

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service	Community Anticoagulation Service
Commissioner Lead	Islington Clinical Commissioning Group
Period	3 years
Date of Review	2019

1. Population Needs

1.1 National/local context and evidence base

Warfarin is an anticoagulant medicine used in the management of increasing numbers of patients and conditions including atrial fibrillation (AF) and venous thromboembolic diseases (VTE). While warfarin is a very effective medicine in these conditions, it can also have serious side effects, e.g. severe haemorrhage. 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 being treated. Warfarin initiation and monitoring aims to ensure that patients’ INR levels are stabilised within set limits to help prevent serious side effects while maximising effective treatment.

NICE has issued guidance on management of AF, (Clinical Guideline 180, 2014) and on VTE, (Clinical Guideline 144, 2012 and Quality Standard 29, 2013). Additionally the National Patient Safety Agency (NPSA) has issued Safety Alert 18: Actions that can make anticoagulant therapy safer. In addition to warfarin, other anticoagulant medicines are available including Newer Oral Anticoagulants (NOACs). Options for anticoagulation should be discussed and agreed between the patient and the prescriber.

Local Pathways

The overall aim of this service is to improve patient access to initiation of anticoagulation therapies and provide monitoring of warfarin across various clinic sites, and in patients’ homes (for housebound patients). This will ensure services are provided a close to patients’ homes, is a convenient service for patients, with increased local capacity to meet the demand for treatment with anticoagulants.

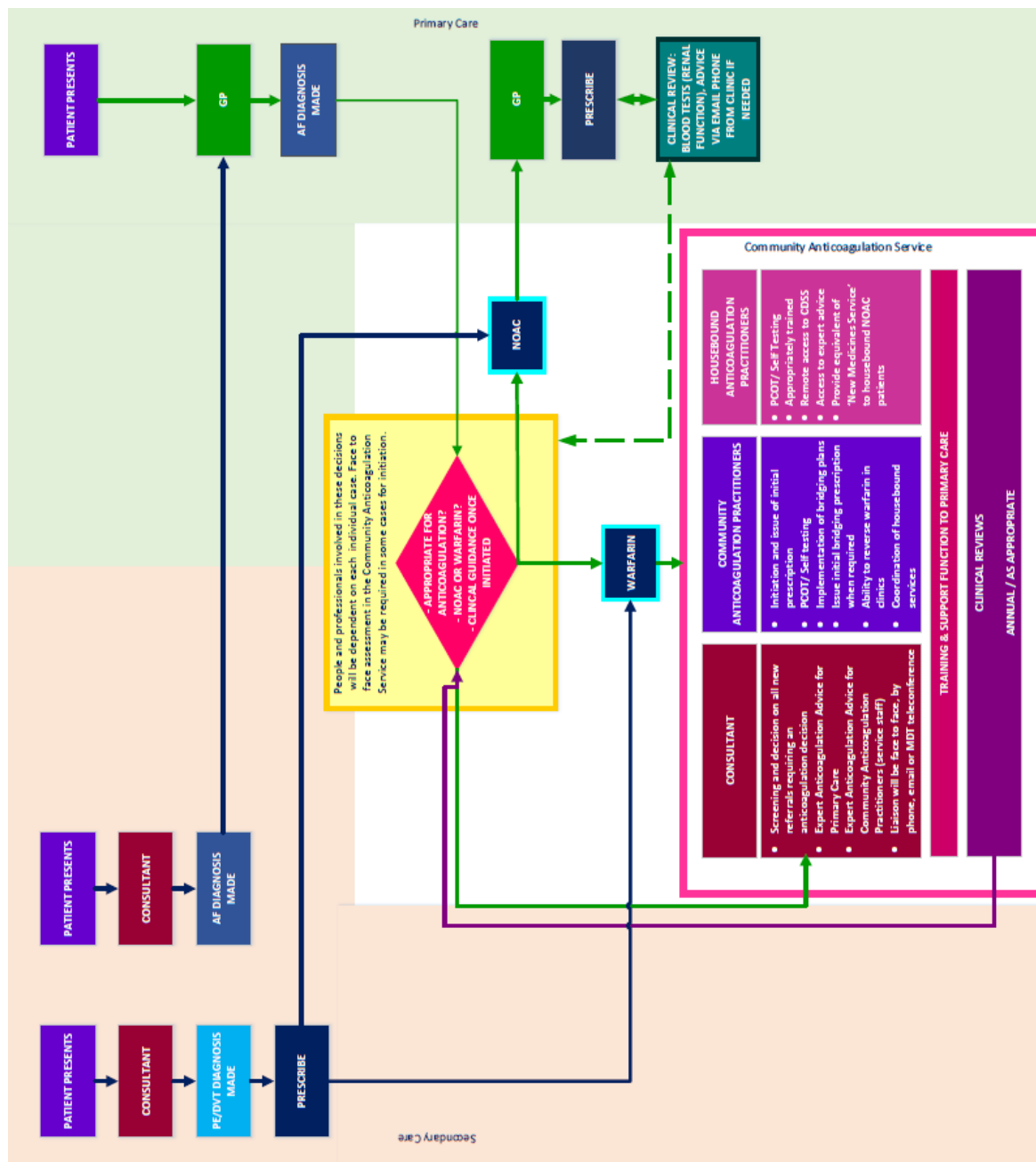
The intention is to provide a comprehensive, community based service for patients needing anticoagulation. The service must be delivered to all appropriate patients registered with GP Practices in Islington and ensure equitable access and quality of service to the entire population group.

Service locations will need to be agreed with the CCG using existing assets to good effect, should minimise travel for patients and maximise access through public transport links.

The service must embrace a person-centred approach to the care of patients and must work as a partner alongside all other health and social care professionals involved in the patient’s care so that patients experience co-ordinated, seamless and integrated services.

The service will also be expected to foster continued quality improvement and to demonstrate a commitment to ongoing review of safety and quality monitoring information about service provision. Additionally the provider will be required to have robust systems for acting on the results of safety and quality monitoring information, including more formal measures to improve provider performance if safety or quality indicators for the service remain persistently below expected standards.

Local Pathway Model



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

Patient experience

The specification requires the provider to adopt a person-centred approach to provision of the services, empowering patients (or their carers where applicable) to self-care, attend anticoagulation clinic appointments and achieve good clinical outcomes. Where appropriate, patients will be advised on managing the effects of their medication and health condition whilst continuing to engage in their regular daily activities e.g. work, family responsibilities etc. The CCG is requires regular evidence of providers collecting and acting on service user and carer feedback and comments on anticoagulation services. This will include feedback on the Friends and Family Test, waiting times, and their experience within clinic.

Access, convenience and responsiveness

The specification requires the service to be delivered as close to a patient's home as is possible, locations will be near excellent transport links for ease of access. Services will be provided across a minimum of 3 sites in the community. There is no cap on the maximum number of service sites; however clinics need to be running with the minimum caseload numbers detailed in 3.2.2.

Equivalent domiciliary services will be provided for housebound and care home patients. The various community clinic locations will provide ease of access for all other eligible patients via road and public transport.

Safety

The CCG requires the service provider to demonstrate a robust approach to clinical protocols and clinical risk and to command local clinician and patient confidence. The provider must ensure they have access to patients' lifelong clinical records held in GP computer systems, this will either be implemented through EMIS Community or the Integrated Digital Care Record (IDCR)(to be implemented in Islington). This is so that informed discussions can be had with the patient and their GP regarding anticoagulation treatment plans, that anticoagulation reviews can take place in the community clinic with access to all clinical information required, that INR results can be interpreted accurately patients and doses shared with health care professionals to minimise the risk of safety incidents.

Quality

The CCG requires the provider to demonstrate a commitment to high quality care in line with NICE quality standards and applicable national and professional standards.

Integrated care

The specification requires the provider to work as a partner alongside local health and social care professionals to improve co-ordination of care for patients taking anticoagulation therapies. The provider will be expected to have interoperable IT systems with all relevant stakeholders to achieve good clinical outcomes and protect patients from avoidable harm. The provider will also be required to have systems and processes for supporting personalised care planning and case management for patients within the service.

3. Scope

3.1 Aims and objectives of service

The overall aims of this service are to improve patient access to safe and effective anticoagulation initiation through collaboration between the patients GP and a Consultant anticoagulation specialist. Monitoring will be provided in a more convenient, efficient service with short waiting times. Dependent on which anticoagulation drug is prescribed this may mostly take place with the patient's GP, or in the community anticoagulation service. The service will provide greatly increased capacity in the community to meet the demand for treatment with anticoagulants and ensure that treatment is offered to patients close to their homes, whilst ensuring value for money in investing NHS funds.

The CCG is commissioning a community based anticoagulation service with the following objectives:

- To make specialist clinical decisions regarding anticoagulation initiation for all new patients (the patient's GP or patient where appropriate will be involved in this decision making process).
- A range of anticoagulation therapies are available and will be considered as appropriate for each individual patient; including Warfarin and NOACS.
- Ongoing monitoring of patients on warfarin using the most efficient method. It is expected that this will be done via point of care testing (POCT), unless it can be clinically justified otherwise.
- Monitoring will be performed using Clinical Decision Support Software (CDSS) at all service delivery points.
- CDSS used at all service delivery points must be interoperable with each other and with GP computer systems used in practices in Islington CCG (this will be via the IDCR)
- Undertake annual, or more frequent if appropriate, reviews for patients on warfarin medication in Islington.

- Clinical expertise and clinical governance of the service will be provided by a Consultant who is a specialist in anticoagulation.
- Healthcare professionals who initiate, monitor and / or review anticoagulation therapy have the training, skills and competencies to meet the requirements of their role having undertaken an accredited course.
- Safety and quality monitoring information from all service delivery points is reviewed by the provider, as a minimum every 3 months, and there is an agreed process for action on the results. This should include more formal measures to improve provider performance if safety or quality indicators for the service remain persistently below expected standards
- GPs in Islington will be supported to provide care for patients' prescribed NOAC anticoagulation medication in a seamless and integrated way through robust communication systems.
- Information flow between the service provider and health and social care professionals is secure and electronic.
- Community settings for service delivery cover care home residents and people who are housebound and disabled. The service experienced by housebound patients will be comparative to those provided in clinic environments.
- The service will hold its own prescribing budget; this is to both provide a seamless service for patients, and also prevent duplication of appointments required elsewhere in the local health system.
- Provides value for money (VFM) to the CCG
- Meets local key performance indicators (KPIs)

3.2 Service description/care pathway

Service Model

The CCG wishes to encourage innovation on the part of the service provider in terms of the service model. The CCG wishes to commission a single delivery model that provides value for money to deliver the comprehensive service. It is anticipated that the service could be provided via different levels of service provision within a single delivery model.

The full service is required to cover:

- Assessment of all new patient's referrals and decision-making regarding initiation of the most appropriate anticoagulation therapy for each individual patient. This will involve considering all options which may be appropriate for each individual patient. Where required, this decision making process will be done collaboratively with the patient's GP, and can include the patient/ carer. This will usually be via remote liaison (by email, telephone etc.) with parties having access to the patient's primary care record to inform the decision.
- However, where it is in the best interest of the patient to have a face to face initiation assessment at the community anticoagulation service, this can be offered to the patient.
- It will be the responsibility of the community anticoagulation service to document the discussion/ assessment appointment, and outcome for each patient. They will then formally send correspondence to the patients GP to confirm the decision made.
- If it is clinically appropriate for a patient to be initiated on a NOAC – the GP will prescribe, will counsel the patient (indications, adherence, side effects etc), be the initial point of contact for the patient, will refer the patient for blood tests to check their renal function as appropriate as part of a medication review. If guidance is required over the patient's anticoagulation management, the GP can access specialist advice from the community anticoagulation service, via email/ phone.
- If it is clinically appropriate for a patient to be initiated on warfarin, the community anticoagulation clinic will prescribe initially, be the initial point of contact for the patient, and will determine with the patient which is the most appropriate monitoring option (POCT, self-testing/ self-management).
- Equivalent services will be provided in the homes of patients who are housebound (this includes Care Homes).
- Patients on NOACs, under the care of their GP's, will be able to access support from the New Medicines Scheme provided by pharmacies. This service is not available on a domiciliary basis therefore; the community anticoagulation service will be commissioned to provide the equivalent to domiciliary patients on NOACs.
- If a decision cannot be made between the anticoagulation specialist Consultant and GP, as other specialist review is required, the necessary referral should be made and actioned prior to initiating therapy for the patient (as long as this is clinically safe). It is the GPs responsibility to make onward specialist referrals required.
- The service will hold its own prescribing budget. They will be responsible for prescribing the patients initial warfarin prescription, and in some circumstances, will prescribe the injectable anticoagulants requested in Bridging Plans.
- Bridging plans will be designed by the patient's operating team. These plans will be communicated to the patient's GP and/ or community anticoagulation clinic to be implemented. If the patient has their first clinical appointment with the community anticoagulation clinic (for POCT testing, or for formal warfarin review), the

community clinic will prescribe the injectable anticoagulants detailed in the patient bridging plan. If the patient sees their GP first, the GP will prescribe in accordance with the bridging plan.

- When a patient is on warfarin but it is felt appropriate to move the patient across on to a NOAC, the community anticoagulation service will counsel the patient, provide the initial prescription and transfer the patients ongoing care to the patients GP.
- All clinical reviews and onward referrals will be in line with local clinical pathways.
- The provider must be able to pass all data collected, including personal identifiable data, to GP Practices electronically for further follow-up where required. The data passed to GPs must be uploaded to the GP records system automatically; all GP Practices in Islington use [EMIS Web](#). Data must be quickly, accurately and securely transmitted to GP practices to ensure prompt clinical follow up of the individual and to ensure programme health outcomes are realized.
- Provision of specialist clinical advice to all community anticoagulation service providers and service wide co-ordination of clinical supervision, liaison with secondary care, contingency planning, equipment and resources.
- Responsibility for review of safety and quality monitoring information from all service delivery points and for implementing action on the results, including more formal measures to improve provider performance if safety or quality indicators for the service remain persistently below expected standards.

3.2.1 Overall service requirements

- Service risk assessment
- Staff training, skills and competency assessments
- Service settings
- Clinic times / appointment system and availability
- Patient register
- Call and recall system for warfarin patients
- Follow up of patients that do not attend (DNA)
- Provision of expert clinical input prior to initiation/ change of anticoagulation therapies for all Islington anticoagulation patients.
- Initiation of warfarin for appropriate patients
- Prescribing of initial warfarin dose and testing strips where appropriate
- Prescribing of injectable anticoagulants in line with the patients bridging plan, when the patient has their first clinical appointment with the community anticoagulation service after the plan has been determined.
- Monitoring, dosing and cessation of warfarin
- Provision of equivalent service to housebound warfarin patients.
- Provision of extra support, equivalent to the New Medicines Service, for housebound NOAC patients.
- Implementation of bridging plans
- Support for patients self-testing INR, dosing, and cessation of warfarin
- Transfer of patients currently on warfarin on to a NOAC, where appropriate.
- Person centred approach
- Patient education
- Primary Care clinical advice and training
- Documentation and electronic sharing of clinical information
- Clinical reviews and reassessments for warfarin patients in line with local care pathways
- Patient referrals in line with local care pathways
- Patient numbers per service delivery site
- Liaison with primary care
- Liaison with secondary care
- Liaison with other health and social care professionals
- Contingency planning
- Systematic, standardised coding and reporting of adverse events
- Arrangements for disposal of sharps and clinical waste
- Clinical supervision
- Monitoring the safety and quality of service delivery at all service delivery sites
- Reporting of and learning from critical incidents
- Implementing action, where appropriate, on the results of safety and quality monitoring

3.2.2 Eligibility criteria

- Ensure that all service delivery points meet Care Quality Commission (CQC) requirements for the delivery of medical services which as a minimum should be those required for the delivery of General Medical Services.
- Undertake and document a full service risk assessment, in line with NPSA template, for every service delivery site prior to starting this service. This will need to be reviewed by the Consultant Haematologist annually thereafter and following critical incidents and key personnel changes.

- Have competent individuals, who are registered health care professionals, named as the service lead and deputy lead at each service delivery site. The service lead and deputy lead will have overall responsibility for ensuring the safe and effective delivery of anticoagulation services at the service delivery site.
- Have at least one registered health care professional who is a prescriber working at each site at all times that initiation clinics are running. This is to ensure all patients' anticoagulation therapy can be initiated and an initial prescription can be provided, providing an efficient and consistent service for all patients.
- Ensure that all staff who are involved in service delivery are clinically competent to deliver the level of service they are required to provide and have appropriate up to date records to demonstrate this. This should involve being a registered health professional and having undertaken expert anticoagulation specific training – this will have included use of Point of Care Testing (POCT) equipment and the CDSS to aid dosing and patient education.
- Maintain written records of all staff involved with the delivery of the service including training undertaken, level of responsibility and assessment of competence as part of the annual audit cycle.
- Ensure the 3+ community premises are suitable and appropriately located for easy access for the provision of the patient service specified and that all relevant Health and Safety regulations are complied with.
- Provide an appropriate waiting area, with sufficient seating, private consultation rooms with desks, chairs, lighting and heating, hand washing facilities, a telephone, and access to the CDSS and patient records.
- The provider will be expected to actively monitor a minimum caseload of 200 patients (per annum) at each service delivery site to maintain clinical safety standards and realise economies of scale.
- All warfarin patients are expected to be maintained within optimal therapeutic range for 65% of the time (excluding the first 6 weeks after initiation).
- Have service continuity plans in place to cover periods of absence for annual leave, study leave, sickness, equipment failure, epidemics and unforeseen events.
- Have adequate storage facilities for equipment and reagents.
- Have adequate indemnity insurance.
- Ensure that all staff involved in service provision has completed Enhanced Disclosure and Barring Service (DBS) checks.
- Ensure that all staff are vaccinated against Hepatitis B and have undertaken training for CPR.

3.2.3 Equipment (to be provided, maintained and insured by service provider)

The service provider will ensure that all equipment:

- Complies with current health and safety regulations
- Is properly maintained and calibrated in accordance with the manufacturer's instructions and is fit for purpose
- Complies with medical devices legislation

The service provider will be responsible for providing:

- All near-patient testing equipment including POCT machines and testing strips for use in clinic or when visiting domiciliary patients.
- All self-testing equipment including POCT machine and initial supply of testing strips (subsequent strip prescriptions will be prescribed via patient's GP).
- Consumables (including single use lancets and personal protective equipment)
- Computer and colour printers in each service delivery site.
- Quality assurance materials
- Clinical waste disposal
- Oral anticoagulation therapy (OAT) information packs (e.g. yellow pack with book)

The manufacturer should supply a service contract and warranty. It is the responsibility of the service provider to ensure this equipment is kept in good working order, is serviced regularly and in line with manufacturer's instructions. It is the service provider's responsibility to ensure that all equipment is insured and to pay for the insurance. The service provider must undertake internal and external quality assurance as appropriate.

3.2.4 Computerised Decision Support Software (CDSS)

The service provider must:

- Provide an appropriate CDSS which is compliant with the European Medical Device Directive, ISO 27001
- Use CDSS to undertake dosing
- Ensure the most up-to-date clinical version of the CDSS software is used
- Ensure that all staff using the software undertake training and are competent to do so
- Ensure all data is stored in line with NHS Information Governance requirements
- Ensure the CDSS used at all service delivery points is interoperable with each other and with GP computer systems used in practices in Islington CCG

- EMIS Web Services is being used in Islington to support integration across primary care. The provider will need to engage with the CCG in implementation of this with their clinical system.

3.2.5 Community based clinic arrangements

- The service provider will be expected to offer service delivery at multiple community locations with a minimum of 3 clinics operating in Islington. The provider will need to evidence how their delivery model will support Islington residents' to access community anticoagulation services.
- The service provider is required to provide a single point of access for booking appointments within the service using Emis Web services.
- The service provider must ensure that there is enough patient appointments available to meet local demand in Islington and must provide patients with a choice of dates and times of appointments across Monday to Friday, from 8am to 6pm.
- Each site should also offer clinic appointments until 8pm one evening each week. These extended sessions should be run on a different day for each site clinic, ensuring availability for working adults across the borough.
- Islington patients have indicated a preference for morning appointments. To meet performance indicators around waiting times and patient satisfaction, the service is expected to be able to flex their clinic times and capacity in accordance with patient demand.
- Patients should expect to be seen within 15 minutes of their appointment time, for 80% of patient appointments, and within 30 mins for 95% of patients.
- The interval between tests will vary, with an expectation that appointments will be far more frequent in the period following initiation; however warfarin patients should have their INR monitored at least every 12 weeks unless it is clinically justifiable to have a longer monitoring period.
- There will be a systematic call and recall of patients on the register which should be set up at the time of registration. This will be for all warfarin patients.
- The provider will have a system for follow-up of patients who do not attend clinic appointments.

3.2.6 Domiciliary patients

The majority of appointments will be based in the community anticoagulation clinics but the service provider must ensure that the service is also provided for patients who are housebound or unable to leave their home environment due to physical or psychological illness.

Within this service, home visits are required for patients in the following circumstances:

- Bed bound
- Leaving home is medically contra-indicated
- They are dependent on specially adapted transportation

In the case of a home or care home visit, the service provider must take all necessary equipment with them to provide the full service at this location.

3.2.7 Self Testing for Warfarin Monitoring

Service providers are required to follow current guidance from NICE and from the British Committee for Standards on Haematology (BCSH) in relation to supporting patients to self-monitor their coagulation status.

3.2.8 Prescribing at Initiation

- For those patients who are initiated on warfarin the service provider will provide the patient with their initial prescription for their medication.
- For those patients who are initiated on warfarin and the decision has been made for the patient to self-test, the provider will provide the patient with their initial prescription for their self-testing strips.
- For those patients who are initiated on warfarin however it is deemed appropriate to transfer the patient on to a NOAC, the service provider will provide the patient with their initial prescription for their NOAC and will transfer the patient back to their GP for ongoing care.
- For those patients who have a bridging plan and are seeing the community anticoagulation service for their first clinical appointment after the plan has been determined, the provider will prescribe the injectable anticoagulants in line with the bridging plan.

3.2.9 Working with Primary Care

A collaborative decision between the Community Anticoagulation Clinic and GP around initiation of anticoagulation may be required via email, or phone call.

Discussion may be required between the Community Anticoagulation Clinic and GP at the clinical review to ensure the ongoing plan is tailored for each anticoagulated patient.

GPs will remain the first point of contact for all NOAC patients.

GPs will be able to remotely access specialist opinion from the Community Anticoagulation Service when they may need clinical guidance to continue safely managing their patient.

The community anticoagulation clinic will provide training events for Primary Care on Anticoagulation therapies and Management. This will take place a minimum of annually.

3.2.10 Initiation in Secondary Care

- Patients who have been seen within secondary care, diagnosed with Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT), are likely to be initiated on an anticoagulant whilst under secondary care. They will be referred directly to the patient's GP if initiated on a NOAC, or to the community clinic if initiated on warfarin.
- Both the community service and GPs are expected to be flexible in re-routing referrals which may be misdirected as the wider system gets used to the new service provision in Islington.

3.3 Clinic Procedure

3.3.1 Decision to Initiate

- The service provider is responsible for providing expert clinical advice, via email or phone to the patient's GP.
- This consultative and collaborative assessment function will be facilitated remotely through both Consultant and GP having access to the patient's primary care record. The provider will have access to the patient record via EMIS Community (or the IDCR, to be implemented).
- This process will take place every time a new AF patient potentially requires anticoagulating.
- The Consultant will determine whether the patient is appropriate for anticoagulation therapy, and if so, whether this should be Warfarin or a NOAC. They may require further information/ discussion with the GP or patient to make this decision.
- Where it is in the best interest of the patient to have a face to face initiation assessment at the community anticoagulation service, this can be offered to the patient.

In this process the GP will:

- Will make an electronic referral to the Community Anticoagulation Service.
- Await a reply, within 7 days, from the service.
- Participate in a discussion of the case, if the Community Anticoagulation Service requires further information to make a clinical decision.
- Makes any further referrals required to be able to make the most appropriate clinical decision on behalf of the patient, e.g to a Cardiologist. The GP will then re-refer the patient to the Community Anticoagulation Service once the outcome of this review is known.
- If the clinical plan is for the patient to be initiated on a NOAC, the GP will organise an appointment with the patient, where they will counsel the patient and initiate their treatment, and provide ongoing management.

In this process the Community Anticoagulation Service:

- Will register all patients referred on the CDSS.
- Will have a consultant who is a specialist in anticoagulation review the patients referral, this is in the context of having access to the patients primary care record to make the most informed decision.
- If a discussion with the patients GP is needed to discuss an individual's referral, the clinic will contact the GP to discuss the case further. The patient or their carer can be invited to join this discussion.
- The clinic needs to provide capabilities to facilitate a tele-conference for multiple people.
- If other expert opinion is required to make the most appropriate clinical decision, the clinic needs to request this via the patient's GP
- Where it is in the best interest of the patient to have a face to face initiation assessment with the community anticoagulation service, this can be offered to the patient.
- The clinic will respond to the GP with either a treatment plan, or request to discuss further within 7 days.
- If the clinical plan is for the patient to be initiated on warfarin, the community anticoagulation service will organise an appointment with the patient within 2 weeks of the initial referral, where they will counsel the patient and initiate their treatment.

It is the responsibility of the Community Anticoagulation Service to determine the finer details of this process, however it is expected that use of all available technologies should be exploited to maximize efficiency for all parties.

3.3.2 Initiation, Monitoring, Dosing

The service provider is responsible for contacting patients to book initial appointments and for populating the CDSS with appropriate clinical information in relation to the use of warfarin for individual patients.

3.3.2.1 Initiation – Monitoring plan in clinic

- At the start of therapy, the service will agree a monitoring plan with the patient or carer including the preferred location of community anticoagulation clinic, likely frequency of visits, and most convenient appointment days/times.
- Considerations should be made regarding the mobility of the patient and travelling distance.

3.3.2.2 Initiation – Dispensing plan in clinic

- At the start of therapy, determine and document on the CDSS arrangements for the future dispensing and administration of warfarin to the patient.
- If the patient currently receives their other medicines in a monitored dosage system (MDS), which is not recommended by NPSA for warfarin, liaise with the patient's community pharmacist to agree appropriate arrangements for the dispensing of warfarin.

3.3.2.3 Initiation – Initial Prescription in clinic

- For those patients who are initiated on warfarin the service provider will need to be able to provide the patient with their initial prescription for their medication at their initiation appointment. This will also need to be provided for those patients who have a face to face initiation appointment, and are prescribed a NOAC.
- This will provide a seamless patient experience ensuring timely access to their new prescription and whilst reducing unnecessary GP appointments.
- This will require the clinic to have at least one trained prescriber amongst their staff at each clinic site, the prescriber needs to be present at all initiation and review clinics. This is to provide all new warfarin prescriptions, but also facilitate transfer to NOACs in review clinics, and prescription of injectable anticoagulants when requested in bridging plans.
- As a minimum, each clinic site will run one initiation clinic every week. These sessions will be run on a different day for each site, ensuring access for working adults across the borough.
- Any actions taken regarding dosage and prescribing should be communicated to the patients GP, securely and electronically, within 48 hours.
- Subsequent prescriptions of warfarin will be prescribed via the patient's GP, based on dosage information which will be held in the patient record, or the patient's yellow book.
- The new provider is responsible for providing and paying for the prescription pads in their clinics, to enable efficient prescribing when patients are initiated on clinic on anticoagulation medication.

3.3.2.4 Dosing – Clinic

- All patients must be seen in person, either at the community warfarin clinic or at home or Care Home, by a registered healthcare professional, who has demonstrated the relevant competencies, to determine their appropriate dosage.
- At every clinic appointment, the service provider should counsel the patient on any concerns they have, and review whether there are any relevant changes in the patients' medical or social status.
- After performing the INR test using POCT, the results should be entered into the CDSS (this will automatically interface with the patient's primary care record).
- The suggestions given by the CDSS for dosing and recall dates should be followed unless clinically inappropriate, for example patient known to be non-adherent to therapy or poor anticoagulation control.
- Current dosage information and any reasons for changes should be recorded in the CDSS and in the patient's yellow book.
- The patient should be given verbal and written instruction regarding dosage; date of next appointment and relevant treatment information.
- The patient's GP should be informed by telephone within 1 working day of the patient's appointment if there are any untoward events/symptoms or any dose changes required. This must be followed up by email and letter within 2 working days requesting confirmation of receipt of the email.

3.3.2.5 Dosing - Self-Testing Patients

For patients who self-test, they must converse with a registered healthcare professional, who has demonstrated the relevant competencies, by email or telephone to determine their appropriate dosage.

The service provider will be expected to:

- Train individual patients to self-test
- Undertake an assessment of patients' competency to self-test and notify their GP of the outcome
- Provide all equipment and disposables for patients that are competent to self-test
- Check equipment for self-testing every 6 months using reliable quality control procedures
- Review patient's ability to self-test on an ongoing basis and provide refresher training
- Provide advice on dosing and on bridging and cessation of warfarin where required

3.3.2.6 Expert Consultant Support

- If in complex cases expert guidance is required, the anticoagulation practitioners will be able to request a case review from the Consultant with a 7 day response time. This review may be performed independently by the Consultant or could be done via telephone or face to face with the anticoagulation practitioners as appropriate.
- In clinical emergencies, an ambulance should be called to gain rapid access to secondary care assessment.

3.3.3 Clinic Reviews

3.3.3.1 Warfarin Review/ Discontinuation

- Routine clinical review of anticoagulants should be undertaken at a frequency appropriate to the indication for warfarin, and the clinical circumstances of the individual patient. As a minimum this should be annually, delivered by a competent, registered health care professional within the service.
- Clinical review and reassessment of warfarin should take into account as a minimum: cognitive function, medicines adherence, illness, interacting medicines, lifestyle factor that could affect INR, renal function and adverse events relating to warfarin.
- Liaison with the patients GP may be required to fully complete the review in complex cases.
- It is the responsibility of the Community Anticoagulation Service to call warfarin patients for their review.
- All reviews should be fully documented and the patient's GP informed by email and letter within 1 week, providing that warfarin dose is not being changed, or discontinued.
- If discontinuing warfarin, the date of cessation and reason should be documented and the patient's GP informed by email and letter on the same working day, requesting confirmation of receipt of the email. Advice should be given to the GP to remove warfarin from the patient's repeat prescribing records.
- The service provider will inform the community pharmacist that fills the patient's MDS of dosage adjustments or warfarin cessation on the same working day by telephone (or next working day if out of hours for the community pharmacy), and then follow up by email and letter within 1 working day, requesting confirmation of receipt of the communications.

3.3.3.2 NOAC Reviews/ Discontinuation

- Medication reviews of patients on NOACs will be carried out by the patient's GP.
- If the GP has queries regarding how best to manage the patient, they can contact the community anticoagulation service for advice from the consultant.

3.4 Domiciliary Procedure

3.4.1 Initiation, Monitoring, Dosing

- The decision to refer and initiate will be as described in 3.3.1. Face to face assessment appointments will be organized where in the patients' best interests.
- In the case of a home or care home visit, the service provider must take all necessary equipment with them to provide the full service at this location.
- At every domiciliary appointment, the service provider should counsel the patient on any concerns they have, and review whether there are any relevant changes in the patients' medical or social status.
- After performing the INR test using POCT, the results should be entered into the CDSS (this will automatically interface with the patient's primary care record).
- The suggestions given by the CDSS for dosing and recall dates should be followed unless clinically inappropriate, for example patient known to be non-adherent to therapy or poor anticoagulation control.
- Current dosage information and any reasons for changes should be recorded in the CDSS and in the patient's yellow book.
- The patient should be given verbal and written instruction regarding dosage; date of next appointment and relevant treatment information.

- The patient's GP should be informed by telephone within 1 working day of the patient's appointment if there are any untoward events/symptoms or any dose changes required. This must be followed up by email and letter within 2 working days requesting confirmation of receipt of the email.
- If the patient currently receives their other medicines in a monitored dosage system (MDS), which is not recommended by NPSA for warfarin, liaise with the patient's community pharmacist to agree appropriate arrangements for the dispensing of warfarin.

3.4.2 New Medical Service Support for Housebound NOAC Patients

- Patients on NOACs, under the care of their GP's, will be able to access support from the New Medicines Scheme provided by pharmacies. This service is not available on a domiciliary basis therefore; the community anticoagulation service will be commissioned to provide the equivalent to domiciliary patients on NOACs.
- This will involve the patient receiving 3 face to face or telephone consultations over the period of the first month following initiation.
- At the point that the decision to initiate is made, the community anticoagulation service will contact the patient to make their first appointment to provide support to the patient.
- Further details of scope of this service can be found here:
<http://www.nhs.uk/NHSEngland/AboutNHSServices/pharmacists/Pages/medicine-service-qa.aspx>

3.4.3 Medication Reviews

- Routine clinical review of anticoagulants should be undertaken at a frequency appropriate to the indication for warfarin and NOACs, and the clinical circumstances of the individual patient. As a minimum this will be annually, delivered by a competent, registered health care professional within the service.
- All reviews should be fully documented and the patient's GP informed by email and letter within 1 week, providing that warfarin dose is not being changed or discontinued, in which case this should be within 1 day.

3.4.3.1 Warfarin Reviews

- It is the responsibility of the Community Anticoagulation Service to organise formal review appointments for warfarin patients.
- Liaison with the patients GP may be required to fully complete the review in complex cases.

3.4.3.2 NOAC Reviews

- Medication reviews of patients on NOACs will be carried out by the patient's GP.
- If the GP has queries regarding how best to manage the patient, they can contact the community anticoagulation service for advice from the consultant.

3.6 Adverse Incidents

- Adverse events associated with all anticoagulants should be documented on the CDSS and communicated to the patient's GP within 1 working day.
- Adverse events associated with all anticoagulants should be reported to NHS England via the National Reporting and Learning System (NRLS).
- The community clinic must have facilities available to be able to reverse warfarin.
- When dealing with high INRs, the patient should be assessed for signs of bleeding. Where the patient is bleeding or there are bleeding concerns, the patient must be urgently referred to secondary care via A&E. If the patient does not have their own transport, transfer via 999 should be considered.
- POCT equipment is not accurate when INR is elevated. The service provider is required to develop and implement a process for patient management.

3.7 Quality & Safety

- Person centered approach
- Service risk assessment
- Staff training, skills and competency assessments
- Clinical supervision
- Patient numbers per service delivery site
- Contingency planning
- Disposal of clinical waste/ sharps
- Maintenance/ calibration of equipment
- Storage of consumables and drugs

- Monitoring the safety and quality of service delivery at all service delivery sites
- Recording and reporting of adverse events associated with anticoagulants
- Reporting of, learning from, and acting on critical incidents

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

The service must comply with the standards produced by the following organisations (where applicable):

- NICE Clinical Guideline 180 on The Management of Atrial Fibrillation (2014)
- NICE Clinical Guideline 144 on Venous thromboembolic diseases (2012)
- NICE Quality Standard 29 on Venous thromboembolic diseases (2013)
- NICE Quality Standard 15 on Patient experience in adult NHS services (2012)
- NICE Diagnostics Guidance 14 Atrial fibrillation & heart valve disease: self-monitoring coagulation status point-of-care coagulometers (2014)
- NHS England, 2014. Patient safety alert to improve reporting and learning of medication and medical devices incidents
- British Committee for Standards in Haematology (1998, updated 2011)
- Guidelines on oral anticoagulation: third edition. British Journal of Haematology, 101, 374-387.
- British Committee for Standards in Haematology (2014) Guidance on Patients self-testing and self-management of oral anticoagulation with vitamin K antagonists.
- National Patient Safety Agency (2007). Patient Safety Alert 18 – Actions that can make anticoagulant therapy safer. Available online at: <http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/anticoagulant/>
- Care Quality Commission registration requirements.
- Medicines and Healthcare Products Regulatory Agency medicines safety information <http://www.mhra.gov.uk/home/groups/plp/documents/websiteresources/con065506.pdf>

All standards of communication should adhere to Caldicott and Data Protection guidelines and NHS Information Governance requirements. All patient identifiable information communicated by email must be sent by secure NHS mail.

In addition, service providers must comply with all relevant legislation including, but not limited to, Health and Safety.

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

The service must comply with guidance produced by the following organisations (where applicable):

Rules of Professional Conduct <http://www.gmc-uk.org/guidance/index.asp>
BCSH guidance

4.3 Standard Operating Procedures (SOPs)

SOPs for all elements of this service must be in place prior to service commencement and must be available for all authorised personnel to refer to when undertaking service delivery. These should be agreed and signed by the lead clinician and reviewed at least annually or in light of further national or local recommendations. In addition all SOPs should be reviewed if a critical incident occurs.

SOPs that must be in place should cover:

- Service risk assessment
- Ordering, storage, maintenance and quality assurance of equipment and supplies
- Testing procedure - Finger-prick (capillary) sampling testing.
- Guidance for use of CDSS including standardised settings and record-keeping
- Domiciliary service provision and lone worker policy
- Supporting patients self-testing INR
- Communication between the service provider and health and social care professionals
- Initiating, maintaining, bridging and cessation of warfarin therapy
- Co-prescribing and drug-drug interactions and drug-food interactions with warfarin
- Dealing with high and low INRs and abnormal results
- Documenting and coding adverse events with warfarin (internally within the service and recommendations for standardized coding for GPs and hospitals)
- Patient counselling and education
- Recall of patients who fail to attend an appointment
- Assessment of risk versus benefits of warfarin for individual patients
- Patients undergoing minor surgery or dental treatment
- Clinical supervision and assessment of staff competences

- Safety and quality review of service
Reporting of and learning from critical incidents in relation to service delivery

4.4 Information management and information sharing

- The Provider and Commissioner shall agree an Information Sharing Agreement and protocols for sharing information with the Commissioner, and GPs, as per the service model outlined in section 3.2.
- The Provider is responsible for developing and managing the information management systems to: receive referrals from all routes, refer onwards; inform GPs in a timely manner of service user referrals and outcomes; provide data to the Commissioner for monitoring and evaluation of the Service or of other adult lifestyle services commissioned by the Commissioner. The service established in Islington is via Emis Web services or Emis Community and there will be a small cost to add the service.
- The Provider should work collaboratively with providers to ensure that information management and sharing systems are as compatible with the information systems of all partners as possible. For example:
 - The Provider should enable GPs to make straightforward referrals
 - The Provider will share data with GPs using EMIS Web services.
 - Onward referrals should include all relevant patient data within the initial referral.
 - The Provider will minimise the need for manual data entry by Other Providers when reporting service user progress and outcomes to the Provider.
- The Provider will share an anonymised dataset with the Commissioner on request, in addition to monthly and quarterly monitoring figures. ICCG will retain ownership of all data and information collected from the Service by the provider. Any data, information or research pertaining to the Service may not be transferred, disseminated or used by the provider without explicit permission from ICCG.
- The Provider will have a Standard Operating Procedure to respond to requests from service users to access to their own records, which will be in line with in line with the Department of Health's information governance and data protection requirements.
- The Service Provider will transmit information in accordance with NHS Connecting for Health data transmission guidelines particularly with respect to the need for the deployment of privacy enhancing technologies such as data encryption. The service provider will ensure N3 connectivity is used when transferring data. The service provider must have access to the internet along with a telephone and fax machine.
- The Provider must adhere to the recommendations of the Information Governance Review (2013), including the updated Caldicott Principles. All systems should be in line with the Department of Health's information governance and data protection requirements. The Provider should be aware of the Department of Health's Information Strategy (2012), including the aim for the NHS Number to become universally used as a patient identifier across the health and social care sector
- The service provide will use Islington Emis web community services infrastructure to manage the service appointments, referrals, monitoring, reporting, data quality and sharing information with GP's.

4.5 Staff training

The service clinical lead and deputy at each delivery site should have responsibility for ensuring that all staff members who support the service at the site have received training and have the appropriate competences to deliver this service in line with the NPSA framework. This includes training in the use of POCT equipment and the CDSS.

Training resources include:

- The NPSA National Reporting and Learning Service (NRLS) commissioned e-learning modules on initiating and maintaining warfarin:
- Starting patients on anticoagulants (BMJ learning website - free registration required)
- Maintaining patients on anticoagulants (BMJ learning website - free registration required)

Face to face courses are available from the following providers:

- National Centre for Anticoagulation Training (Birmingham):
<http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PCCS/anticoagulation/index.aspx>
- University of Sunderland:
http://www.sunderland.ac.uk/courses/appliedsciences/cpd/cid953anticoagulation/#tab_overview

- University of Hertfordshire (for pharmacists, specialist nurses and medical laboratory scientific officers)
<http://www.herts.ac.uk/courses/anticoagulation-for-healthcare-professionals>

A minimum annual review of training and competence should be undertaken by the clinical lead or deputy and documented on the CDSS for all staff at the service delivery site. Any gaps in competence should be addressed immediately and the staff member should not be involved in service provision until deemed competent by the clinical leads.

All health professionals working within the service should be able to demonstrate regular, relevant continuing professional development (CPD) to ensure that they meet service requirements in line with NPSA standards for workforce competence.

4.6 Equal Opportunities

Service providers must demonstrate how they meet equal opportunity requirements.

Service providers must:

- Be committed to equal opportunities and must not discriminate in performance of the service towards any service user
- Be able to provide chaperones at the patient's request
- Be able to provide premises, facilities and treatment rooms that are compliant with disability legislation
- Be able to provide access to an interpreter if necessary
- Be able to provide a range of clinic appointment days and times
- Accept all referrals, regardless of gender, culture, disability or domiciliary status.

4.7 Referrals

The service provider is required to develop and maintain a referral template which can be completed, sent and received electronically. For referrals from General Practice, it is expected that an auto-populating EMIS template will be designed and implemented.

The service provider must distribute the referral template and instructions for use of it to all GP practices in Islington and to appropriate hospitals.

The patient's GP or referring hospital should complete the referral template in full and send it to the service provider by electronic communication.

When receiving referrals for patients already on warfarin, the service provider must acknowledge receipt and acceptance of the referral within 1 working day. Until written acceptance of a patient has been received from the service provider, patients remain the responsibility of the referring service.

The referring GP or hospital should:

Inform the patient about transfer to the Community Anticoagulation Service.

Make the referral to the Community Anticoagulation Service and advise them of the date that the next INR measurement is due.

Cancel further appointments and any transport booked once the patient has been accepted by the service provider. Patients with non-valvular AF must be seen by the service within 2 weeks from date of referral. Patients with other indications for warfarin should be seen sooner, as clinical circumstances dictate.

5. Applicable quality requirements and CQUIN goals

The provider will be required to present the commissioner, all data to evidence achievement of the service Key Performance Indicators (KPIs) to the specification and schedule detailed in Appendix 1.

The provider will also be required to submit monthly reports to the commissioner detailing the following activity related metrics:

- Number of referrals received
- Outcome of all referrals
 - Options: Warfarin/ NOAC/ Further information required / Discharged – patient choice/ Discharged – clinically inappropriate/ Discharged – patient moved out of area. Other options to be agreed.
- Community Clinic- clinic based caseload number & type of monitoring
- Community Clinic- housebound caseload number & type of monitoring
- Numbers of patients discharged from warfarin monitoring service
- Reason for those discharged from warfarin monitoring service – Patient moved on to NOAC/ Anticoagulation no longer clinically required/ Patient choice/ Patient moved away from the area. Other options to be agreed.
- Numbers of patient referrals discussed with referring GPs (by email or telephone)
- Numbers of patients discussed with GPs (by email or telephone) to support their NOAC treatment.

It is expected that this be provided in form of a dashboard, or similar, utilising the clinical decision software and other information technology where possible to aid the process.

6. Provider Premises

The Provider's Premises are located at:

Multiple (minimum of 3) community based sites.

The new provider is encouraged to explore the potential of offering services from the community sites currently being used to provide anticoagulation services. This will be dependent on local negotiation, where capacity allows, and with agreement from the commissioner (Islington CCG).

Any premises to which service users may require access for face-to-face support must have access arrangements which are convenient for all users, including wheelchair access.

The Provider must comply with any obligations it has under the Disability Discrimination Act 2005 and Health and Safety at Work Act 1974 (and legislation under that Act).

All premises should have N3 connectivity.

Appendix 1 - Local Quality Requirements – Key Performance Indicators (KPIs)

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Monthly or annual application of consequence	Applicable Service Specification
<p>1. Evidence of ongoing feedback gained from all patients seen in the service. The mechanism of which should be devised to utilise technology and produce electronic reports.</p> <p>The questions are to be agreed with the commissioner, however are likely to include:</p> <ul style="list-style-type: none"> • Friends and Family Test • Satisfaction around waiting times in clinic • Satisfaction of patients feeling they are treated with consideration and respect by clinic staff 	<p>80% of all responding patients rate the top 2 options on the Likert Scales used for all questions.</p> <p>E.g</p> <ul style="list-style-type: none"> • Very likely/satisfied • Extremely likely/satisfied 	<p>A report showing results & actions taken, sent quarterly to commissioners.</p>	<p>Financial</p> <p>(***5% total contract value, measured quarterly)</p>	<p>Escalating process:</p> <ul style="list-style-type: none"> • Joint meeting between provider & commissioner. (If not deemed excusable, action plan developed) • Financial Penalty (***) • Contract Breach 	<p>3.2.2</p>
<p>2. All patients on vitamin K antagonists will be maintained within target range (as defined in best practice guidelines) for 65% of the time.</p>	<p>65%</p>	<p>EMIS/CDSS report</p>	<p>Financial</p> <p>(***5% total contract value, measured quarterly)</p>	<p>Automatic 2% retention per month when achievement not made across the delivery sites.</p> <p>Escalating process:</p> <ul style="list-style-type: none"> • Joint meeting between provider & commissioner. (If not deemed excusable, action plan developed) • Financial Penalty (***) • Contract Breach 	<p>3.2.2</p>

3. All patients with Atrial Fibrillation referred to the community anticoagulation clinic will have a referral to treatment time of no more than two weeks.	90%	EMIS/CDSS report/ Service records - to be verified by impartial clinician organized by the commissioner.	Financial (***5% total contract value, measured quarterly)	Escalating process: <ul style="list-style-type: none"> • Joint meeting between provider & commissioner. (If not deemed excusable, action plan developed) • Financial Penalty (***) • Contract Breach 	3.3.1
4. Evidence of minimum quarterly review of information about quality and safety of INR control at all service delivery sites and evidence of action taken if indicators for a service are below expected standards.	100%	Service Records – to be verified by impartial clinician organized by the commissioner.	Financial (***5% total contract value, measured quarterly)	Escalating process: <ul style="list-style-type: none"> • Joint meeting between provider & commissioner. (If not deemed excusable, action plan developed) • Financial Penalty (***) • Contract Breach 	3.1