
(*at the end of the year please detail below the practice's results for this* criteria)

5. Untoward events

It is a condition of participation in this NES that practitioners will give notification to the PCO 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.

6. 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.

7. Ongoing Measurement & Evaluation

The ongoing measurement is outlined in the various criteria in the previous section.

In addition the practice is required to agree with the PCO this service specification/plan at the start of the year and to submit the completed document at the end of the year for evaluation purposes.

8. 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.

9. Variation and Termination of Contract

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

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

Annex

Warfarin prescribing guidelines

General guidance

1. This protocol sets out details for the care of patients taking warfarin. The patient should also have received advice and written information on anticoagulant therapy, normally in the form of an anticoagulant booklet.

Background

2. Warfarin use is increasing as new indications for its efficacy have been recently identified. Nevertheless, its use is associated with adverse effects, particularly bleeding, and optimum management can be achieved by shared care between hospital and general practitioner. The present indications for warfarin, together with the presently agreed degree of anticoagulation for that indication are shown in the attached Tables 1 and 2.

Table 1

Therapeutic recommended uses and International Normalised Ratios (INRs) for those uses (British Society of Haematology)

Prophylaxis of postoperative deep vein thrombosis (general surgery)	2.0-2.5
Prophylaxis of postoperative deep vein thrombosis in hip surgery and fractures	2.0-3.0
Myocardial infarction: prevention of venous thromboembolism	2.0-3.0
Treatment of venous thrombosis (DVT)	2.0-3.0
Treatment of pulmonary embolism (PE)	2.0-3.0
Transient ischaemic attacks	2.0-3.0
Tissue heart valves	2.0-3.0
Atrial fibrillation	2.0-3.0
Valvular heart disease	2.0-3.0
Recurrent deep vein thrombosis and pulmonary embolism	3.0-4.5
Arterial disease including myocardial infarction	3.0-4.5
Mechanical prosthetic valves (see table 2)	
Recurrent systemic embolism	3.0-4.5
Intravascular stent	2.5-3.5

Table 2

Recommended INR for prosthetic valves

	Sinus rhythm normal left atrial size (i.e. most aortic valve replacement patients)	**Atrial fibrillation enlarged left atrium (i.e. most mitral valve replacement patients)**
Low thrombogenicity prosthesis	2.0 - 3.0	2.5 - 3.5
Other Prostheses	3.5 - 4.5	3.5 - 4.5

Dosage regimens

3. The average dose of warfarin required daily is around 5 mg (range 1-9 mg) but may vary markedly because of several factors. Warfarin should be given once daily (5-6 pm is an ideal time) and is given as a tablet for oral administration. [Tablet strengths are 1 mg (brown), 3 mg (blue), 5 mg (pink).]

Duration of therapy

4. After a single episode of venous thromboembolism, it is likely that three months' therapy is necessary. The duration of therapy needed after a second episode of DVT or PE is uncertain but 6-12 months' therapy is normally advocated. Patients with repeated episodes or in whom risk factors persist may require long-term (even life-long) therapy. In other indications long-term therapy may be necessary.

5. For patients in whom no new factor has arisen, the frequency of monitoring can be determined by the criteria shown in Table 3.

Table 3

Warfarin therapy: maximum recall periods during maintenance therapy*

*(not initiation)

One INR high:	recall in 7-14 days (stop treatment for 1-3 days) (maximum 1 week in prosthetic valve patients)
One INR low:	recall in 7-14 days
One INR therapeutic:	recall in 4 weeks
Two INRs therapeutic:	recall in 6 weeks (maximum for prosthetic valve patients)
Three INRs therapeutic:	recall in 8 weeks, apart from prosthetic valve patients
Four INRs therapeutic:	recall in 10 weeks, apart from prosthetic valve patients
Five INRs therapeutic:	recall in 12 weeks, apart from prosthetic valve patients

NB Patients seen after discharge from hospital with prosthetic valves may need more frequent INRs in the first few weeks.

(Based on data from Ryan et al (1989) British Medical Journal 299, 1207-1209)

6. When a condition known to cause alteration in the dose requirement of warfarin occurs (eg a potentially interacting drug), or the patient has an acute intercurrent illness, frequency of monitoring should be increased.

7. The following conditions cause warfarin sensitivity (ie need for reduced dose):
   (i) liver dysfunction
   (ii) heart failure
   (iii) hyperthyroidism
   (iv) some drugs
   (v) acute pyrexial episode.

8. Some conditions cause warfarin requirements to be increased (ie need for greater than normal dose):
   (i) hypothyroidism
   (ii) vitamin K containing remedies, eg some herbal remedies and enteral feeds
   (iii) some drugs.