SCHEDULE 2 – THE SERVICES

A. Service Specifications

Mandatory headings 1 – 4: mandatory but detail for local determination and agreement
Optional headings 5-7: optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

Service	Level 4 Anticoagulation Monitoring in Primary Care
Commissioner Lead	Derby and Derbyshire ICB
Provider Lead	General Practice

1. Population Needs

1.1 National/local context and evidence base

This specification covers the management of vitamin K antagonists (VKA) within primary care for all licensed indications.

All newly diagnosed non-valvular atrial fibrillation (NVAF) patients should have a discussion with their clinician about anticoagulation. If anticoagulation is offered, first line treatment is a Non-vitamin K antagonist oral anticoagulant (NOAC). Examples of these are: apixaban, dabigatran, rivaroxaban and edoxaban. Where a NOAC is contraindicated, not tolerated or not suitable in people with atrial fibrillation, offer a vitamin K antagonist (VKA). The clinician should discuss the options for anticoagulation with the patient and drug choice should take into account clinical features, preferences and bleeding risk.

Warfarin remains the first line VKA for all patients. Phenindione and acenocoumarol are not recommended unless in exceptional circumstances. To ensure these patients receive the same quality of care as patients on warfarin, we have included these in the specification. Phenindione and acenocoumarol should only be started by a clinician with suitable experience (such as in secondary care). For any patients newly started on phenindione or acenocoumarol, the initiating clinician must accept responsibility for monitoring if the primary care clinician does not feel competent to do so.

Anticoagulation management and monitoring is one of the enhanced services under the GP contract. GPs may provide the service to all eligible service users from their own practice or neighbouring practice if commissioned to provide the service on their behalf or refer to other service providers. Due to the nature of the service, delivery can be achieved by both GP practice and community pharmacists if the appropriate training has been successfully undertaken.

Anticoagulants are also indicated for prophylaxis of embolisation in rheumatic heart disease, after insertion of prosthetic heart valves, and prophylaxis and treatment of venous thrombosis and pulmonary embolism. It is expected that prescribing for these indications will be initiated and stabilised in secondary care.

Payment for this service is linked to the management of patients prescribed vitamin K antagonists. To manage their anticoagulation appropriately there are a number of processes which have to be recognised: anticoagulants have to be discussed, explained and initiated, and a number of patients will require home visits to complete their monitoring requirements.

NHS Derby and Derbyshire ICB has reviewed this current specification in line with NICE guidance for the delivery of Primary Care Anticoagulation services.
The attached specification is a legal document that has been written in the style required. Practitioners should be in no doubt that the intentions are to deliver a service which is safe and effective for the patient, accurately reflects the workload upon the provider, and allows good clinical quality and practice to flourish.

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

To provide a primary care based service model which ensures the safe management of patients needing oral anticoagulation that anticipates any associated risk thereby reducing the risk of complications.

- All patients supported to make an informed choice as to type of anticoagulation taken based upon Joint Area Prescribing Committee (JAPC) guidelines.
- All patients taking vitamin K antagonists achieve the best level of anticoagulation possible subject to their individual characteristics, verified by 6 monthly audits of relevant parameters.
- To increase the times that patients on warfarin, acenocoumarol or phenindione are within their therapeutic range.
- Provider to monitor any critical incidents/untoward events over the review period that relate to the service and share this and resulting learning points with the ICB.

- To clearly identify the number of patients receiving vitamin K antagonists in primary care, indications for treatment and the anticipated duration.
- Provider to monitor number of bleeding episodes, during the review period, that required admission or referral to secondary care and share resulting learning points with the ICB.
- Provider to monitor number of strokes, TIAs, DVTs or PEs for patients on vitamin K antagonists, and share information with the ICB.
- All referrals back to secondary care are analysed and deemed clinically appropriate. Monitor the number of complaints received over the review period that relate to the service.

3. Scope

3.1 Aims and objectives of service

The overall aim is to provide a safe and effective VKA prescribing and management service across primary care in Derby and Derbyshire. In particular, the Enhanced Service will:

- Ensure a safe, effective, timely and consistent high quality service is delivered to patients by all anticoagulation service providers using appropriately trained staff;
- Ensure shared decision making is carried out between health care professional and patient to achieve desired improvements in healthcare outcomes
- Ensure consistent procedures relating to testing, sampling and dosing across service providers and between Primary and Secondary Care services;
- Ensure that maintenance of patients is controlled and the need for continuation of therapy is reviewed regularly and therapy is discontinued where appropriate;
- Enhance the confidence and develop the skills of all service provider staff who have an interest in anticoagulation management;
- Provide face to face or telephone consultation with an accredited practitioner for all mobile service users
- Dosing done by an accredited practitioner
- Provide more services that are near to service users and are easily accessible and flexible.

3.2 Service description/care pathway

Service Description:

The ICB will fund the provision of community based oral anticoagulation management clinics in primary care utilising Near Service user Testing (NPT) for INR monitoring and computerised decision support software (CDSS) for dosing advice.

All service providers must have a named clinician as the clinical lead who will be responsible for ensuring that the service is delivered in accordance with the specification. All service providers must have an up to date knowledge of the patients current and previous medical history and communicate with secondary care where clinically required.

The dosing of warfarin and the interval decision between test dates is the responsibility of an accredited healthcare professional.
All housebound patients will be seen in person by a health professional that has undergone appropriate training at least every 6 months.

The service can be delivered by a GP or registered nurse or registered pharmacist within the GP practice or a clinical nurse /pharmacist specialist working on an outreach basis to provide the service. Service providers must run anticoagulation clinics to meet the needs of their cohort of service users. Providers must have robust processes in place to manage any self-monitoring patients safely and effectively, which must be communicated and agreed with the patient.

Providers can utilise Healthcare Assistants (HCAs) and Pharmacy Technicians to carry out some aspects of the service (e.g. blood sampling and use of coagulometer) but all INR results must be reviewed by an accredited provider. Clinical decisions including dose changes must be made by an accredited service provider (see accreditation pathway for further details)

The length of time between test dates will vary but every service user must be checked and dosed at least once every 12 weeks. Less stable and new service users will require more frequent tests. The management and monitoring procedures are included in the ICBs guidelines.

The provider should ensure that a systematic call and recall system is in place and should be able to provide data to demonstrate the effectiveness of the system. Under normal circumstances, a patient who fails to attend a clinic at an agreed time should be contacted initially by telephone. The provider must implement appropriate and effective strategies for monitoring and targeting non-attendees. Where a patient fails to attend consideration should be given to stopping the anticoagulant until the patient is seen. In the case of an alternative provider, should this occur, this must be clearly communicated to the patient's home GP practice.

Service providers are clinically responsible for all patients under their care for anticoagulation management and must ensure that explicit contingency plans are in place to cover periods of absence for annual or sickness leave both for the running of clinics and for advice to patients who have queries or problems.

Where the service is not provided by the service users' GP practice, the service provider and the patient's own GP practice have shared responsibility in ensuring a robust communication system is in place. This must be demonstrated in the form of a written communication protocol defining the communication between referring GP practice and the provider of the service and vice versa and which will include the communication of each INR test, recommended dosage, any significant events according to agreed protocols and any other change to service user information which may affect their anticoagulation management.

Service Pathway:

Clinicians should refer to The Derbyshire Joint Area Prescribing Committee (JAPC) 'Guideline on Oral Anticoagulation' (Appendix 1) and appropriate national guidelines issued by NICE (Appendix 2).

Providers shall take into account the JAPC Atrial Fibrillation Guideline (Appendix 3) when considering whether warfarin is appropriate at initiation and on-going review.

Clinical Management:

Anticoagulant initiation:

Only the GP or independent prescriber or appropriately qualified person in secondary care should determine diagnosis of condition requiring initiation of warfarin.

All GP anticoagulation providers must be able to initiate and stabilise their own patients.

Initiation, dosing and monitoring requirements:

Warfarin prescribing and monitoring guidelines have been provided in the ICBs 'Guideline on Oral Anticoagulation'. Clinicians must:

- NOACs are first line treatment options for NVAF. If NOACs are unsuitable then discuss and educate the patient on all aspects of warfarin treatment to come to a shared decision in the best interests of the patient. If the provider is not the patients current GP (for example a community pharmacist), then communication should be sent to the current GP to inform them of the outcome of the conversation and arrange the prescribing of warfarin (if necessary).
- Perform baseline tests before initiating warfarin including blood pressure, renal function, LFTs, FBC, TFTs and clotting screen
- Issue the patient with an Oral Anticoagulation Treatment (OAT) pack (can be obtained from https://pcse.england.nhs.uk/) including yellow book in which INR levels, dosing information, date of next test and contact numbers for advice are recorded.
- Ensure that patients reach target INR within 6 weeks (slow induction)
- Maintain patients at target INR (± 0.5 INR units).
- Monitor treatment via NPT of INR at intervals usually between 2-12 weekly, where INR results will be recorded into an appropriate computer record system (INRstar or equivalent, using a NICE recommended dose-calculation protocol)
- Maintain TTR at ≥65% (excluding initial 6 weeks treatment period).
- Assess every 3 months:
- Compliance and reinforce advice regarding the importance of a regular dosing schedule.
- Adverse effects (e.g. bleeding)
- Thromboembolic events (e.g. symptoms of stroke or breathlessness)
- Patients that are unable to comply with current treatment should be considered for alternative oral anticoagulant if not previously been considered.

Patient education:

Patients receiving their first primary care appointment for anticoagulation monitoring either at a clinic or through a home visit must receive information on the management and prevention of secondary complications of their condition. If the patient has a carer, they must be involved. This information will be reviewed with them and delivered by the accredited practitioner and educational counselling will be provided at the initial appointment, using an induction process (as per Scenario: Warfarin | Management | Anticoagulation - oral | CKS | NICE) and this will be reviewed regularly to ensure the service user is continually aware of and understands the following:

- Name of drug and current dose, including tablet colours for warfarin
- The contents of the yellow book and service user held information
- Target INR and range;
- Reason for and objectives of treatment;
- Anticipated length of treatment;
- What to do in the event of a missed or wrong dose.
- Symptoms of under dose and overdose and what to do if these occur;
- Complications of treatment including side effects and bleeding;
- Drug and food interactions;
- Changes in medication or new medication requiring early monitoring
- Which medications (e.g. antibiotics) including over the counter (OTC) medications require particular care;
- What to do if dental treatment or surgery is required (Appendix 1)
- Contact details for the provider in case of concerns.
- Atrial Fibrillation (AF) patient information booklet (see Appendix 4)

Hand-held records for patients taking anticoagulant drugs:

Each patient must be issued with a 'yellow book' in which INR levels, dosing information, date of next test and contact numbers for advice are recorded, which they will take with them if they move from secondary to primary care and which should be maintained by the primary care service. Patients should be encouraged to always carry their yellow book with them and to show it to any health professional whenever they seek treatment or advice. Each patient must also be issued with a yellow anticoagulant alert card, completed with all relevant details, which they should be encouraged to always carry with them.

Each new service user will be issued with the new Oral Anticoagulation Treatment (OAT) pack and existing service users will be issued with replacement OAT/yellow book when required; these should be ordered direct from https://pcse.england.nhs.uk/

Record-keeping:

Anticoagulation providers will keep a comprehensive record for each patient that will be updated at appointments and will include:

- Service user's INR;

- Dose of anticoagulant;
- Date of next appointment;
- Information from the patient about unusual bleeding or bruising, adherence to treatment, other medication, changes in diet, changes in alcohol or smoking, or planned surgery;
- Information from the prescriber (where appropriate) as above and below;
- Additional information from the patients' medical notes (where appropriate);
- Prescribed medication, medication changes, OTC medication including homeopathic and herbal remedies.

If the provider is the GP, the patients' medical records must be updated.

In addition, the provider must be able to provide the following for any patient under their care and share with the patients own GP practice for any patients who are not registered with the provider

- Patient name and address;
- NHS number;
- Date of birth;
- Name of initiating Consultant or GP;
- Indication for treatment;
- Oral anticoagulant prescribed;
- Length of treatment;
- Target INR and range;
- Discontinuation date (if applicable);
- Relevant notes supporting dose decision, counselling and self-management;
- Information relating to performance indicators and audit such as time spent within target range;
- Frequency of missed appointments;
- Medical conditions, hospital admissions likely to affect anticoagulation such as increased risk from haemorrhage;
- Bleeding episodes and adverse events including submission to the ICB of all patient safety incidents.
- Any actions taken other than dosing and retest dates.
- Any other significant information which may have an impact on their care (eg carer information, alternate contacts, hearing/reading difficulties, memory loss issues etc)

A CDSS solution must be used to record the necessary information.

Each service user will require an individual clinical record (for example, a GP medical record or pharmacy record) that contains all clinical information that cannot be stored on the CDSS.

Medication:

The prescribing of medication will remain the responsibility of the patients GP even if the monitoring of the INR and dosing is provided elsewhere (such as by a community pharmacy). Decisions on dosing and the anticoagulant used will be the clinical responsibility of the provider.

Dosage of warfarin should be calculated in conjunction with using the CDSS. However, it is the responsibility of the clinician to make a clinical decision on dosing. If the CDSS does not support acenocoumarol or phenindione dosing, it is the responsibility of the clinician to calculate the dose.

The anticipated duration of overall treatment will be documented at the point of the initial referral. Whether treatment should be discontinued should be reviewed regularly, before due date for end of treatment and at least annually. Responsibility for the decision to discontinue anticoagulation will reside with the patients GP or specialist, but the anticoagulation provider should raise the issue when appropriate. Oral anticoagulants will be discontinued on an agreed defined date and the patients and all people involved in the patients care informed.

Individual annual review:

Service providers will be required to conduct a formal review of a patient's health, relating to anticoagulation, at least annually, including continued need for anticoagulation, potential complications and, as necessary, a review of the patients own monitoring records and duration of treatment. Service providers must liaise with the referring practice to determine the patients continued need.

Referrals out of Primary Care:
Patients with either of the symptoms below should be treated as a medical emergency and referred appropriately.

- Signs or symptoms of major bleeding or thromboembolism;
- A low INR and thromboembolism or stroke.

For warfarin patients; administration of small doses of oral or IV vitamin K will readily reverse INR within 16 to 24 hours to therapeutic doses. Each service provider must have readily available vitamin K for oral use (Konakion MM paediatric may be administered by mouth). All service providers will need to sign up to the PGD for the Supply of Oral Administration of Vitamin K in over anticoagulated patients (Appendix 7). Expert advice must be sought immediately from the relevant Haematology Department when it is felt by the service provider that the management of a patient is outside their sphere of competence.

Adverse events:

It is a service requirement that any adverse event related to anticoagulation of any patient covered under this service is reported via NHS England » Learn from patient safety events (LFPSE) service. If the patient has a reaction to treatment this should be reported to MHRA via Yellow Card | Making medicines and medical devices safer (mhra.gov.uk).

Near service user testing and quality control for patients taking warfarin.

Service providers will be expected to provide Near Service user Testing (NPT) to determine service users' INR levels using accredited coagulometers. The ICB recommends Coaguchek XS (plus) system monitors for consistency and accuracy. Service providers will pay for all NPT equipment and supplies including the test strips, finger prick equipment and internal quality control solution. The NPT equipment must be maintained and calibrated as per the manufacturer's guidance and recorded. It is good practice also to be able to track the time of testing and lot number of test strip used for each service user should the need arise. Cleaning procedures recommended by the manufacturer should be adhered to and health and safety standards should be followed at all times.

The disposal of sharps should be in accordance with national guidance and the providers' waste disposal and infection control policy.

Service providers will be expected to follow a prescribed Internal Quality Control (IQC) system that will include testing control samples with a known INR to ensure their coagulometer is calibrated correctly and working accurately. Quality control should be performed:

- At the beginning of each clinic,
- Each time a new box of strips is started or a new batch is used;
- Following an unexpected result.

Service providers must participate in the UK National External Quality Assessment Scheme (NEQAS) for Blood Coagulation that monitors the performance of coagulometers. Service providers will be sent at least four surveys per year each comprising two samples for INR determination so that the quality of testing equipment can be assured and maintained. Comprehensive records of quality checks to include batch numbers of strips and control samples, time of test and operator must be kept.

Patient testing should be reviewed/stopped following any failure to produce an acceptable result as a result of the IQC system or if the instrument receives a result outside the consensus from NEQAS. Consideration should be given to stopping the service if judged unsafe by the responsible clinician for the premises. In such circumstances, advice from the ICB Primary Care Commissioning Team must be obtained to ensure that an alternative provider can be sourced.

3.4 Population covered:

Patients registered with the member practices of Derby and Derbyshire ICB who require anticoagulation, irrespective of indication, duration or ambulatory status.

3.5 Any acceptance and exclusion criteria and thresholds:

Overall Scope of Local Enhanced Service (LES)

In Scope:

- Patients registered with the member practices of Derby and Derbyshire ICB who require anticoagulation and who fit the criteria below will be eligible for the Primary Care anticoagulation service.
- Secondary Care patients considered 'stable' by the Consultant Haematologist will be referred to Primary Care.
- The ICB recognise that some patients may wish to self-monitor their anti-coagulation but the ICB does not specifically commission a self-monitoring service within this specification. However, anticoagulation providers/practitioners can consider individual requests to self-monitor on a patient-by-patient basis. Clinical risks should be assessed and provision of the service will be the responsibility of the provider.

The ICB will pay for the management of self-monitoring patients at the same level as other patients under this specification. The ICB will not however bear the cost of the equipment/consumables required to provide this service, either directly or via a practice's prescribing budget. Practices that agree for patients to self-monitor should provide the patient with testing strips if they are claiming for them under this service. The ICB will periodically monitor ePACT data and may require providers to provide audit data that demonstrates patients treated under this scheme are not prescribed relevant consumables on an FP10.

The provider should clearly define how self-monitoring patients are managed to ensure safe and effective prescribing and management of warfarin and this should be included in its service SOP.

Out of Scope:

The following are deemed to be out of scope of this LES:

- Patients that are self-monitoring **and** self-dosing warfarin are excluded from this locally commissioned service.
- Unstable service users with complex needs.
- Service users with the following conditions/problems should be excluded from the primary care service:
- A known hereditary or acquired bleeding disorder;
- Children under 16;
- Pregnant women;
- Other conditions the Consultant Haematologist considers should exclude the service user from management in primary care.
- Service users with Deep Vein Thrombosis (DVT) or Pulmonary Embolism initiated on warfarin who have not been stabilised in Secondary Care before being discharged from hospital.
- Patients taking novel oral anticoagulants (NOACs)
- Patients with ACS (Acute Coronary Syndrome) unless stabilized and deemed appropriate

Caution should be taken when monitoring patients with the following conditions/problems and where required advice from the Haematology department should be sought:

- A known hereditary or acquired thrombophilia;
- Have had a DVT/PE in previous month;
- Liver failure;
- Documented evidence of Central Nervous System haemorrhage in the previous 6 months;
- Gastro-intestinal bleeding in the previous 6 months;
- A known alcohol problem;
- IV drug users;
- Service users in care homes (because of other problems rather than being in a care home per se);
- Severe heart failure;
- On chemotherapy for malignant tumours;
- Some medications interact with warfarin and product information for any concurrent therapy should always be consulted for specific guidance on warfarin dose adjustment and therapeutic monitoring. If no specific information is provided the possibility of an interaction should always be considered.
- There are a range of medications that are contraindicated for use in concurrence with warfarin therapy. Therefore, patients using these drugs, where a satisfactory non-contraindicated medication is not available, could potentially fall outside the scope of this service
- Other conditions the Consultant Haematologist considers problematic for management in primary care.

3.6 Interdependence with other services/providers:

Secondary Care
Derbyshire Community Health Service (DCHS)
Pharmacy
UK National External Quality assessment Scheme.

3.7 Monitoring:

One of the important advantages of CDSS is that it provides a facility for audit of performance on a regular basis. The audit parameters will include measures on therapeutic control as well as clinical outcomes measures. The time patients spend within therapeutic range can be calculated using the software package provided. Patients should expect to be within their own therapeutic range (i.e. +/_ 0.5 of target INR) for at least 65% of the time and within +/- 0.75 of their target INR 80% of the time. Measurements of TTR should exclude the first 6 weeks of treatment while the patient is being stabilised.

Providers are required to complete an annual audit indicating the achievement of quality criteria both in terms of systems management and clinical outcomes.

Audits will be performed to assess:

- Whether INR results are within the recommended target range;
- The number of critical incidents/adverse events

If the audit results fall out of the scope it must be reported through the significant event process and the ICB Clinical Lead informed. The provider must deliver, implement and review an action plan within the specified timescales.

All service providers involved should perform an annual summary audit report including:

- The number of patients being monitored, indications for treatment and the anticipated duration;
- Details of the Near Patient machine used (make, model and serial number);
- Age and performance of machine against quality checks;
- Details of IQC and EQC;
- Details of trained staff, qualifications, and skill review dates;
- Number of complaints received over the review period that relate to the service;
- Number of serious incident/ patient safety incidents over the review period that relate to the service and a report of any learning taken from these;
- Number and percentage of patients within, above and below target INR range over the review period (within 0.5 and 0.75 of target INR);
- Number of bleeding episodes, during the review period, that required admission or referral to secondary care;
- Number of patients and occasions requiring vitamin K administration;
- Number of patients referred back to Secondary Care and the clinical reason for the referral.

Most of this information should be derived from the CDSS or electronic patient record.

The provider is required to have clear policies, practices and procedures for clinical governance, including:

- Clinical Governance Lead
- Serious Incident Reporting/ Patient Safety Reporting – including the notification of all incidents to the ICB and other bodies are required
- Infection control
- Complaints
- Record Keeping
- Managing alerts (equipment etc)
- Quality Assurance
- Home Visiting

Serious incidents/ patient safety incidents in relation to the delivery of this specification should be reported at time of occurrence to DDICB.

Providers may be required to produce further reports to the ICB upon request, which may form part of Post Payment Verification audits.

The provider will be requested to produce an annual self-declaration of competence to deliver this specification.
All relevant training records to be maintained on site to demonstrate compliance with this accreditation pathway and be available if requested.

3.8 Payment:

Warfarin	
£100.30 per patient initiated on Warfarin within the clinic setting £100.30 per patient initiated as a Restart within the clinic setting	
£186.56 - per patient per year (including patients who are self-monitoring but are managed by the service provider).	
Plus **£20.06** per home visit – see conditions below	

The initiation fee will be paid for new patients who have never had warfarin, and for patients discharged by Secondary Care and taken on before three stable INRs are established or where patient has had a planned stop and restart (e.g. operation) initiated by an accredited practitioner at the practice. The fee cannot be claimed for restarting after stopping treatment due to a high INR or other management issues.

Where the service requires a domiciliary visit to a housebound service user and is provided by an accredited practitioner, **£20.06** will be paid for each service user visited at a separate address. For service users at the same address seen at the same time £20.06 will be paid for the second service user and £6 for each subsequent service user. This fee is in addition to the £186.56 per service user per year. This will be on the basis that a level 4 service, as specified by the CCGs is provided at the home by an accredited practitioner.

Where a provider can demonstrate that a member of staff is competent to carry out domiciliary visits (perform the finger prick test to gain a sample and use the coagulometer to determine the INR), the provider can claim via an 'unaccredited' rate. The fee is £6.02 for each service user visited at a separate address. For service users at the same address seen at the same time, £6.02 will be paid for the first two service users and then £1.80 for each subsequent service user.

It will be the service providers' responsibility to ensure staffs are adequately trained. The dosing in all circumstances will have to be done by an accredited practitioner and all relevant information (date of test, INR and dosing information) must be recorded in the patient's Yellow book at the visit. An accredited practitioner will need to see each permanently housebound patient every 6 months.

Providers will be required to keep detailed records of each home visit and initiation claims.

The payment methodology contained within this specification will be reviewed annually.

Payments will be made on a monthly basis, on the understanding that all relevant quality indicators have been achieved, via the Enhanced Service online claim system.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE):

Atrial fibrillation: diagnosis and management, NICE guideline [NG196]
Overview | Atrial fibrillation: diagnosis and management | Guidance | NICE

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges):

4.3 Applicable local standards:

The Derbyshire Joint Area Prescribing Committee (JAPC) 'Guideline on Oral Anticoagulation'

http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_2/Oral_anticoagulation.pdf

Derbyshire Medicines Management Prescribing and Guidelines. Management of non-valvular Atrial Fibrillation
Atrial_fibrillation.pdf (derbyshiremedicinesmanagement.nhs.uk)

DDICB will:

- Ensure that the service is only commissioned from appropriate providers who can demonstrate that they have achieved Care Quality Commission (CQC) registration requirements if applicable;
- Ensure payments are made in a timely fashion when a claim is made;
- Approve Clinical Decision Support Software (CDSS) management programmes and Near Service user Testing (NPT) equipment prior to implementation;
- Publicise CPD training (which meets the requirements of this specification) for service providers where we become aware of it;
- The ICB will communicate any information that affects the delivery of the service to all providers;
- Ensure anticoagulation guidelines are available for the management of under/over-anticoagulation. **Available at http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_2/Oral_anticoagulation.pdf**

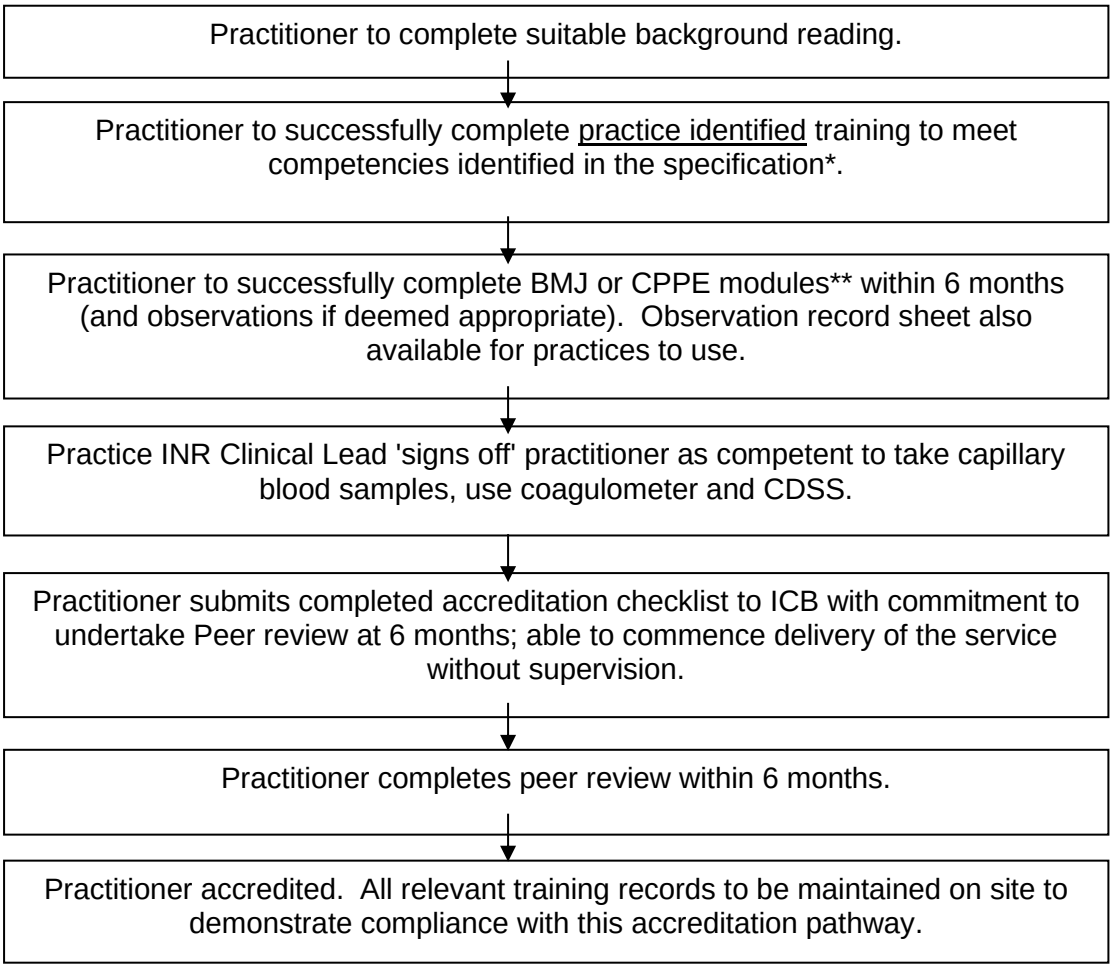
The anticoagulation provider will be responsible for ensuring that the service is provided according to the service specification. In particular, that:

- Dose recommendations and recall are made according to approved guidelines, in conjunction with approved CDSS;
- Patient education regarding anticoagulation therapy is provided and recorded and the service user hand-held record/yellow book is kept up-to-date;
- The provider will support patients to make an informed choice about type of anticoagulation taken
- Patients referred to A&E or Secondary Care or their own GP where required;
- Adverse events are reported to DDICB Clinical Quality team;
- Contingency plans are in place to cover annual/sickness leave and staff turnover;
- Comprehensive policies and procedures are in place to ensure that all elements of the specification are met;

- Ensure that a system is in place for patients to receive urgent medical advice relating to anticoagulation through the Standard Operating Procedures (SOP);
- The provider is registered with and participates in the National External Quality Assessment Scheme (NEQAS) for Blood Coagulation;
- Maintain a regular system of clinical audit and annual reviews;
- Ensure that any staffs involved in the delivery of the service have received appropriate training and maintain competences.

4.4 Training and Accreditation Requirements

Anticoagulation Accreditation Pathway



Practitioner will be the practice identified registered nurse with responsibility for the delivery of this specification.
Clinical Lead will be the practice identified GP with lead responsibility for the delivery of this specification

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The theoretical elements of the course should ensure that the practitioner of each Primary Care service has:
- The ability to safely manage a Primary Care based anticoagulation clinic using near patient testing for INR estimating, interpreting INR results and assessing the dose of oral anticoagulation in order to maintain results within their appropriate therapeutic ranges;

- A comprehensive understanding of the conditions requiring oral anticoagulation therapy, the different anticoagulants, and the target ranges for Warfarin therapy;
- The ability to evaluate which target INR is required when treating different conditions;
- An understanding of the pharmacology of Warfarin and determine the relevant medication, side effects, antidotes, interaction and dosing;
- The ability to critically analyse all aspects of anticoagulation management and therefore evaluation aspects for safe practice.

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Maintaining patients on anticoagulants: how to do it'
(http://learning.bmj.com/learning/main.html)
'Cardiovascular disease: anticoagulation'
(www.cppe.ac.uk)

Starting patients on oral anticoagulants in primary care: how to do it online course | BMJ Learning

This pathway puts the responsibility on the provider INR Clinical Lead to assess the practitioner's scope of knowledge and competencies relating to anticoagulation management and decide which path of accreditation best meets their learning needs to provide safe quality services to patients.

Practitioners have a duty to ensure they do not work outside their scope. External peer reviews within 6-months of starting the service will provide added reassurance. Copies of all relevant training documents must be retained by the provider to show compliance with the accreditation pathway. Commissioners may check that all the requirements are met as part of the quality assurance and monitoring process.

It is the provider's responsibility to access and fund any relevant training determined appropriate to meet the requirements specified.
As part of business continuity plans, providers need to maintain accredited practitioners and resources required to continue to provide the service.

Providers can use unaccredited staff (e.g.Health Care Assistant/Pharmacy Technician) to carry out domiciliary visits where they can demonstrate that they are competent to do so. The staff member must have:

- Worked with an accredited practitioner to understand the scope of the service;
- Been trained in how to obtain a sample;
- Been observed and deemed competent by an accredited practitioner in taking samples;
- Been trained in the use of the relevant coagulometer and the method of determining the INR;
- Been observed and deemed competent by an accredited practitioner in the use of the relevant coagulometer;
- Understands the use of the Yellow Book and the information that must be recorded in it.

The provider must record that any unaccredited practitioner utilised in delivery of this service has received the above training and has understood it and had the chance to ask questions.

5. Applicable quality requirements

5.1 **Applicable Quality Requirements** CQC Registration and those required under the GP Core Standard Contract.

6. Variation and termination notice period

6.1 Service Variation

The Commissioner reserves the right to vary this service specification by giving 3 months' notice.

6.2 Service Termination

The Commissioner or the Provider may reserve the right to terminate the service described within this service specification by giving 6 months' notice.

APPENDICES

Appendix 1:

The Derbyshire Joint Area Prescribing Committee (JAPC) 'Guideline on Oral Anticoagulation'

http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_2/Oral_anticoagulation.pdf

Appendix 2:

Overview | Atrial fibrillation: diagnosis and management | Guidance | NICE

Appendix 3:

Derbyshire Medicines Management Prescribing and Guidelines. Management of non-valvular Atrial Fibrillation
Atrial_fibrillation.pdf (derbyshiremedicinesmanagement.nhs.uk)

Appendix 4:

AF_Patient_Booklet.pdf (derbyshiremedicinesmanagement.nhs.uk)

Appendix 5:

Patient Group Direction (PGD) Vitamin K

http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Patient_Group_Directions/Vitamin%20K%20PGD%20October%202020.pdf