Service Specification for Integrated Community Anticoagulation Service

Service Specification No.	TBC
Service	Integrated Community Anticoagulation Service
Commissioner Lead	Croydon Clinical Commissioning Group (CCG)
Provider Lead	TBC
Period	1 October 2018 – 30 September 2023
Date of Review	TBC between the Commissioner and Provider

1. Population Needs

Anticoagulants are a group of medicines used to prevent blood clots. The purpose of these drugs is to mitigate the occurrence of a more severe condition such as strokes and heart attacks. These drugs are prescribed to those patients who are at risk of developing blood clots and could in turn block a vessel which could reduce the flow of blood to part of the body.

There are a number of conditions where blood clots are the cause these include:

- Stroke/Transient Ischaemic Attacks (TIAs)
- Deep Vein Thrombosis/Pulmonary Embolism
- Atrial Fibrillation

1.1 National/local context and evidence base

1.1.1 Stroke/ Transient Ischaemic Attacks (TIAs)

NICE Clinical Guidance [CG180] 2014 states "Stroke is a preventable and treatable disease. Over the past two decades a growing body of evidence has overturned the traditional perception that stroke is simply a consequence of aging that inevitably results in death or severe disability. Evidence is accumulating for more effective primary and secondary prevention strategies, better recognition of people at highest risk, and interventions that are effective soon after the onset of symptoms."

Effective management with the use of Anticoagulants has the ability to reduce the probability of stroke and TIAs in patients.

1.1.2 Deep Vein Thrombosis/ Pulmonary Embolism

NICE Clinical Guidance [CG180] 2014 states "Venous thromboembolism (VTE) is a condition in which a blood clot (a thrombus) forms in a vein, most commonly in the deep veins of the legs or pelvis. This is known as deep vein thrombosis, or DVT. The thrombus can dislodge and travel in the blood, particularly to the pulmonary arteries. This is known as pulmonary embolism, or PE. The term VTE includes both DVT and PE."

1.1.3 Atrial Fibrillation

NICE Clinical Guidance [CG180] 2014 states "Atrial fibrillation is the most common sustained cardiac arrhythmia, and estimates suggest its prevalence is increasing. If left untreated atrial fibrillation is a significant risk factor for stroke and other morbidities. Men are more commonly affected than women and the prevalence increases with age."

Anticoagulation to reduce the risk of stroke is an essential part of AF management but the Department of Health says that patients are not always appropriately anticoagulated. It suggests that 7,000 strokes could be avoided and 2,100 lives saved each year in England with appropriate AF management. (From the NICE Implementation Collaborative Consensus (2014) to support local implementation of NICE guidance on anticoagulation).

The diagnosed prevalence of AF in Croydon is 1.03% and the estimated prevalence is 1.92% (Public Health England, 2017). In 2017 Croydon GP Profiles indicate the prevalence of patients with Stroke/Transient Ischaemic Attacks is 1.2% which is slightly higher that London (1.1%) and which is significantly lower than England (1.7%). Croydon CCG is committed to commissioning a good quality and easily accessible anticoagulation service that continues to enhance and protect the quality of life for people at risk of stroke and other clotting-related conditions.

Croydon University Hospital is the local acute anticoagulation service which manages complex/unstable patients.

Since 2015, a community anticoagulation service has been in operation, seeing stable Warfarin patients. The anticoagulation service will continue to provide care for those patients on Warfarin but will also provide a high quality, community integrated anticoagulation service supported by consultants and/or MDTs and include initiation and monitoring of Direct Oral Anticoagulants (DOACs).

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

Service Outcomes

The expected outcomes that relate to access and performance are:

- Swifter triage and access to care for a range of community based service and a domiciliary

service across the borough.

- Improved access to prompt expertise in the assessment and treatment of people with anticoagulation-amenable conditions
- Shift of appropriate anticoagulant outpatient activity from hospital into community services and the use of integrated pathways when appropriate.
- Optimised management of patients with anticoagulation-amenable conditions in primary care and the community and avoidance of inappropriate hospital admissions.
- Improved access for patients by delivering services closer to home and by increasing the number of investigations carried out during a single appointment, therefore reducing the need for multiple visits to a variety of locations
- Increased patient and carer satisfaction with their access and quality of care
- Increased understanding of public, patients and carers regarding lifestyle changes which can improve their health and wellbeing
- Improved communication between specialist clinicians and GPs and IT integration
- Improved primary care education of anticoagulation-amenable conditions through effective clinical leadership.
- Optimised use of resources to ensure value for money
- Improved engagement with voluntary / patient groups (where applicable to develop and implement joint initiatives to enhance local services).

Clinical Outcomes:

- Improved clinical outcomes (such as time in range) supported by at least annual review of all patients including the review of the indication and appropriateness of continued anticoagulation.
- Improved safety by implementation of a robust approach to clinical protocols and clinical risk and to command local clinician and patient confidence
- Improved safety through robust information management and communication across the anticoagulation pathway
- Improved partnership working alongside local health and social care professionals to improve co-ordination of care for patients taking anticoagulant therapies
- Improved integration and communication through the use of interoperable IT systems with all relevant stakeholders to achieve good clinical outcomes and protect patients from avoidable harm.

Patient Outcomes:

The expected outcomes that relate to the quality of patient care are:

- Improved quality of care within primary and community settings
- Reduced waiting times
- Improved patient access to assessment and care closer to home in their local community
- Provision of systems and processes for supporting personalised care planning/self-management and case management in relation to anticoagulation for patients within the service
- Improved self-management through on-going education and offering self-monitoring of warfarin for appropriate patients
- Improved quality of house-bound and disabled patients and care home residents to ensure the service is accessible for all eligible people
- Increased patients' satisfaction with anticoagulant services

It is important to demonstrate an improvement of health outcome of patients and experience within the new service.

Equality and Social Value

To achieve equality, sustainability and social value the Integrated Community Anticoagulan Service will need to ensure that it:

- Provides access to the right care in the right place by the right person;
- Establishes standards for quality of care within an effective and integrated service or network;
- Improves patient care and outcomes from the anticoagulant service;
- Maximises prevention, either as part of the Service or another closely related service;
- Reduces supply induced demand, by ensuring that need has been demonstrated
- Uses best available evidence of effectiveness in deciding details of service design and local population need.

3. Scope

3.1 Aims and objectives of the service

The overall aims of this service are to improve patient access to safe and effective anticoagulation treatment through collaboration between the patients GP and the appropriate clinicians within the Integrated Community Anticoagulation service. Monitoring will be provided in a convenient, efficient service with short waiting times. Dependant on the drug prescribed this may take place with the patients GP, or in the Integrated Community Anticoagulation service.

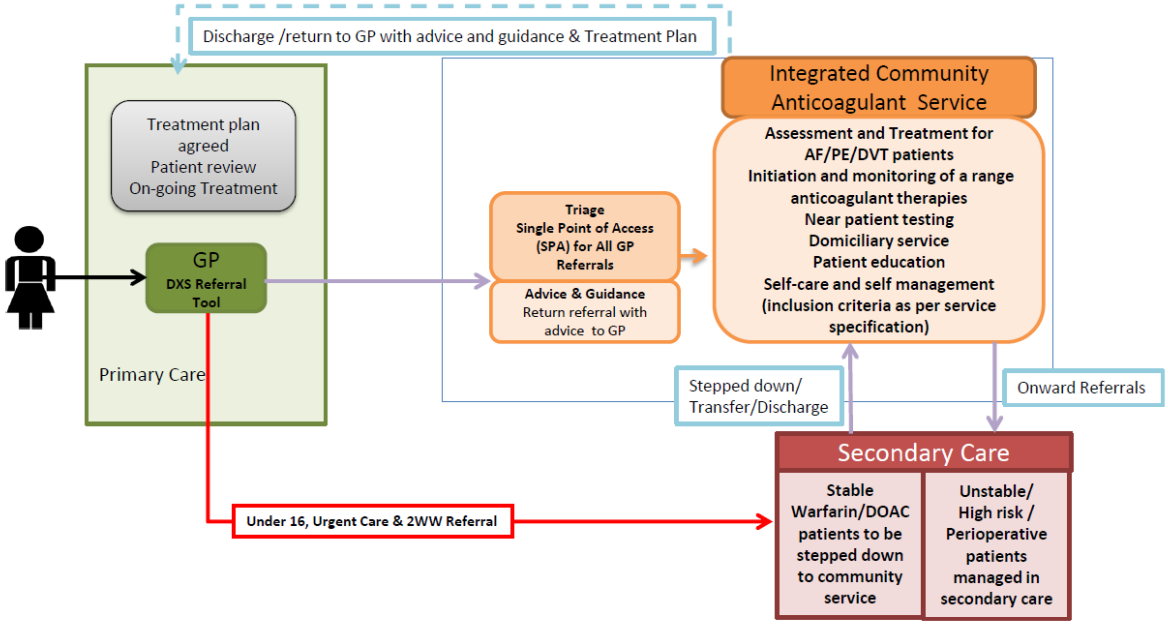
The Integrated Community Anticoagulation service will deliver a service consistent with the following objectives:

- To provide an evidenced based, high quality, Integrated Community Anticoagulation service which provides a one-stop approach to treatment
- To work with partner organisations to ensure a seamless, integrated anticoagulation pathway and to maximise use of specific resources for the benefit of patients requiring anticoagulation.
- Provide the appropriate clinical expertise and governance of the service by a clinician who is a specialist in anticoagulation (NB. all patients must have access to consultant support when clinically necessary, and the Provider must be able to provide this directly).
- To provide specialist clinical discussion and decisions regarding anticoagulation initiation for all new patients (the patient and/or their GP will be involved in this decision)
- A range of anticoagulation therapies will be made available including warfarin and Direct Oral Anticoagulants (DOACs).
- On-going monitoring of patients on Warfarin will be undertaken using the most efficient method. It is expected this will be done via point of care testing (POCT), unless it can be clinically justified otherwise (i.e. a viable alternative that is clinically effective and safe)
- Face to face communication must occur between the patient and the health care professional responsible for deciding doses on their test result and any action required as a result unless not feasible e.g. housebound patients. Where face to face communication is not feasible, the provider must have a robust standard operation procedure in place outlining alternative method to be used and clear lines of accountability.
- Monitoring will be done using Clinical Decision Support Software (CDSS) at all service delivery points. CDSS used at all service delivery points must be interoperable with each other (if different CDSS systems are used) and with GP computer systems used in practices in Croydon e.g. EMIS & Vision

- To offer and support appropriate patients to self-monitor their Warfarin where they are both physically and cognitively able to do so effectively in a method that is in line with best practice guidelines (e.g. BHS and NICE)
- The service will be expected to foster continued quality improvement and to demonstrate a commitment to on-going review of safety and quality monitoring information relating to all aspects of service provision that is in line with national and local quality standards pertaining to anticoagulation e.g. NICE, NPSA etc.
- The service will ensure robust systems for reporting and acting on 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
- To ensure that healthcare professionals who initiate, monitor and / or review anticoagulation therapy have the training, skills and competencies to meet the requirements of their role
- 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
- Health and social care professionals (specifically general practitioners, community pharmacists, community nurses, dentists, care home staff and hospital teams) are supported to provide care for patients prescribed anticoagulation in a seamless and integrated way through robust communication systems (including advice and support where INR levels may be affected in urgent situations)
- Information flow between the Provider and health and social care professionals is secure and electronic. It is the responsibility of the Provider to ensure that their clinical systems are interoperable with GP computer systems used in practices in Croydon CCG e.g. EMIS web, Vision.
- Supports GP practices in case finding and joint initiatives to support the improvement of local services.
- Educate patients in understanding their treatment, in terms of their condition requiring warfarin, target range for INR, the effects of over or under anticoagulation, diet, lifestyle and drug interactions
- To have robust systems in place to appropriately manage patients who are over anticoagulated
- To review the need for continuation of therapy at each visit and ensure that the patients' needs can most effectively be met or that onward referrals are made in a timely way where clinically appropriate

3.2 Service description and pathway

The Provider will be clinically responsible for all patients under their care for anticoagulation initiation and monitoring.



3.2.1 Service Model

The CCG intends to commission an Integrated Community Anticoagulation service. A key objective of the service will be to clearly demonstrate a movement in the existing clinical threshold for accessing community services for assessment, diagnosis and treatment, with a view to moving the majority of, or all of the exiting anticoagulation service provision into a community setting as outlined below:

Initiation of Anticoagulation Therapy
Initiation and monitoring of anticoagulation should be in line with the recommendations in Sections 7 and 8 of London Clinical Network's Excellence in Anticoagulant Care (2016).

i. Non-complex anticoagulation care for patients with a range of conditions and comorbidities:
- Initiation, monitoring and cessation of Warfarin
- Initiation and cessation of Low Molecular Weight Heparin LWMH (in some cases this will require coordinated-management with other specialists involve with the patient e.g. obstetrician, oncologist etc.)
- Initiation of Direct Oral Anticoagulants (DOACs)

ii. Complex anticoagulation:
- Initiation, monitoring and cessation of Warfarin for complex patients
- Initiation and cessation of LWMH for complex patients
- Initiation of Direct Oral Anticoagulants/Novel Oral Anticoagulants (DOACs/NOACs) for complex patients
- Bridging procedures
- Review and counselling of patients unstable on warfarin and consideration of alternative treatment
- Administration of anticoagulation reversal agents (e.g. vitamin k administration) where clinically appropriate

Complex care delivered in a community setting may require consultant or medical review for patients with a range of conditions or complex comorbidities, or for people who require frequent specialist input/review. It is anticipated that specialist consultant expertise will be required for the management of complex patients which could be provided by the service directly or in collaboration with another Provider.

People who fit the profile for complex care may include:

- Known hereditary or acquired bleeding disorder or thrombophilia
- Clinically significant bleeding
- Within 72 hours of major surgery with risk of severe bleeding
- Within 48 hours postpartum
- Pregnancy
- Drugs where interactions may lead to significantly increased risk of bleeding
- Have had a DVT/PE in the previous month
- Congenital heart disease
- Liver failure
- Kidney diseases
- Cognitive disorders
- Documented evidence of haemorrhage in the previous 6 months including
- GI and stroke
- Antiphospholipid syndrome
- On Chemotherapy for cancer
- Substance misuse
- Polypharmacy

iii. Domiciliary care for both complex and non-complex patients on a range of anticoagulation medications

iv. Self-monitoring support for appropriate patients on Warfarin

v. Education for patients and GP's to improve outcomes across the whole anticoagulation pathway

The Provider will need to ensure that the appropriate workforce and skill mix is available to deliver the service safely. Consultant haematologist is required to oversee and supervise clinical management of non-complex and complex patients where appropriate by the service. In addition the service will need to ensure a robust clinical accountability and governance structure is in place to provide clear assurance of patient clinical care, quality, safety and risk across the anticoagulation pathway.

3.3 Service Delivery

3.3.1 Triage

All referrals should be directed electronically to the single point of access (SPA), except red flags and 2 weeks wait cancer rule (2WW) where referrals should be made directly to the acute provider. GPs will send referrals for any anticoagulant condition (not included in the Exclusions or Red Flags) to the SPA via the agreed pathways.

Admin triage: All in-scope referrals will be made to a SPA. The Provider will be responsible for

ensuring an efficient and effective administrative process. The referral will be acknowledged and will undergo a paper admin triage by the admin team to ensure the minimum data set has been fully completed. Any incomplete, inappropriate or poor quality referrals will be returned to the referrer.

Local clinical triage: The referral will then undergo clinical triage to allow the referral to be directed into the appropriate service in accordance with agreed care pathways. Clinical triage of referrals must be a local function for Croydon CCG and must be led by local clinicians - Lead Consultant/Pharmacist for the Integrated Community Anticoagulant service and be carried out by appropriately trained and qualified member, or members, of the MDT. It should include assessment and/or advice, as appropriate to the referral.

Triage turnaround time is within **1 working day** from referral receipt for each triage point.

The outcomes of the Local Clinical Triage will include, as appropriate:

- Prioritising review and accepting urgent referrals, offering patients an appointment within timelines specified by the contract;
- Appointment arranged
- Ordering diagnostic or blood tests for the patient, under the direction of the appropriate clinician, before the patient attendance at the service to see a specialist where appropriate;
- Undertake a telephone assessment/consultation where clinically appropriate;
- Onward referral of patients that are clinically appropriate straight to secondary care
- Directing referrals to a range of other primary care services or provide signposting to other services; and
- Directing referral back to the Patient's GP with advice for further work up and management where referral information is inadequate and appropriate clinical assessment cannot be made.
- Other services – Community Cardiology and Respiratory Service.

Booking is to take place following local clinical triage. Once triage has taken place there should be no delay in contacting the patient. Patients will be given adequate notice and a choice of appointment.

- Waiting time following referral receipt to first appointment attended by patient must not exceed 10 working days
- Waiting time following first appointment to follow-up appointment attended by patient must not exceed 10 working days for urgent appointment and 20 working days for non-urgent appointment

GP advice line (email or telephone, see section 3.3.8 of core specification) responses to be offered within 2 working days for routine queries and within 4 hours for urgent queries;

A choice of appointment days and times will be offered and patients will have the option of booking appointments outside of the 20 working days period for eventualities determined by patient's circumstances (a record must be kept of reasoning for patients whom are not seen within 10 and 15 working days).

Local clinical triage to directly book into:

- Community anticoagulant services (detailed above),
- Secondary Care Outpatients,
- Diagnostic/blood tests
- Other services – Community Cardiology and Respiratory Service; community Pharmacists.

3.3.2 Population covered

The service should be available to the following:

- All patients aged 18 or older registered with a Croydon CCG member practice
- All patients aged 18 or older temporarily registered with a Croydon CCG member practice

3.3.3 Accessibility/Acceptability

The service will have equitable access, and ensure that patients are treated with dignity and respect.

- The Provider must work with commissioners to identify locations which ensures the best possible access for patients
- The Provider must demonstrate how they will ensure equality of access for all patients meeting the duties of the Equalities Act 2010 for protected characteristics including but not limited to age, gender, disability, race, religion and sexuality, including where appropriate, positive outreach to patients and case finding.
- The Provider must contribute to reducing health inequalities through offering an inclusive and accessible service to vulnerable and easily over looked groups.
- The Provider must ensure all patients are given every opportunity to fully engage with the service
- The Provider must provide appropriate access at variable times for all patients

The Provider should give relevant information to patients as to what services to access should a treatment complication arise outside these normal hours.

The Provider must comply with NHS Standard Contract 2017/18 and 2018/19
Service Conditions: SC13 Equity of Access, Equality and Non-Discrimination, page 17
https://www.england.nhs.uk/wp-content/uploads/2018/01/2-nhs-standard-contract-1718-1819-service-conditions-full-length.pdf

The Provider has a responsibility to ensure that every service actively promotes equality of health outcomes for people with learning disabilities and cognitive impairment. The Provider shall:

- Provide training to relevant staff to ensure that health professionals gain a greater awareness of the health issues for people with learning disabilities and the 'reasonable adjustments' to services that may be required to meet their needs.
- Provide information both pre and post appointment in an accessible format with the use of pictures or symbols to back up information.
- Use clear concise language and seek confirmation that people understand what is communicated to them.
- Provide flexibility in appointment times, with longer time being allotted, appointments at the beginning or the end of the session to avoid waiting or allowing time for people to feel comfortable.

- Consult parents, family or paid carers on the needs of the individual and the best way to meet those needs where appropriate.
- Where made available by the referrer, consult the person's 'Care Plan' on the needs of the individual and the best way to meet those needs where appropriate
- Consult local specialist learning disability or liaison staff on the needs of the individual and the best way to meet those needs where appropriate.

3.3.4 Any acceptance and exclusion criteria and thresholds

Exclusions

- Children under the age of 18 years
- People who are not registered with a Croydon GP and those who are not temporary registered with a Croydon CCG member practice
- Patients who are outside the scope of the service specification
- NHS England Prescribed Specialist Commissioning Services

3.3.5 Referral policy

Referrers will be expected to complete a standardised referral form and sent via e-Referral system (eRs). The Provider has the right to refuse to accept a patient or continue to offer a service if the referral form is not completed in full (the referral form should be returned to the originator within one working day for full completion)

3.3.6 Requirements of Provider(s)

Providers working under this contract must:

- 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 services' lead clinician 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 therapy initiation and monitoring at the service delivery site
- Ensure that all staff 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 includes competence in use of Point of Care Testing (POCT) equipment and the CDSS to aid dosing and patient education. Competencies are available at the following link: http://www.nrls.npsa.nhs.uk/resources/?entryid45=61790&q=0%C2%ACanticoagulant%C2%AC
- 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 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, consultation room with desk, chairs, lighting, heating,

hand washing facilities (and access to toilet facilities where able) and a telephone
- Ensure that clinicians delivering the service actively monitor at least 20 patients per annum to ensure that professional competency is maintained and to provide initiation of warfarin and bridging services at every service delivery site
- 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 have completed Enhanced Disclosure and Barring Service (DBS) checks
- Ensure that all staff are vaccinated against Hepatitis B and have undertaken training for CPR

3.3.7 Registration

The Provider will keep comprehensive registration and management records for all patients referred into the service by using the agreed proprietary software. Providers will be responsible for the licensing of the software, ensuring compatibility with their own clinical system or on either an integrated or on a "stand-alone" basis. All documents must be stored safely and securely by the Provider and be open to clinical scrutiny as appropriate. The Provider will also be expected to operate a robust call and recall system for each patient.

3.3.8 Interdependence with other services/Providers

- Acute Medical Unit (AMU) and Edgecombe Unit at CHS
- A&E departments
- Cardiology, or other acute services at CHS
- Consultant haematologists at CHS
- Other Trusts
- GP practices
- Community pharmacists
- Specialist services
- Commissioners
- GP IT system Providers (EMIS and VISION)
- Nursing and residential homes
- CCG's Medicines Optimisation team
- CCG Quality and Safety teams

3.3.9 Informing patients and carers

The Provider undertaking this service will:

- Ensure patients are fully educated regarding their condition and are fully involved in the planning of their treatment programme including the use of visual aids to support concordance
- Prepare with the patient an individual management plan; that outlines the diagnosis, planned duration and therapeutic range to be obtained

- Ensure that each patient receives both verbal and written advice (NPSA Oral Anti-coagulation Therapy Pack including the "Yellow Book") and that this information is in the appropriate format depending on the needs of each patient.
- In some circumstances, provided the patient has given consent, treatment and planning may be discussed with the patient's family and/or carer
- Ensure all staff are sensitive to the cultural, ethnic and communication needs for people whom English is not a first language, including BSL users or who may have cognitive and/or behavioural problems or disabilities. These factors should be taken into consideration to facilitate effective consultations. Arrangements for consultation with non-English speakers and those with sensory impairments should be provided at no additional cost to the commissioner of this service or the patients.
- Ensure a telephone advice line or other appropriate medium depending on the needs of all service users, is in place for patients who require advice regarding their anti-coagulation management. Contact details must be clearly printed on the patient's information booklet and must state when advice is available. The Provider will make arrangements for efficient and timely response to patient enquiries within one day of receipt.
- Ensure the patients are aware of how they obtain advice or treatment out of hours (OOHs) of the service being provided
- Ensure all patients referred to the service (and/or their carers and support staff where appropriate) understand how to manage and prevent complications of their condition including the provision of patient-held booklet, referring back to their GP as appropriate for further support
- Where patients do not have the capacity to make decisions, healthcare professionals should follow the DH guidelines – 'Reference guide to consent for examination and treatment' (2009).
- Any communication material for release to patients and public or potential referrers will be agreed in advance with the commissioners.

3.3.10 Community based clinic arrangements

- The Provider will be expected to offer service delivery at multiple community locations with a minimum of 6 clinics operating to cover the 6 GP networks in Croydon. The Provider will need to evidence how their delivery model will support Croydon residents' to access community anticoagulation services
- All premises should be easily accessible, with good transport links and fit for purpose; they may be subject to inspection on an annual basis by the commissioner of the service which will include the following:

- Compliance with the Equality Act 2010
- Infection Control
- Safe and Secure Handling of Medicines and waste

- The Provider will grant visiting rights to relevant public and patient involvement forums in respect of premises provided or used by the service for delivering healthcare under this contract e.g. HealthWatch
- The Provider is required to provide a single point of access for booking appointments at all community service delivery sites
- The Provider must ensure that there are enough patient appointments available to meet local demand in Croydon, and must provide patients with a choice of dates and times of appointment five days a week. To ensure availability for working adults there needs to be at least one clinic that commences at 8am and one that extends to at least one day in each week in each of the GP networks

- Patients should expect to be seen within 30 minutes of their appointment time at their chosen anticoagulation clinic
- All service delivery sites must offer a dedicated anticoagulation clinic
- An up to date register of all patients using the service must be provided
- There should be a systematic call and recall of patients on the register which should be set up at the time of registration. The interval between tests will vary but patients should have their INR monitored at least every 12 weeks
- The Provider should have a system for follow-up of patients who do not attend clinic appointments.

3.3.11 Domiciliary service

Patients whom are eligible for domiciliary visits will have one or more of the criteria below, either on a permanent or temporary basis. Patients in care homes who meet the criteria will be covered by the domiciliary service. The Provider is responsible for determining a patient's eligibility and will review patients regularly to ensure they still meet the following domiciliary criteria:

i. Housebound;
ii. Requiring to be hoisted in order to transfer into and out of a chair;
iii. Requiring a stretcher for hospital transfer;
iv. On oxygen therapy who are not considered mobile enough to travel to a clinic for service provision;
v. Mental health issues, including Dementia, and following a mental capacity assessment where appropriate;
vi. Severe frailty – this may be measured using the Rockwood frailty score of 7-9;
vii. Patient cannot leave the home without assistance;
viii. Requiring lifting by special crew, down at least one full flight of stairs;
ix. Too distressing for a patient to use patient transport in the judgement of a healthcare professional, with special consideration given to the terminally ill;
x. Need for continuous proximity to a toilet due to urinary or bowel issues.

The Provider will work collaboratively with the patient and other healthcare providers to ensure that there is no delay to a patient receiving anticoagulation treatment when their domiciliary status changes. E.g. When a patient becomes temporarily housebound following an operation.

Management of patients being assessed at home remains the responsibility of the Provider(s) and all dosing and decisions to treat should be made by the community Provider(s). In the case of home or care home visit, the Provider(s) shall take all necessary equipment with them to provide the full service at this location.

Where a healthcare professional attends a patient's home or care home, dosing should be carried out on the same day and patient held records updated to reflect any change in dose. The patient's GP should be informed by telephone within 1 working day of the visit if any dose changes are required. This must be followed up by email and letter within 2 working days, requesting confirmation of receipt of the email.

3.4 Clinical Protocol

3.4.1 Service elements

The service will broadly comprise the following elements. These are:

- Registration- the registration of the patient including completion of software database
- Assessment and initiation – the confirmation of indication for anticoagulation, counselling for initiation and patient education
- Monitoring – including any required monitoring to safely initiate treatment e.g. U&Es, point of care testing so that current INR status can be ascertained during clinic visit with the provision of accredited equipment including test strips
- Dosing – Deciding the appropriate dosing of anticoagulant based on applying clinical experience to the findings of the decision support software and Summary of Product Characteristics (SPC).
- Prescribing – The issuing a prescription based on the dosing decision
- Formal review of a patient's health, relating to anticoagulation monitoring, at least annually, including checks for need for continuation of anticoagulation, potential complications and, as necessary, a review of the patient's health relating to anticoagulation including the patient's own monitoring records and duration of treatment. In addition, an assessment of whether the service is the most appropriate to meet the patient's needs, and whether any onward referrals are necessary. A copy of this report should be sent to the patient's GP
- Domiciliary – the ability of the Integrated Community Anticoagulation clinic to visit patients within their home setting to carry out the core service elements
- Alternatives to warfarin – the ability of the Integrated Community Anticoagulation clinic to offer DOACs within local clinical guidelines
- Self-Testing – the ability of the Integrated Community Anticoagulation clinic to offer self – testing with the provision of testing strips, yearly external quality control of monitoring machine and remote dosing on a named patient basis. The service should be in line with the Pan London framework for adult patients who self-monitor their INR.
- Temporary Residents – the ability of the Integrated Community Anticoagulation clinic to sign on temporary residents and offer the core service

3.4.2 Standard operating procedures

The Provider must operate according to a clinical protocol that will comply with the recommendations of national regulations and directives relating to anticoagulation and shared with the lead commissioner prior to service commencement.

The Provider must ensure that the clinical protocols include arrangements for the patient to access a safe supply of anticoagulant medication. The Provider must ensure that the patient understands how to do this.

The Provider must ensure that there are clear standard operating procedures (SOPs) in place for all elements of the service prior to service commencement. SOPs are to be shared with commissioners in a timely manner should they be requested in the interest of maintaining public safety. SOPs are to be agreed and signed by the lead clinician and reviewed at least annually or in light of further national or local recommendations. In addition SOP's should be reviewed if a critical incident occurs.

SOP's in place should cover:

- Service risk assessment
- Options to support the therapeutic decision making with patients
- Ordering, storage, maintenance and quality assurance of equipment and supplies
- Testing procedure - Finger-prick (capillary) sampling including use of POCT equipment
- Guidance for use of CDSS including standardised settings and record-keeping
- Domiciliary service provision and lone worker policy
- Supporting patients self-monitoring INR
- Transfer of care for anticoagulation services across different settings including for acute/urgent/complex patients
- Communication between Providers and health and social care professionals
- Initiating, maintaining, bridging and cessation of anticoagulation therapy
  Co-prescribing and drug-drug interactions and drug-food interactions with anticoagulation
- Dealing with high and low INRs and abnormal results, and warfarin reversal (administration of vitamin k)
- Documenting and coding adverse events with anticoagulation (internally within the service and recommendations for standardised coding for GPs and hospitals)
- Patient counselling and education
- Recall of patients who fail to attend an appointment
- Assessment of risk versus benefits of anticoagulation 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

3.4.3 Testing Issues

Where the operative is unable to obtain an INR from a near patient testing device or where there is cause for concern about the reliability of the result, the Provider shall make appropriate arrangements for a venous sample to be taken. The management of INRs outside the required therapeutic range should follow an approved protocol.

3.4.4 Did Not Attend Appointments

If a patient did not attend their appointment (either new or follow up) they will be contacted by telephone within 5 working days (if urgent) or sent a letter in an accessible format for the patient to book a new appointment in 10 working days. If the new appointment is not attended they will be discharged except in exceptional circumstances. DNAs will not be paid for by the CCG.
Once discharged if a patient makes contact with the service they will be advised to go back to their GPs for another referral if they still require treatment.

In exceptional circumstances a patient may be offered another appointment once discharged.

The service should develop an accessibility and non-attendance policy to be approved by the commissioning organisation prior to mobilisation and go-live.

3.4.4.1 Cancellation Policy

If a patient cancels their appointment they will be offered another appointment.

If a patient cancels twice on consecutive appointments they are liable to be discharged except in exceptional circumstances. A warning will be given after the first cancellation.

If a patient cannot book a further appointment for valid reasons, the appointment may be left open for a maximum of one month.

3.4.5 Communication and Coordination with Primary Care

The engagement and support of local GPs will be vital to the success of the Service. The Provider will work effectively with local GPs and GP networks, including:

- Keeping GPs informed about the diagnosis, care provided, plan for on-going care, expectation of practices in primary care (including review dates). All activity include advising the GP of any symptoms of ill health, significant events, death, INR over 8, administration of vitamin K, clinic non-attendance, details of annual reviews or referral or admission to hospital.
- Ensure adequate medication information is provided at discharge from the service to support medication review by local GPs and pharmacists;
- Any CCG approved shared care or transfer of care documentation.
- Involve GP/clinical networks in the on-going development of services;
- Involving primary health care teams in delivery of care (including shared care arrangements); and
- Education and skills development of GPs and the wider primary health care team, and support for condition management in primary care.

The new service will be accessible for local GPs, who will be able to ask for advice and guidance via email (or through an arranged phone call) before or instead of referring a patient.

3.4.6 Discharge Process

- At the end of the required treatment course (as specified above) or if otherwise indicated, anticoagulants should be discontinued as recommended in line with current standards and national guidelines e.g. BHS and NICE. and the patient's GP should be informed in writing within **five** working days.
- GPs to be notified of all patients discharged due to non-attendance or cancellation within 5 working days.
- The Provider should maintain a record when treatment is discontinued as to the reason for discontinuation / discharge from the service in line with data regulations. This information should be stored safely and securely and retained by the service and made available for inspection and audit if required.

3.4.7 Response Time and Prioritisation

- Referred patients have a confirmed appointment booked within 5 working days of receipt of the referral
- Routine assessment and treatments must be carried out within 10 working days of referral receipt
- Urgent assessment and treatments must be carried out within 8 working days of referral receipt
- Reports and letters following assessment/treatment to be sent to GPs within 5 working days

3.4.8 Computerised Decision Support Software (CDSS)

It is expected that the Provider will use an accredited bespoke Computerised Decision Support Software (CDSS) system for dosing and monitoring vitamin K antagonist therapy that is in agreement with the CCG. The chosen system should allow GP practices read only access to patient's INR readings and the Provider will be responsible for the cost of the license fee (s) for the agreed system.

The Provider must:

- Use CDSS to undertake dosing and ensure records are updated in real time.
- Ensure the most up-to-date clinical version of the CDSS software is used including read only access for GP practices.
- Ensure that all staff using the software undertake training and are then assessed as being competent to use the software
- 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 Croydon CCG.

In addition, the decision support system should have the facility to generate patient information including visual prompts for their warfarin dose with both numerical and colour diagrammatic representation of tablets required.

All information systems, where possible must be interoperable with primary and secondary care systems to support seamless transfer of electronic information. In all circumstances relating to transfer of patients from one Provider / referrer to another robust communication between different Providers will be vital to allow for safe transfers of care to happen. The referral and registrations forms should be used as minimum requirements for ensuring the right patient information is transferred and communicated. Provider will have a standard operating procedure for the handling of patient information and the content of such. This will be shared with Commissioners prior to service commencement.

3.4.9 Equipment

The Provider will be responsible for the purchase and maintenance of all equipment inclusive of the agreed tariff.

The Premises may contain equipment, furniture, furnishings and consumables used in the delivery of the Services (e.g. reception and office desks, consulting room furniture, fridges used for storing drugs, syringes, sample collection materials, bandages, etc.). Collectively these will be known as the "Equipment". The Equipment may include permanently installed Equipment as well as Equipment used in the maintenance and upkeep of the Premises.

The Provider will ensure all equipment:

- Complies with current health and safety regulations and maintain minimum standards for satisfactory patient care
- Is regularly maintained, serviced and calibrated in accordance with manufacturer instructions.
- Is fit for purpose
- Complies with Medical Devices Legislation

The Provider will be responsible for:

- All necessary near-patient testing equipment (including single use lancets and test strips)
- Consumables
- Quality assurance materials to be commissioned through accredited suppliers
- Clinical waste

The Provider must ensure that external quality assurance checks are conducted on a minimum quarterly basis to verify the accuracy of blood testing machinery and dosing. Using NEQAS (National External Quality Assessment Scheme), these quality assurance checks will be funded by the Provider and will be submitted to the CCG quarterly as part of the minimum dataset and as an annual report.

3.4.10 Provider workforce training & competency

The designated clinician retains clinical responsibility and must be involved in all dosing decisions as this is a prescribing action. All new and existing non-GP practitioners with clinical responsibility for prescribing medications must have completed an accredited course to provide an anticoagulation service.

The Provider shall be responsible for ensuring the training, assessment and accreditation of their staff providing anticoagulation services. All health professionals delivering direct patient care should be registered with an independent UK health regulator i.e. GMC, NMC or GPhC. Completion of training, followed by yearly refresher courses is expected of all staff treating patients within this service specification.

The Provider shall ensure that staff employed in the provision of the service meet the following Anticoagulation competencies 1,2,3 and 6 outlined by the NPSA Anticoagulation Patient Safety Alert 18:

- Initiating Anticoagulation Therapy
- Maintaining Warfarin Therapy
- Reviewing the safety and effectiveness of an anticoagulant service.

The Provider shall ensure that they have an identified clinical lead of the service who has:

- The ability to safely manage an 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 and the target ranges for oral anticoagulation therapy;
- The ability to evaluate which target INR is required when treating different conditions;
- An understanding of the pharmacology of the oral anticoagulants 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.

Providers will release nurses/HCAs for training and periodic updates. Below is the minimum training standard expected; and the training required to carry out the service includes;:

- Basic theory of anticoagulation
- Clinical aspects of Warfarin (side effects, contraindications, interactions, dosing regimes)
- Detailed training in the use of the point-of-care testing device

- Detailed training in Clinical Decision Support Software (CDSS)
- The standard operating procedure
- Health and Safety procedures
- Quality control procedures
- Record Keeping systems and audit systems
- Knowledge of NRLS/NPSA requirements

The Provider shall ensure that any newly recruited staff shall be supported by a trained senior clinician for a period of 8 weeks post commencement of service provision. On-site clinical supervision and support must be provided by an accredited pharmacist or doctor, where the service is nurse-led or delivered by a non-medical prescriber. All clinicians are required to attend and complete an accredited course on initiation and management of oral anticoagulants and LMWH. It is essential that this course be approved by the Commissioner.

All staff shall be trained and regularly updated in Basic Life Support, Safeguarding Adults and Infection control in line with guidance by the Croydon Clinical Commissioning Group.

Appropriate time must be built into staff contracts to permit them to have protected learning time and enable attendance at mandatory training in accordance with the legislation, guidance and policy relating to safeguarding Adults.

The Provider shall develop and maintain a robust recruitment, induction and training programme which ensures that all staff employed by the service have thorough understanding of the specific requirements of the service and that all standards are met. This includes the following:

- Ensuring there is a robust staff appraisal system in place
- Ensuring that all staff carry personal identification cards whilst on duty
- Ensuring that frontline staff are appropriately dressed in uniform where applicable
- All staff must have an enhanced CRB check and safeguarding training.

The Provider must demonstrate a commitment to develop new roles in line with service requirements and support staff in acquiring the skills and competencies to deliver these.

3.4.11 Education, training and support for GPs/referrers:

- The Provider shall provide support, training and advice to GP practices in the management of anticoagulant amenable conditions in primary care whilst also delivering care to Service Users.
- GPs and other healthcare professionals having access to specialist advice and guidance services, by telephone or email, to support them in the diagnosis and the on-going management of patients in primary care.
- The Commissioner expects the Provider to turnaround these requests within a maximum of 4 hours for advice relating urgent requests. Advice for non-urgent requests must be provided within two working days.
- The Provider will be expected to work with local GPs to audit referral and service activity and to provide targeted and relevant educational support and training to GPs. This will build upon the clinical skills for the diagnosis and management of service users with anticoagulant amenable conditions, as well as providing advice in the clinical decision making of the Service User's care.

- The Provider will be required to deliver joint structured education sessions (at least 2-4 sessions per year) with interface services to local GPs, in order to clarify for referrers and providers the additional vocational rehabilitation services, mental health and third sector organisations available to service users and to encourage collaborative working.

3.4.12 Patient Self-care/Self-management

Patient self-care must be promoted through education and supported self-management plans. As part of self-care/management plan for patients, the provider will be required to use creative approaches that support compliance to the prescribed treatment plan that improve clinical outcomes and the patient's recovery.

A variety of tools and techniques should be utilised to support patients in understanding their conditions, what the treatment plan may be and that they are involved along the pathway of care. A specific focus on patient support and care planning for patients with long term conditions is essential.

On discharge from the Provider, patients should receive care-planning support, supported by a self-management care plan. This will describe the patient's self-care action plan and a copy will be held by the patient, the GP as well as the Provider. The care plan should be developed jointly with a patient, respecting the specialist opinion and advice that is pertinent to clinical needs. More complex patient's care plans may be uploaded on to a shared care record system with access by secondary care with the consent of patients.

All patients referred are offered structured education designed to help increase participants' self-efficacy, increase motivation and attitudes to self-care, thereby reducing complications and unplanned use of secondary care health services.
Patients attending structured education are able to set their own goals and develop their own personal action plan with regard to their future anticoagulation management.

3.4.13 Prescribing

Ensure there are robust governance processes and comprehensive prescribing policies that are in line with the national and locally agreed policies and guidance (attached)*:*

a) Formulary selection /recommended drugs ,
b) Use of pre-packs and the dispensing of drugs
c) The supply of medicines including the use of patient group directions (PGDs) and FP10 prescriptions.
d) The prescribing of controlled drugs
e) Make arrangements for the ordering, recording, handling, safe keeping, safe administration and disposal of medicines, in line with national guidance and regulations, in particular controlled drugs and pharmaceuticals requiring refrigeration.
f) The ordering, receipt, storage, distribution, and disposal of NHS FP10 prescription forms and other medicines-related secure stationery (e.g. antiviral vouchers

3.4.13.1 Prescribing
Where a prescription is considered clinically necessary the provider shall prescribe the most

clinically and cost effective medicines in accordance with national and local guidance.

3.4.13.1.1 Any medications prescribed will be in accordance with national and local guidance:

(a) NICE guidance, NPSA, MHRA and Department of Health directives relating to prescribing
(c) Good Prescribing Practice as defined by BNF
(d) Croydon Prescribing Committee recommendations and South West London Interface Prescribing Policy:

Croydon Joint Medicines Policy

http://www.croydonccg.nhs.uk/news-publications/publications/Pages/A---Z-of-publications.aspx

SWL Interface Prescribing Policy 2017/19
SWL Interface Prescribing Policy Factsheet
Hospital / Specialist Only Drug List
Shared Care Prescribing Guidelines
Decision support tool to determine place of prescribing
Proforma for changes to Hospital/Specialist only drug list
SWL Principles of Shared Care
Shared Care Prescribing Guidelines template
Transfer of Care template

3.4.13.1.2 Any PbR Excluded Medicines prescribed will be in accordance with:

SWL Commissioning Principles for PbR Excluded Drugs 2017/19
SWL PbR Excluded Drugs LIST 2017/19
SWL Gainshare Biosimilars 2017/19
SWL Local agreements for PbR excluded drugs delivered via homecare 2017/18

3.4.13.1.3 Any medicines prescribed will be in line with SWL Position Statements (approved at Croydon Prescribing Committee)

SW London Clinical Commissioning Groups (Croydon, Kingston, Merton, Richmond, Sutton and Wandsworth) do not support the routine NHS prescribing of certain medicines. These medicines are items that are:

- Of low clinical effectiveness i.e. where there is a lack of robust evidence of clinical effectiveness or have significant safety concerns
- No longer licensed in the UK
- Are clinically effective but are not cost effective for the NHS
- Are clinically effective but there are more cost effective products available
- Are available over-the-counter and inexpensive to purchase

The NHS in SW London is currently facing a significant financial challenge and must focus its resources on the areas of greatest need. We need to prioritise and make tough decisions to secure the future of local health services for everyone in SW London.

Prescriber: professional and contractual context
During discussions with the patient, when considering what treatment and ongoing monitoring is required, clinicians are asked to be mindful of the following:

- That within their Primary Medical Services contract with NHS England, GPs have a contractual obligation relating to patients with chronic disease to make available such treatment (including any prescription deemed to be appropriate after discussion with the patient) as is necessary and appropriate, and to provide advice in connection with the patient's health, including relevant health promotion advice.
- That reference to local prescribing guidelines is good professional practice.
- That consideration of GMC professional obligations to use NHS resources wisely is good professional practice.

3.4.13.1.4 Any medicines and appliances prescribed will be clinically appropriate:

(a) Ensure appropriately qualified prescribers are available throughout the opening hours of each service area. Where treatment requires the provision of a medicine this should be done through the writing of a prescription

(b) Promote the self-care and prevention agenda, particularly in respect to homely remedies or supplements e.g. cough and cold remedies, vitamin D, paracetamol etc.

(c) Support the principles of antibiotic stewardship in ensuring appropriate use and selection of antibiotics. This includes addressing patient beliefs about the clinically appropriate use of antibiotics and ensuring consistency in the messages given to patients in primary and secondary care. This particularly applies to patients attending urgent care centres or primary care hubs who may already have seen a healthcare professional in primary care.

(d) Ensure all medicines related incidents are monitored and reported via an appropriate route e.g. NRLS through http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/ and the CCG informed of any errors that may have or actually caused patient harm.

3.4.13.2 Controlled drugs

The provider shall:

(a) Ensure a system is put in place that properly protects patients from the potential misuse of controlled drugs, particularly unregistered patients that includes sharing information with other out-of-hours providers and providing only sufficient quantities to cover period until they can see their regular GP practice.

(b) Monitor and develop systems to share information on patients with addictive personalities, those on high risk medicines and frequent fliers to the service with their regular care provider, GP practice or other out-of-hours and extended hours providers in a timely manner to reduce the risk of harm from inadvertently obtaining excessive supplies and to avoid misuse of the service to obtain repeat medication.

3.4.13.3 Record keeping and Communication

The provider shall

(a) Ensure that any medicines supplied, administered or prescribed is recorded in the patient's clinical notes using auditable record keeping, supported with an appropriate computerised infrastructure, including home visits

(b) Ensure that the patient's registered GP is provided with information on the supply of

medicines within a timely manner e.g. in real time for EMIS practices and with Vision practices within 48 hours, as agreed with the commissioner.

(c) Ensure that HCPs receive appropriate communication e.g. community pharmacists to support adherence, prescription information, counselling and other queries

3.4.13.4 Monitoring and Performance management

The commissioner's medicines management team will be responsible for setting up allocated prescribing cost codes for the provider for the purpose of monitoring the quality and cost of prescribing within the service.

All prescribing and drug (including diagnostic, analgesic, anaesthesia and discharge)/ appliance costs associated with the service remain the responsibility of the provider and will be included in the financial envelope of the contract. This will include both the reimbursement cost associated with the drug/appliance and any remuneration fees associated with the dispensing service.

The CCG will cross-charge the provider the costs incurred against their allocated prescribing cost code. On a regular basis (initially monthly then quarterly).

The provider shall

(a) Agree a mechanism with the CCG's medicines management team for monitoring prescribing data and addressing any areas of inappropriate prescribing that is identified.
(b) The provider will monitor their prescribing and audit internal prescribing as good practice and provide a report every 6 months on request
(c) Ensure that all prescribers are allocated and prescribe using the appropriate prescribing codes when working within the service.
(d) Ensure that the appropriate authorities are informed when new prescribers start or leave the service.
(e) The Provider will be responsible for funding medicines stocked within the bases/carried by clinicians from within the total agreed contract value.
(f) The Provider must also be able to supply the commissioner with information pertaining to the number of people on caseload (at any given time) and the number of people annually on each medication type separated by condition. See appendix 3 for information reporting requirements.

3.4.13.5 When the patient is discharged from the service (or after episodes of care as appropriate) information should be provided to the GP including:

- Details of any medicines that have been stopped, the reason why the medicine has been prescribed and the intended duration of any new medicine
- Any adverse reactions or allergies
- Appropriate contact details where the GPs can communicate any issues
- Any special arrangements made with Community Pharmacists or Community Nurses to supply/administer medicines

The patient pathway should include community pharmacies to address medication adherence, information on prescriptions, counselling on first supply, any other queries.

3.4.14 Information Technology

The CCG requires the Provider to use an IT operating system via a secure N3 connection to deliver the service and that has the ability to interface or interoperable with GP practice IT systems (primarily EMIS with some VISION). To enable the service to share/access patient records with GPs and to support integrated care between the service and primary care.

The Provider will be responsible for the provision, maintenance and cost of all Information Management & Technology (IM&T) hardware and software, licenses and IT support services required to meet the needs of the Service. The provider will install and maintain IM&T systems that enable secure storage and transfer of information between providers in the care pathway.

The Provider must ensure that appropriate "IM&T Systems" are in place to support the Service before Service Commencement. "IM&T Systems" means all computer hardware, software, networking, training, support and maintenance necessary to support and ensure effective delivery of the Services, management of patient care, contract management and of the organisation's business processes, which must include:

- Single point of access;
- e-Referral service;
- Clinical services including ordering and receipt of pathology, radiology and other diagnostic procedure results and reports;
- Prescribing;
- A single electronic patient health record for every patient, which is identifiable by a unique number (e.g. patient NHS Number);
- Inter-communication or integration between clinical and administrative systems for use of patient demographics;
- Systems for referral management and booking for both GP referrals to the Provider and onward referral from the Provider to a specialist.

The provider will work with the CCG and other key partners involved in the care pathway to improve the use of information in support of patient care. This may include participation in audits.

3.4.15 Patient transport

Patients will be expected to arrange their own transport to the services unless they qualify under the Healthcare Travel Costs Scheme guidance found at:
http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Travelcosts.aspx

The Provider is expected to advise the patient on all local transport options on request, this includes community transport availability

3.4.16 Continuity of Service and access for patients

Patients with long-term conditions, under the care of the Provider , must be provided with access to telephone or email support by the appropriate MDT member within the service, with a response to be provided preferably within 24 hours but no more than 48 hours.

3.4.17 Acute Services

Key to the success of the new community service will be strengthening arrangements to ensure that hospitals only see those patients who must be seen in hospital and all other referrals will be seen in the community service. The provider will be required to participate in reviews of referrals going direct to acute services and facilitate the redirection of referrals appropriate for the community services, by for example participating on MDT panels and contributing to care planning decisions for patients. Rates of re-direction will be monitored within the contract via a KPI. The provider will be expected to develop referral pathways and protocols with providers within the local healthcare economy where necessary. The new community service will be accountable for ensuring local acute trusts are aware of the service and referral arrangements.

3.4.18 Clinical governance & patient safety

The Provider is required to carry out clinical audit of the care of patients set criteria recommended by the British Committee for Standards in Haematology and the National Patients Safety Agency.

3.4.19 Information Requirements

The Provider will fully complete the required dataset for every patient referred to and accessing the service. It will be the Provider's responsibility to ensure the submission of the quarterly clinical audit to commissioners in a timely manner.

3.4.20 Audit

The Provider is required to carry out a clinical audit after the first 3 months of service, and quarterly thereafter, of the care of patients against criteria recommended by the British Haematological Committee for Standards in Haematology and the National Patient Safety Agency.

3.4.21 Set up arrangements and costs

- Set up arrangements and the costs of the monitoring process will be met by appointed Provider(s)
- Anticoagulant blood monitoring must be undertaken using appropriate devices validated by the Purchasing and Supply Agency (PASA) with appropriate Standard Operating Procedures which include appropriate quality assurance processes.

3.4.22 Risk management and adverse event reporting

All staff are expected to adhere to guidance on the assessment of risk and the management of risk appertaining to the treatment of patients and the safety of staff as described at: http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/riskassessment-guides/

The Provider's policy on accidents and significant event reporting and monitoring should accord with CCG requirements. This should comply with NHS recommendations and including reporting to the NPSA or its replacement body. Providers will be expected to update their risk reduction strategies on a regular basis and according to updated research.

Significant events should be recorded and reported one working day to the CCG Quality & Safety Lead**.** If the CCG Quality & Safety Lead is not available then reports should be made to a CCG Senior Management Team member**.** A report on action taken and action to be taken will be sent to the CCG within 10 working days of any reported accident or significant event.

All enquiries from the press, media and politicians etc. to be directed to the Commissioner to agree an appropriate response, in line with the CCGs Media Handling Policy.

3.4.23 Compliance with relevant legislation

The Provider must ensure that staff comply with all relevant legislation, for example:

- Health and Safety legislation and Control of Substances Hazardous to Health (COSHH) legislation
- NICE guidelines on Infection Control (2003)
- Statutory employment legislation including that relating to equal opportunities and anti-discriminatory practices.

3.4.24 Complaints

The Provider must provide and operate a complaints policy for both patients and staff which reflects the principles contained with the CCG Complaints Policy and is in accordance with NHS guidance. The Provider must make available details of complaints received as required by the CCG.

4. Applicable Service Standards

4.1 Applicable national standards

Treatment will be consistent with the following clinical evidence and best practice:

- National Institute of Health and Care Excellence (NICE) clinical guidance, quality standards and technology appraisals
- Recommendations from the British Society of Haematology (BSH), National Patient Safety Agenda (NPSA), NHS England and the Medicines and Healthcare products Regulatory agency (MHRA)

Applicable national standards (e.g. NICE)

i. British Committee for Standards in Haematology
The diagnosis of deep vein thrombosis in symptomatic outpatients and the potential for clinical assessment and D-dimer assays to reduce the need for diagnostic imaging.

ii. British Journal of Haematology 2006, 136, 26-29

http://www.bcshguidelines.com/documents/safety_indicators_oral_anti_coag_bjh_2007.pdf

iii. Guidelines on oral anticoagulation with Warfarin-fourth edition

British Journal of Haematology 2011
http://www.bcshguidelines.com/documents/Warfarin_4th_ed.pdf

iv. BCSH standards on point of care testing to this list
http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2008.07274.x/full

v. NICE Guidance - Management of Atrial Fibrillation. NICE Clinical guideline CG180. June 2014 http://www.nice.org.uk/nicemedia/live/10982/30052/30052.pdf

vi. Venous thromboembolic diseases: The management of venous thromboembolic diseases and the role of thrombophilia testing NICE Clinical guideline CG144 June 2012 http://www.nice.org.uk/nicemedia/live/13767/59720/59720.pdf

vii. National Patient Safety Agency

Viii. NHS London Clinical Networks 2016: Excellence in anticoagulant care- Defining the elements of an excellent anticoagulation service
London Clinical Network's Excellence in Anticoagulant Care (2016).

Actions that can make anticoagulant therapy safer. National Patient Safety Agency Alert no 18. 28 March 2007 http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814

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 applicable local standards for the service include:

- South London Cardiac and Stroke Network recommendations Croydon CCG Medicines Management, Quality and Performance policies
- NHS Croydon CCG Safeguarding Policies
- NHS Croydon CCG Information Governance Policies
- NHS Croydon CCG Updated Anticoagulation Policy (when available)

4.3.1 Locally defined, general requirements for providers

Requirement	Applicable service category
Provider delivers their community medical and surgical services contractual and statutory requirements. No breaches in the last 12 months.	Community Service
Provider is CQC registered with no conditions	All
Provider has a clear waiting list.	Community Service
Same day appointments are available for patients clinically assessed	All

as requiring them.	
Provider shares information with commissioners to support quality improvements (subject to IG rules).	All
Provide collects demographic data/equality data on the protected characteristics to: • demonstrate equality of access • demonstrate good experience for all • demonstrate good outcomes for all • analyse the data to ascertain if there any gaps in the percentage of communities/people with protected characteristics accessing services and the percentages in Croydon's population • seek to understand why a particular group might be underrepresented – typically by asking individuals from that group, community leaders, community charities who can represent those communities/groups.	All
Provider actively collects analyses and acts on feedback from patients and carers.	All
Provider participates in clinical audit cycles and peer review external to their practice.	Community Service
Provider provides agreed list of community out of hospital services	Community Service

4.3.2 Locally defined, service-specific requirements for providers

Requirement	Applicable service category
Individuals will have access to relevant and comprehensive Anticoagulant service information, in the right formats, to inform choice and decision-making about their care.	All
Providers will signpost patients to local relevant services which could help them.	All
Information and services will be available for individuals who are able to self-manage their conditions or who need care plan support.	All
Providers will consider whether working with other providers would increase the efficacy of new service (e.g. third sector, schools, libraries, religious organisations).	All
Providers demonstrate that they have identified any potentially hard to reach groups (as defined by the JSNA) that exist within their target population, and have taken appropriate action to improve access to the service for these groups.	All

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements

Robust data collected via INR Star and other IT systems and reported on a monthly basis to the CCG Contract and commissioning leads.

The Provider and Commissioner will meet formally at Contract Monitoring meetings on a monthly or quarterly basis. Consideration will be made by both parties whether to meet less frequently during the length of the contract. However, it is expected that monthly meetings will take place.

The provision of data relating to the KPIs and their timely submission is viewed as a significant aspect of the contract management. Consequently, the non-supply of KPI data or late submissions will be viewed seriously by commissioners. The Commissioner will confirm to the Provider those breaches that do require further investigation.

Both parties will endeavour to resolve KPI breaches through routine contract monitoring and the monthly contract management meetings. In the event that the Commissioner can demonstrate that a deficit in the information supplied or the absence of KPI submissions by the due date for a period of greater than 2 calendar months by the Provider, this will result in further investigation and analysis leading to both parties agreeing priorities, timescales and actions required.

If all reasonable endeavours to resolve matters have failed (in the view of the commissioners) the commissioners will consider applying the terms of, and the escalation processes, contained in the NHS Standard Contract regarding non-compliance.

This sequence of events and processes does not remove or restrict the right of the Commissioner to raise individual queries regarding KPIs or any other aspect of the service provision as defined within the service specification.

5.1 Quality reporting requirements

- See Appendix 1 for the key performance indicators
- See Appendix 2 for Schedule 4 – Quality Requirements.

5.2 Information reporting requirements

- See Appendix 3: Summary of Monthly Activity and Quality Performance Report

5.3 Applicable CQUIN goals

- Not Applicable

6. Location of Provider Premises

The Provider should deliver services from sites locally defined by Croydon but as a minimum there should be two sites to allow equal provision to the North and South of the borough.

7. Individual Service User Placement

Not Applicable

Appendix 1 : Key Performance Indicators

NO.	Quality Requirement	Threshold	Method of Measurement	Frequency	Consequence of breach	Timing of application of consequence	Applicable Service Specification
1.	**Patients on Warfarin therapy** **(a) INR Monitoring**	95% of patients established on warfarin seen for INR monitoring once every 12 weeks **Numerator:** Number of patients on warfarin had INR monitoring once every 12 weeks on warfarin **Denominator**: Total number of patients on warfarin.	Establish a robust INR monitoring and reporting process for patients established on Warfarin i.e. CDDS	Monthly	**0.5 % Financial Penalty Weightings (Annual Invoice Value)**		
	(b**) Time in Therapeutic Range (TTR)** (excluding patients in the first 6 weeks of treatment)	(i) Number and % of patients with target TTR >65% (ii) Number and % of patients with target TTR less than 65% (iii) All patients with TTR less than 65% who have their anticoagulant control reassessed (iv) Number and % of INR tests > 5 (v) Number and % of INR tests > 8 (exception report on management)	Robust mechanism in place to reassess, monitor and address out of range INR results and individual patient TTR.	Monthly	**1.5% Financial Penalty Weightings (Annual Invoice Value)**		

NO.	Quality Requirement	Threshold	Method of Measurement	Frequency	Consequence of breach	Timing of application of consequence	Applicable Service Specification
		(vi) Number and % of INR tests < 1.5 (exception report on management)					
2.	**Waiting Times** (a) First appointment - Percentage of patients seen or/and treated within 10 working days of receipt of the referral (b) Follow-up appointment - Percentage of patients seen or/and treated within 10 working days for urgent and 20 working days for non-urgent in receipt of the referral	(a) First appointment - 90% seen or/and treated within 10 working days (b) Follow-up appointment - 90% seen or/and treated within 8 working days for urgent appointment and 10 working days for non-urgent appointment **Numerator**: Number of patients seen or/and treated within 10 working days for First appointment and 8 working days for urgent and 10 working days for non-urgent Follow-up appointments. **Denominator**: Total number of patients referred within 10 working days for First appointments and 8 working days for urgent and 20 working days for non-urgent Follow-up appointments.	Performance Report	Monthly	**0.5% Financial Penalty Weightings (Annual Invoice Value)**		

Appendix 2 - SCHEDULE 4 – QUALITY REQUIREMENTS

A. Local Quality Requirements

Quality Requirement	Threshold	Method of Measurement and Frequency	Consequence of breach	Monthly or annual application of consequence	Applicable Service Specification
Improve quality and access to services – • More patients diagnosed and treated within the community. • Services closer to home. • Avoid unnecessary delays or waits for secondary care appointments • Better signposting and cross referral to relevant services • Reduce the number of appointments a patient needs to attend • High quality of service and outcome for patients with common musculoskeletal problems • Clinical audits	1. 75% of patients report satisfaction and positive experience with service 2. Audit data provided of breakdown of annual activity in terms of ethnicity and age 3. Triage >90% of referrals to service within 1 working day 4. 90% of patients to be seen at initial assessment or first routine appointment within 10 working days of being triaged into the service 5. Urgent appointments offered and seen by the service within 8 working days of being triaged into the service 6. 100% of onward referrals to secondary care have a set of investigations and results completed appropriately where known. 7. Undertake bi-annual clinical audits, including 'value-added' by contact with the service (reduction in pain, improvement in pain / symptoms / ability to self-manage 8. Compliance of staff with statutory and mandatory training (Threshold 95%) 9. Outpatient letter and discharge summaries to meet minimum dataset as detailed in the service specification (for both clinicians and patients)	Monthly, quarterly and cumulative annual reports to the CCG must include: Audits of: • Outcomes of patient satisfaction and remedial action/development plans • The total number of referrals received for triage in the community service; • The number of immediate onward referrals to secondary care following paper triage; • The number of onward referrals to secondary care following a minimum of one appointment/attendance within the community service; • First and follow-up activity within the community service. • Bi-Annual staff training report	As per GC9		
More efficient and targeted use of clinical resources • Reduce the number of secondary		• Quarterly and accumulative annual monitoring from acute activity report	As per GC9		

Quality Requirement	Threshold	Method of Measurement and Frequency	Consequence of breach	Monthly or annual application of consequence	Applicable Service Specification
care outpatient attendances • Reduce the number of referrals or investigative/ diagnostic procedures to secondary care and Accident & Emergency attendances					
Support for GPs • GPs are better supported and advised for the provision of anticoagulant care • Provider will arrange educational activities for GPs and support for referrers with the aim of improving the quality of referrals and anticoagulant knowledge of referring clinicians	1. Annual consultation with GPs within the networks about availability of support and training demonstrates high satisfaction 2. A minimum of one educational workshop/ session per practice or as required annually	• GP consultation confirms high satisfaction with support and training processes through on-going dialogue and feedback. This will take place through Network meetings and Service meetings. • Submission of annual training records by GP practice	As per GC9		

Appendix 3: Summary of Monthly Activity and Quality Performance Report

Performance Indicators to be Monitored	
Measure	**Threshold**
% Referrals triaged at each triage point within one working day	>90%
DNA % of first contacts	<10%
DNA % of follow up contacts	<10%
% of appointments cancelled by the service	<5%
First urgent appointment offered and seen within 8 working days	90%
First routine appointment offered and seen within 10 working days	90%
Percentage of SUIs managed within 60 working days	100%
Compliance of staff with statutory and mandatory training	95%

Activity & Quality Indicators	
Measure	
Number of first contacts	*Local activity*
Number of follow ups	*Local activity*
Total contacts	*Local activity*
Number of referrals	*Local activity*
Number of discharges	*Local activity*
% Patients triaged and rejected at referral	
Number of OP first appointment with no OP follow up	
Number of Serious Untoward Incidents (SUIs) in the period	
Number of Clinical Incidents (CIs) in the period	
Number of Complaints in the period	
Complaints received as % of total number of patients treated	<2%
Number of Compliments in the period	
% of appointments cancelled by the patient	
Numbers waiting more than 10 working days to first appointment	
% of patients who have expressed satisfaction with the appointment offered and accepted	
Number of patients on each medication type separated by condition	
% of referrals for initiation patients who are contacted within 5 days of receipt of referral (once all info received) as a proportion of all referrals during the reporting month	
Number of unique patients on caseload (at any one time) and annually	
Number of major bleeding (had a major bleed e.g. CNS/G.I in the last 6 months requiring intervention) in patients on anticoagulation reported in the reporting month	
Number of referrals to A&E due to INR over 8	
Number of referrals for unstable INRs e.g. for other drugs such as DOACs/NOACs	
Number of AF patients discharged back to referring clinician/GP. (excluding those referred for cardioversion)	
Referrals to Acute anticoagulant from triage	
Outcomes of Patient satisfaction surveys and reports with remedial action/development plans	