NHS Standard Contract - SCHEDULE 2 – THE SERVICES

Anticoagulation Service Specification

Service Specification No.	
Service	Anticoagulation Service Specification
Commissioner Lead/s	Dr Avanthi Gunasekera, Strategic Clinical Executive Stuart Lakin, Head of Medicines Management
Provider Lead	As signed
Period	1 April 2022 to 31 March 2023 ~~1 April 2021 to 31 March 2022~~
Date of Review	End of contract period or as necessary

1. Population Needs

This service provides standardised and clinically effective anticoagulation management to patients within Rotherham CCG who are receiving warfarin therapy using Near Patient Testing (NPT) and Computer Decision Support Software (CDSS) by GP practices.

As per the NHS Rotherham CCG Quality Contract, if practices do not wish to deliver this service it must be sub-contracted to another practice following discussions with the CCG. All patients must have access to this service.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

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

3. Scope

3.1 Aims

The overall aim is to provide an integrated anticoagulation service across primary and secondary care that benefits patients. All patients that are not required to attend a hospital outpatient service will be able to have their anticoagulation therapy monitored and reviewed in primary care. GPs may provide the service to all eligible patients from their own practice. Patients must be referred to alternative primary care health care providers, including other practices, if their GP is unable to offer an anticoagulation monitoring service.

3.2 Objectives

- To initiate and titrate warfarin in patients where clinically appropriate.
- To measure and monitor the INR of patients who are prescribed warfarin therapy by their GP or hospital consultant, following stabilisation of their International Normalised Ratio (INR) at the hospital clinic, or after initiation at the practice.
- To maintain the patient's INR within their therapeutic range by appropriately adjusting their warfarin dosage.

- To provide feedback to the patient's medical practitioner on issues relating to their anticoagulation, along with other medical issues that arise during consultation.
- To ensure that all patients registered with the clinic have had a documented medication review of their need and suitability for anticoagulation assessed within the last 12 months.
- To counsel and educate patients in order for them to understand their treatment with respect to their condition, target INR, the effects of over and under coagulation, diet, lifestyle and drug interactions.

3.3 Target population and eligibility criteria
All patients within Rotherham CCG who require anticoagulation monitoring will be eligible for the primary care anticoagulation service. This includes domiciliary visits as well as in-practice clinics. Patient's requirements for anticoagulation should be assessed taking account of the exclusions, cautions and risk factors in the Anticoagulation Appendices 2020-212-23 - Quick Reference Document on Anticoagulation with Warfarin.

3.4 Training
All providers must ensure that staff involved in providing any aspect of care under this scheme have the necessary skills, and the Lead Clinician should discuss the requirements of the role as part of their appraisal. The CCG will provide an update training session every two years as part of Protected Learning Time, and recommends that if further training is required in the interim (e.g. for new starters) the MHRA online oral anticoagulants training module is undertaken http://www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/Medicineslearningmodules/Oralanticoagulants/CON437443

3.5 Standard Operating Procedure
The service provider must produce a Standard Operating Procedure (SOP). This will detail how the provider is going to deliver the service and if necessary the CCG can provide examples of SOP from other participating practices. Details of the requirements of the SOP are in Appendix A.

3.6 Patient education
Patients and/or their carers arriving for their first visit for anticoagulation monitoring in primary care may have had information on the management of, and prevention of, secondary complications of their condition. This will be reviewed with them and educational counselling should be provided at the initial appointment, using an induction process and then regularly to ensure the patient is aware of and understands the following:
- Name of drug and current dose including tablet colours
- 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 (e.g. progressive worsening of thrombotic signs or new symptoms such as PE) and overdose and what to do if these occur
- Complications of treatment including side effects and bleeding
- Drug and food interactions *(*see latest BNF interactions*)*
- Changes in medication or new medication requiring early monitoring
- Which medications (e.g. antibiotics) including over the counter (OTC) medications that require particular care if taking warfarin.
- What to do if dental treatment or surgery is required
- Contact details for the provider in case of concerns

3.7 Handheld records
Each patient will have an individual hand-held record 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. This will be maintained by the primary care service. Patients should be encouraged to carry their handheld record with them at all times and to show it to any health professional whenever they seek treatment or advice. Any changes to the handheld record and safety checks introduced by the National Patient Safety Agency should be explained to all patients.

3.8 Recordkeeping

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

- Patients INR
- Dose of anticoagulant
- Date of next appointment
- Information from the patient about any 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)
- Additional information from the patient's medical notes (where appropriate)
- OTC medication including homeopathic and herbal remedies

In addition, the provider should be able to provide the following for any patient under their care:

- Patient name and address
- Date of birth
- Indication for treatment
- Length of treatment
- Target INR
- 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 PCT of all patient safety incidents
- Discontinuation date
- Name of initiating Consultant or GP
- Any actions taken other than dosing and retest dates

The Computerised decision support software (CDSS) provided by the CCG must be used to record the necessary information. Service providers will also be required to ensure that all clinical information, including what cannot be stored in CDSS, related to the service is recorded in the patient's own GP record, including the completion of the 'significant event' record that the patient is on warfarin.

3.9 Primary care clinic arrangements

- All providers will need to name an individual as the clinical lead who will be responsible for ensuring that the service is delivered in accordance with the specification.
- All patients will be seen in person either in a clinic or at home by a health professional that has the necessary skills. The service can be delivered by a GP, registered nurse or HCA with adequate supervision within the practice or, alternatively, the primary care anticoagulation provider can be a pharmacist trained in anticoagulation management, a practitioner with a specialist interest (PwSI) in anticoagulation management or a clinical nurse /pharmacist specialist working on an outreach basis to provide the service. Service providers will be expected to provide availability for anticoagulation patients to be seen at least once during the week.
- The length of time between test dates will vary but every patient must be seen at least once every 12 weeks. Less stable and new patients will require more frequent tests. The frequency of testing should be stipulated in the providers Standard Operating Procedures (SOP).
- Service providers are clinically responsible for all patients under their care for anticoagulation management and should 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 patients GP practice, the service provider has responsibility to ensure robust communication systems and must notify the patient's GP of each INR, recommended dosage and any significant events according to agreed protocols.
- The overall responsibility for managing patients treated under this agreement remains with the prescribing general practitioner. When an INR result is provided by a third party (for example the district nursing service) the prescribing general practitioner will as part of their standing operating

procedure for the service have a robust policy in place to act on these results.

3.10 Indications for treatment

~~The target INR and duration of therapy depends on the indication for anticoagulation.~~

~~***Indication***~~	~~***INR Range****~~
~~Recurrent DVT~~	~~2-3~~
~~Recurrent PE~~	~~2-3~~
~~Treatment of TIA~~	~~2-3~~
~~Prophylaxis in mechanical heart valves~~	~~3-4~~
~~Prophylaxis in AF~~	~~2-3~~
~~*British Haematology Guidelines*~~	

~~*This may vary depending on the clinical decision of the lead clinician.~~

The following indications and target INRs for adults for warfarin take into account recommendations of the British Society for Haematology guidelines on oral anticoagulation with warfarin—fourth edition. Br J Haematol 2011; 154: 311–324, and https://cks.nice.org.uk/topics/anticoagulation-oral/management/warfarin/#target-inrs

An INR which is within 0.5 units of the target value is generally satisfactory; larger deviations require dosage adjustment. Target values (rather than ranges) are now recommended.

INR 2.5 for:

- treatment of deep-vein thrombosis or pulmonary embolism (including those associated with antiphospholipid syndrome or for recurrence in patients no longer receiving warfarin sodium)
- atrial fibrillation
- cardioversion—target INR should be achieved at least 3 weeks before cardioversion and anticoagulation should continue for at least 4 weeks after the procedure (higher target values, such as an INR of 3, can be used for up to 4 weeks before the procedure to avoid cancellations due to low INR)
- dilated cardiomyopathy
- mitral stenosis or regurgitation in patients with either atrial fibrillation, a history of systemic embolism, a left atrial thrombus, or an enlarged left atrium
- bioprosthetic heart valves in the mitral position (treat for 3 months), or in patients with a history of systemic embolism (treat for at least 3 months), or with a left atrial thrombus at surgery (treat until clot resolves), or with other risk factors (e.g. atrial fibrillation or a low ventricular ejection fraction)
- acute arterial embolism requiring embolectomy (consider long-term treatment)
- myocardial infarction

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INR 3.5 for:

- recurrent deep-vein thrombosis or pulmonary embolism in patients currently receiving anticoagulation and with an INR above 2;

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Mechanical prosthetic heart valves:

- the recommended target INR depends on the type and location of the valve, and patient-related risk factors
- consider increasing the INR target or adding an antiplatelet drug, if an embolic event occurs whilst anticoagulated at the target INR.
- See Table 1 for the recommended target INRs for mechanical valve

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Table 1. Recommended target international normalized ratios (INRs) for mechanical valves.

Prosthesis thrombogenicity	INR target (no patient risk factors)	INR target (patient-related risk factors)*
Low	2.5	3.0

Medium	3.0	3.5
High	3.5	3.5
*Patient-related risk factors for thrombosis include mitral, tricuspid, or pulmonary position; previous arterial thromboembolism; atrial fibrillation; left atrium diameter >50 mm; mitral stenosis of any degree; left ventricular ejection fraction <35%; left atrial dense spontaneous echo contrast		

Warfarin should be taken once daily (5-6pm is an ideal time for compliance and to ensure that if the dosage is changed at an appointment the new dosage can be started that evening) and is given as a tablet for oral administration.

Tablet strengths are:
0.5mg (white)* (Not recommend for prescribing)
1 mg (brown)
3 mg (blue)
5 mg (pink)* (Not recommend for prescribing)

*NB There have been incidences of patients confusing 0.5mg with 5mg so it may be preferable to suggest taking half a brown, (1mg) tablet in patient's where dosing of 0.5mg is necessary.

Rotherham CCG recommends that only 1mg (brown) and 3mg (blue) tablets are used.

Rotherham CCG procedure for INRs above 8

INR above 8 but below 10; discuss with the admission unit at Rotherham FT / local hospital
INR above 10; admit to hospital

Practice to report all INRs above 8 onto the National Reporting Learning System (NRLS).

3.11 Drug interactions
A variety of drugs and food are known to interact with warfarin leading to an alteration in INR levels. For drugs and foods known to cause an interaction with warfarin see latest BNF interactions. If an interacting drug is newly prescribed or a lifestyle event occurs that is likely to affect the INR, then consider an early recall to re-test (within 5-7 days) and document in the patient records the decision regarding to retest or otherwise.

3.12 Initiations and discharges by Rotherham Foundation Trust
When a patient has commenced on warfarin or their dose has been altered during an admission to the Rotherham Foundation Trust, the responsibility lies with the hospital to contact the provider before discharge to ensure the patients GP accepts responsibility for their community monitoring. This process is clearly laid out in TRFTs Anticoagulation Prescription and Referral Document, a copy of which should be sent to the provider with the discharge letter. As a minimum, the provider should expect to receive:

- Indication for treatment
- New starting treatment? Yes ☐ No ☐ (usual dose …mg)
- Target INR Range
- Duration of therapy: 3 months ☐ 6 months ☐ Permanent* ☐
- *Stop only after review by Medical Consultant, review date……

Practices are not obliged to accept the anticoagulation care of temporary patients if the practice feels it would compromise patient safety to do so.

3.13 Near patient testing and quality control

- Near patient testing equipment will be provided by Rotherham CCG and providers will be supplied with a CoaguChek XS plus monitor. The near patient testing equipment remains the property of the CCG. The CCG will be responsible for the replacement of the equipment when the manufacturer deems the equipment to be beyond economical repair due to wear and tear, however, if the equipment is lost or damaged due to negligence the practice will be responsible for the costs incurred.

- The equipment will be used and calibrated in line with manufacturer's guidance that will also include internal quality assurance. Providers will be registered with the United Kingdom National Quality Assurance Service (UKNEQAS) and have their equipment externally quality assured through the UKNEQAS organisation. Reimbursement for the cost of NEQAS subscription can be sought from the CCG. Providers will maintain and make available on request a record of all the internal and external quality assurance for each piece of near patient testing equipment they hold. Test strips and calibration strips for the CoaguChek XS plus should be ordered from the manufacturer.
- It is expected that the anticoagulation service will be delivered using near patient testing for routine INRs, and venous sampling will only be used by exception.
- In such circumstances where the lead clinician judges the service to be unsafe, patients should be referred to an alternative provider until the problem is identified and resolved. The CCG should be advised immediately.
- NHS Rotherham CCG has commissioned the District Nursing Service to undertake home visits for the near patient testing / phlebotomy for anticoagulation monitoring of housebound patients. Practices can use this service or undertake their own home visits, but payment will be made to whichever service visits housebound patients. Where the prescribing general practitioner asks the District Nursing Service or other provider to deliver the patient testing element of this service, the clinician managing the patient will be responsible for ensuring the test results are recorded in the patient record and the warfarin therapy is adjusted as required. Once the INR result has been provided to the practice by the District Nursing Service or other provider, the District Nursing Service or other provider will have no further responsibility for the patient or their on-going warfarin management.

3.14 Computerised decision support software (CDSS)
Rotherham CCG directly funds the purchase, upgrade and annual license fee of INRstar Computerised Decision Support Software (CDSS). The software will provide guidance on dosing as well as record patient details and outcomes. If additional patient licenses are needed they should be requested from the software company and the CCG should be notified of the request. Where anticoagulation is sub-contracted to another provider, the CCG will pay for the patients practice to have access to the viewing module of INRstar so they can view their patient's anticoagulation results and dosing information directly.

3.15 Data returns and key performance indicators
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 in-line with NICE ~~clinical~~ Guideline ~~cg180~~ NG196 ~~Atrial fibrillation management~~ Atrial fibrillation: diagnosis and ~~management~~https://www.nice.org.uk/guidance/cg180/resources/atrial-fibrillation-management-pdf-~~35109805981381~~ https://www.nice.org.uk/guidance/ng196. Data relating to time in range and other key performance indicators will be requested via the LES data worksheet by the Primary Care Team on a quarterly basis.

3.16 Patient satisfaction
In order to ensure patients are satisfied with the community anticoagulation service, the CCG will undertake a rolling Smart Survey to monitor patient satisfaction. GP practices will provide the patient with the appropriate link for completion.

3.17 Remuneration
The CCG will make payments at the following rates, and remuneration will be adjusted quarterly to reflect the increase or decrease in patients being monitored following the submission of the quarterly data return.

Monitoring and adjusting warfarin doses	£122.09/patient
Initiation of warfarin *(one off payment)	£50.85/patient
Home visit testing (To be paid to whoever undertake the visit practice/DN team etc.)	£7.68/patient

Consequences for late submission of activity data:
- 1 – 7 days: 5% of payment

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- 8 – 14 days: 10% of payment and payment won't be released until the next payment run
- 15 – 21 days: 50% of payment and payment won't be released until the next payment run
- Submissions received after 21 days (3 weeks) will receive no payment.

A reminder by email will be sent out at least one week prior to submission date. It is the responsibility of the practice to ensure that any changes to contact details for the Practice lead/ practice manager are notified to the GP Commissioning team.

In the event of unforeseen exceptional circumstances e.g. unplanned admission to hospital, there is scope for the CCG to process a payment without precedent. It is however a practice responsibility to put in place sufficient contingency arrangements to ensure activity is submitted by the date specified.

If the CCG makes a payment to a practice under the LES and :

a) The practice was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment **or because the payment was calculated incorrectly** (including where a payment on account overestimates the amount that is to fall due);or
b) the CCG was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money is already been paid,

then the CCG is entitled to repayment of all or part of the money paid.

Any suspicions of fraud will be referred to the CCG's Counter Fraud Specialist for further investigation. It is important to recognise that claiming for procedures that do not fall within the service specification may constitute fraud and will be referred to the CCGs Counter Fraud Specialist for further investigation.

3.18 Audit – Compliance with the Scheme

Practices will be selected at random for audit (and also if the GP for Primary Care identifies any potential irregularities). Practices selected for audit are required to work with the auditors to demonstrate to them that all parts of the scheme have been complied with.

3.19 Termination of Agreement

This service forms part of the basket of enhanced services of the Rotherham Quality Contract, and is therefore subject to the terms outlined in the Quality Contract.

Following the recent publication of the 'Investment and Evolution: A five-year framework for GP contract reform to implement The NHS Long Term Plan' the CCG acknowledges that further guidance may influence the future delivery of Local Enhanced Services.

All Local Enhanced Services will be subject to regular review in line with the development of Primary Care Networks (PCNs). Three months' notice will be given to Providers if services are to transfer to PCN delivery and/or payment

The Practice and/or CCG may give three months written notice to terminate the service for reasons other than those outlined above.