NHS
Somerset
Clinical Commissioning Group

Service Specification No.	11X-01
Service	Anti-Coagulation Monitoring (level 4)
Commissioner Lead	Sheryl Vincent, Commissioning Manager
Provider Lead	
Period	1 April 2015 – 31 March 2018
Date of Review	2014/15

1. Population Needs

National/local context and evidence base

1.1 Warfarin is being used in the management of increasing numbers of patients and conditions including patients' post-myocardial infarction, atrial fibrillation, DVTs and other disorders. While it is a very effective drug in these conditions, it can also have serious side effects, e.g. severe haemorrhage.

1.2 These side effects are related to the International Normalised Ratio (INR) level, which measures the delay in the clotting of the blood caused by the warfarin. While the "normal" INR is 1, the specific range of INR values depends on the disease and the clinical conditions. Warfarin monitoring aims to stabilise the INR within set limits to help prevent serious side-effects while maximising effective treatment.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	✓
Domain 2	**Enhancing quality of life for people with long-term conditions**	✓
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	✓
Domain 4	**Ensuring people have a positive experience of care**	✓
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	✓

2.2 Local defined outcomes

Not applicable

3. Scope

Aims and objectives of service

3.1 The Provider shall ensure that the Anti-Coagulation Monitoring Service (Level 4) includes the provision of:

- blood sampling (Capillary and Venous)
- blood testing and determining the INR
- anticoagulant dosing with prescribing in accordance the latest guidance issued by the

British Committee for Standards in Haematology

- domiciliary visits to housebound Patients who require anti-coagulation monitoring.

3.2 The Provider shall ensure that the Anti-Coagulation Monitoring Service is one in which:

- there is a minimisation of potential side effects of warfarin by utilising regular monitoring to stabilise the International Normalised Ratio (INR) levels of patients while continuing to maximise the effective benefits of such treatment;• the maintenance of Patients is within agreed levels
- the requirement for the continuity of therapy is reviewed regularly; and
- therapy is discontinued when appropriate.

Service description/care pathway

SERVICE REQUIREMENTS

3.3 The Provider will need to nominate a GP as the clinical lead who will ensure that the service within the Practice is established in accordance with the specification and national guidance and recommendations.

3.4 The nominated GP as the clinical lead will ensure that arrangements are in place to undertake a review of the service to ensure that the specification and national guidance and recommendations are being adhered to. This review will be undertaken on an annual basis or, as required by the CCG in the event of any significant/adverse incident as detailed in clause 10 below.

3.5 The Provider is clinically responsible for all patients accepted under their care for anticoagulation management and must ensure that explicit contingency plans are in place to cover absence for annual leave and sickness leave for both the running of the clinics, supervision of staff and for advice to patients who have queries or problems.

3.6 The Provider shall ensure that the Anti-Coagulation Monitoring Service adheres to the following specification and criteria:

- The service is an oral anti-coagulation monitoring service for the prescribing of Warfarin.
- The Provider will run anticoagulation clinics at least weekly or, have available appointments and domiciliary visits each week for a period sufficient to accommodate the number of patients requiring anticoagulation monitoring.
- The management of clinics and appointments adheres to the current and future guidance and recommendations issued by NICE (clinical guidance CG36), the British Committee for Standards in Haematology, the National Patient Safety Agency (NPSA) and Somerset CCG after consultation with the Local Medical Committee.
- All newly diagnosed registered patients (and/or their carers and support staff when appropriate) receive advice on the appropriate management and prevention of secondary complications for their condition; including the provision of Patient-held booklets.
- The provider will prepare individual management plans with registered patients, which give the diagnosis, planned duration and therapeutic range to be maintained during therapy
- That at initial diagnosis and at least annually, an appropriate review of the registered patient's health is carried out including checks for potential complications and, as necessary, a review of the registered patient's own monitoring records. Where a patient

is under the care of a hospital then the Provider must ensure it adheres to any agreed local protocol that exists between the Provider and the hospital.

- The use of clinical decision support system software and any in house near patient testing equipment must be approved by Medicines and Healthcare products Regulatory Agency (MHRA) and Medical Devices Agency (MDA).
- When appropriate, promptly referring registered patients to other appropriate services using locally agreed guidelines where these exist.
- Ensuring that systematic call and recall of registered patients on the register takes place as detailed in the guidance issued by British Committee for Standards in Haematology
- Contacting patients that fail to attend a clinic or appointment, at an agreed time by, in the first instance telephone and then by standard letter. The provider should monitor regular non-attendance of patients and take reasonable steps to ensure that regular testing takes place and to assess any risk of over coagulation. Where necessary the Practice should seek haematological advice in accordance with the guidance issued by British Committee for Standards in Haematology.
- The education of all patients in understanding their treatment in terms of their condition requiring warfarin, target range for INR, the effects of under/over anticoagulation, diet, lifestyle and drug interactions.

3.7 The Provider will ensure that this Enhanced Anticoagulation Monitoring Level 4 Service excludes patients that are self-monitoring their own INR.

3.8 The Provider will ensure that the following data is collected and recorded for all patients within Enhanced Anticoagulation Monitoring Level 4 Service.

- An up-to-date register of all registered patients using the Anti-Coagulation Monitoring Service, indicating patient name, date of birth, and the indication and length of treatment, including the target International Normalised Ratio: blood test result (INR) as recommended by the British Committee for Standards in Haematology and National Patient Safety Agency.
- Adequate records of the Anti-Coagulation Monitoring Service, including relevant known information, as appropriate, including for example, the number of bleeding episodes requiring hospital admission and deaths caused by anti-coagulants;
- Maintaining records and acting upon the outcomes of the quality assurance tests completed each month;
- Ensuring that the Anti-Coagulation Monitoring Service is provided in accordance with the latest British Committee for Standards in Haematology and any other national and local guidance relevant to the service; and
- If a patient requires Vitamin K for over-coagulation this should be arranged by discussion with a suitable clinician in the appropriate haematology Department and the Practice should complete an Adverse Incident Form in accordance with section 10 below. Please note, some practices have the facility to administer oral IV paediatric vitamin K as required by a GP.

CONSENT

3.9 In each case the patient should be fully informed of the treatment options, risks and the treatment proposed.

3.10 National guidelines suggest that written consent should be obtained from patients. The CCG wishes the providers to note that their interpretation of 'written consent' in this context is the recording of consent by READ code. Where the provider READ codes consent given, the CCG will take this to mean that the patient has been fully informed of the treatment options and risks, has been offered written information and has given consent.

3.11 The General Medical Council (GMC) guidance on "Consent: patients and doctors making decisions" state that the records made should include the information discussed, any specific requests by the patient, any written visual or audit information given to the patient, and details of any decisions that were made and details further guidance regarding the legal framework for capacity issues.

HEALTH RECORD

3.12 The Provider shall ensure that all clinical information related to the National Enhanced Service (NES) is recorded in the registered patient's own GP held lifelong record, including the completion of the record that the registered patient is on anticoagulation treatment, the drugs used and the level and duration of dosage. Where a patient ceases to be on anticoagulation treatment then the patient record should be duly updated and in the event of an adverse incident all relevant information must be recorded.

QUALITY ASSURANCE

3.13 The Provider shall ensure that:

- when undertaking point of care testing in the surgery or clinic It uses appropriate dosing software in order to maintain the INR levels within the therapeutic range, extend the time between INR tests and effectively manage anticoagulation records facilitating service audit. Each patient will receive printed information from the clinical decision support system software or, written information confirming their INR reading and dosage before leaving the surgery or clinic
- when undertaking point of care testing during a domiciliary visit the results should be recorded in the patient's hand held record at the time of testing and recorded using the clinical decision support system software within (24) hours of the test in order, to verify the dosage and maintain up to date patient records. If the clinical decision support system software recommends any changes in dosing this should be notified to the patient before the next dose of oral treatment is due.
- in the event of the failure of the blood testing equipment for more than 24 hours, the Provider will liaise with the equipment provider to determine whether replacement equipment can be obtained. Should this not be feasible, then the Provider will utilise the services of a level 4 service provider approved by the CCG or revert to a level 3 service. The provider must inform their Commissioner at the CCG within 48 hours of the action and the date when the Level 4 service will resume.
- in the event of failure of the clinical decision support system software the Provider will, within 48 hours either rectify the fault, or utilise the services of a level 4 service provider approved by the CCG or revert to a level 3 service. The provider must inform their Commissioner at CCG within 48 hours of the action and the date when the Level 4 service will resume. The provider may continue to use the blood testing equipment during the initial 48 hour period where in the opinion of the practitioner patient safety may be compromised by the complete withdrawal of the service.
- In the event of a patient requiring vitamin K for over anticoagulation then should be reported as an incident as detailed in Section 10 below.
- In addition to their statutory obligations, the Provider will give notification, within 72 hours of the information becoming known to him/her, of all emergency admissions or

deaths of any patient treated by the Provider under this enhanced service, where such admission or death is or may be due to the Providers treatment of the relevant underlying medical condition covered by this specification. Notifications are to be sent to the Director of Quality, Safety and Governance with a copy to the Commissioner for the specific locality.

- The Provider must ensure that when information on a patient is received, following discharge from hospital by fax/letter/telephone concerning warfarin dosing, this must be immediately communicated to the patients GP or the Lead Clinician.
- quality assurance must be carried out in accordance with recommendations of the British Committee for Standards in Haematology and National Patient Safety Agency.
- internal quality assurance checks and the cleaning of equipment must be carried in accordance with the manufacturers' instructions on each day that the equipment is used prior to their use on that day.
- strips and reagents must be stored in accordance with manufacturer's guidance. If refrigeration is required the reagents or strips are stored must have temperature checks recorded on each working day.
- external quality assurance checks must be conducted on a three-monthly basis to verify the accuracy of blood testing machinery and dosing. The Provider will be need to be registered with an approved External Quality Assurance organisation that provides testing samples for the blood testing of equipment used.
- any External Quality Assurance organisation used to test blood as part of the Anti-Coagulation Monitoring Service has established quality assurance schemes in place and is accredited by Clinical Pathology Accreditation (UK) Ltd
- a standard operating procedure must be in place regarding the operation of the equipment in accordance with the manufacturers guidelines and training for both POCT and CDSS.

TRAINING AND ACCREDITATION

3.14 The Provider shall ensure that each member of staff undertaking Point of Care Testing has received appropriate training and accreditation approved by the CCG and has completed an assessment form as detailed below:

- GPs to complete a self-assessment form as detailed in Appendix 1
- Nurses to be assessed by the completion of the assessment form as detailed in Appendix 2 (TBC)

3.15 Appropriate training is summarised below:

- GPs will confirm that they have the knowledge and experience or mentoring support in place to undertake this Service by completing the self-assessment form detailed in Appendix
- nurses and other non-prescribing clinical staff will have to have completed the courses provided by or, on behalf of the CCG or have demonstrated that they have the knowledge and experience to undertake this Service
- all members of the Provider team conducting point of care testing will have completed the appropriate training from the manufacturer or supplier of their chosen testing equipment. (this may take the form of an E-training module) or, receive training from a clinician that has previously undertaken training from the manufacturer or supplier. Dates of any training and any following supervision should be recorded as part of the individuals Continuing Professional Development (CPD) log.

- all members of the Provider team conducting point of care testing will have completed the appropriate training from the supplier of their chosen clinical decision support system software. (this may take the form of an E-training module) receive training from a clinician that has previously undertaken training from the manufacturer or supplier. Dates of any training and any following supervision should be recorded as part of the individuals Continuing Professional Development (CPD) log
- all staff involved in providing this service should have their role reviewed by the nominated GP as part of the annual appraisal process to identify any further training needs over and above the training required in this specification;
- all staff performing INR testing should have two yearly updates/refresher training following the initial training.

3.16 Training will be expected to cover:

- sample requirement and specimen collection
- sample preparation
- stability of sample and reagents
- analyse measurement
- maintenance, calibration and cleaning of instrument
- appropriate use of equipment and consequences of inappropriate use
- reporting of results
- knowledge of normal and abnormal results and actions in the event of an abnormal result
- performance of quality control
- documentation of test and quality control results
- health and safety.
- Determining the INR
- Patient education
- Drug interactions with warfarin

3.17 The CCG will require evidence of the training completed (if using the accredited courses provided by Birmingham and Salford universities) including equipment training. In addition the dates of the cascade training to other members of staff should be recorded and may be requested by the Clinical Commissioning Group.

3.18 Providers should ensure that they are familiar with and working to the workforce competencies identified by the National Patient Safety Agency.

INFECTION CONTROL

3.19 Providers must have infection control policies that are compliant with national guidelines and current handling protocols, which include:

- disposal of clinical waste
- needle stick incidents
- environmental cleanliness, and

- standard precautions, including hand washing
- Reference to lone worker policy especially for Domiciliary visits

3.20 Providers must ensure that all staff undertaking Point of Care testing have an up to date Hepatitis B vaccination.

REVIEW AND AUDIT

3.21 The Provider shall carry out a monthly clinical audit of the care of patients using the safety indicators for anticoagulation services that have been developed by the National Patient Safety Agency and the British Committee for Standards in Haematology. Patients INR results will be reported against these indicators to the CCG on a quarterly basis as part of the Quality Outcomes Framework (QOF).

3.22 In the event of the failure of blood testing equipment and, or dosing software for a period greater than 24 hours the Provider will report the incident to the commissioner.

3.23 The Provider shall conduct an annual review of the Anti-Coagulation Monitoring Service which will be sent to the Anticoagulation Specialist Nurse / Coordinator in order to inform best practice and assist in the identification of training requirements. The review must include:

- Performance against the safety indicators as detailed above.
- Information on the number of patients being monitored, the indications of anticoagulation, e.g. DVT etc, the duration of treatment and the number of results in range
- Brief details as to arrangements for recording, monitoring and adapting each of the aspects highlighted above
- Details of any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance
- Details of training and education relevant to the Anti-Coagulation Monitoring Service received by practitioners and staff; and
- Details of the standards used for the control of anticoagulation

SIGNIFICANT / ADVERSE EVENTS

3.24 The Department of Health emphasises the importance of collected incidents nationally to ensure that lessons are learned across the NHS. A proactive approach to the prevention of recurrence is fundamental to making improvements in patient safety.

3.25 The Provider should be aware of the various reporting systems such as:

- the National Patient Safety Agency National Learning and Reporting System
- the Medicines and Healthcare products Regulatory Agency reporting systems for adverse reactions to medication (yellow card system), and accidents involving medical devices; and
- the legal obligation to report certain incidents to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)

3.26 In addition to any regulatory requirements the CCG wishes the Provider to use a Significant

Event Audit system (agreed with the Clinical Commissioning Group) to facilitate the dissemination of learning, minimising risk and improving patient care and safety.

3.27 In addition to their statutory obligations, the Provider will notify the Anticoagulation Specialist Nurse / Coordinator with a copy to their Commissioner within 72 hours of being aware of the hospital admission or death of a patient being treated by the Provider under this enhanced service where the Provider believes that the anticoagulation treatment was a significant contributor to the cause of admission or death.

3.28 The Provider will notify the Anticoagulation Specialist Nurse / Coordinator with a copy to their Local Enhanced Services Commissioning Manager within 24 hours of an INR result of > 5 for any patient undergoing treatment.

PRICING

3.29 This service is subject to a local price per patient, which is set out in Schedule 3 Part A.

3.30 Additionally, the Practice will be entitled to claim for backfill of one Nurse to attend the training and the retainer elements which includes support for audit, support for Quality Assurance, Software license reimbursement and a fee for Hardware replacement. These costs are set out in Schedule 3 Part A.

3.31 Anticoagulation training, based on clinical competencies, is also provided for Practice staff free of charge.

3.32 If for any reason the Provider is unable to offer a level 4 service for a period greater than 7 days the cost per patient tariff will immediately revert to the level 3 tariff cost per patient, which is set out in Schedule 3 Part A.

3.33 Community nursing services staff may only take samples for those housebound patients already on their caseload once the INR has been maintained within 0.5 of the designated range.

3.34 This Service has been adequately funded to cover the cost of the purchase of testing strips and reagents, as a result of this there are no circumstances where testing strips and reagents may be obtained by the provider via the prescription route without prior consent from the commissioner.

PAYMENT

3.35 Payments will be made on a monthly basis using a budget based on the previous years out turn position.

3.36 Reconciliations will be completed after the end of the financial year by the commissioner.

PATIENT AND PUBLIC INVOLVEMENT

3.37 The service will conform to professional and legal requirements especially clinical guidelines and standards of good practice issued by National Institute for Clinical Excellence (NICE) and professional regulatory bodies, and legislation prohibiting discrimination. It is anticipated that for the majority of enhanced services translated information will be available via the Department of Health. If a patient wishes to communicate via a language that is not covered via these leaflets please let the CCG Equality and Diversity Lead know and use the commissioned interpretation and translation service[1] to facilitate the consultation and provision of information to the patient. Use of the interpretation/translation service should be recorded in the patient's lifelong medical record including confirmation of the first language

[1] Somerset CCG Interpretation and Translation Service – the PIN for accessing this service has been given to each provider, for queries please email: translations@somerset.nhs.uk.

of the patient.

3.38 Practices should encourage, consider and report any patient feedback (positive and negative) on the service that they provide and use it to improve the care provided to patients, particularly if there are plans to alter the way a service is delivered or accessed.

Population covered

3.39 The registered practice population.

Any acceptance and exclusion criteria and thresholds

3.40 The Provider will ensure that this Enhanced Anticoagulation Monitoring Level 4 Service excludes patients that are self-monitoring their own INR.

3.41 Interdependence with other services/providers

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

Not applicable

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

4.3 Applicable local standards

- Baglin TP et al, British Journal of Haematology 2006: 132, pp277-285
- Baglin TP et al, British Journal of Haematology 2007: 136, pp 26-29
- The Health Act 2006: Code of Practice for the Prevention and Control of Healthcare Associated Infections. The Stationary Office, 2006.
- British Society for Haematology. 2005. 132, pp.277-285.
- Cardiovascular Thrombosis: Thrombocardiology and Thromboneurology, Second Edition, Chapter 53 (Publishers Philidelphia 1998)

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4A-D)

5.2 **Applicable CQUIN goals (See Schedule 4E)**

6. Location of Provider Premises

6.1 The Provider's Premises are located at:

As defined in Schedule 5 Part A of the Contract Particulars

7. Individual Service User Placement

Not applicable