

Initiation of Warfarin for patients not registered with Provider Practice 2019-20

1. Purpose of Agreement

This Agreement outlines the service to be provided by the Provider, called Initiation of Warfarin for patients not registered with provide practice.

2. Duration of Agreement

This agreement is for a period of six months, commencing **1st April 2019** and ending on **30th September 2019**.

3. Background

Warfarin is being used in the management of increasing numbers of patients and conditions including patients' post-myocardial infarction, atrial fibrillation, DVTs and other disorders. While it is a very effective drug in these conditions, it can also have serious side effects, e.g. severe haemorrhage. These side effects are related to the International Normalised Ratio (INR) level, which measures the delay in the clotting of the blood caused by the warfarin. While the "normal" INR is 1, the specific range of INR values depends on the disease and the clinical conditions. Warfarin monitoring aims to stabilise the INR within set limits to help prevent serious side effects while maximising effective treatment.

4. Aims

The overall aims of this service are to improve patient access to safe and effective Warfarin initiation through collaboration between the patients GP and the provider service.

The CCG is commissioning a community based initiation 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).
- 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 – INR Star) at all service delivery points.
- Undertake reviews for patients on warfarin medication
- Information flow between the service provider and patient's GP practice should be secure and electronic
- The service delivery should cover people who are housebound and disabled
- Healthcare professionals who initiate, monitor and / or review anticoagulation therapy must have the appropriate training, skills and competencies to meet the requirements of their role having undertaken an accredited online course(s).
- The service must provide value for money to the CCG
- Meet local key performance indicators (KPIs)

5. Service outline

5.1 Service description/care pathway

The CCG wishes to commission a single delivery model that provides value for money to deliver the comprehensive service.

The full service is required to cover:

- Assessment of all new patient referrals, for patients not registered with the provider practice, 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 may be done collaboratively with the patient's GP, and may include the patient/ carer.
- When a patient is referred to the provider for initiation of Warfarin they will prescribe medication and will be the initial point of contact for the patient and will determine with the patient which is the most appropriate monitoring option.
- Equivalent services will be provided in the homes of patients who are housebound.
- All clinical reviews and onward referrals will be in line with local clinical pathways.
- The provider must be able to pass on all data collected, including personal identifiable data, to the patient's GP practice electronically via secure system (NHS mail to NHS mail).

5.2 Overall service requirements

- Service risk assessment
- Staff training, skills and competency assessments
- Clinic times/appointment system and availability
- Patient register identifying patients not registered with provider practice
- Call and recall system for Warfarin patients
- Follow up patients that do not attend (DNA)
- Provision of expert clinical input to initiation/change of anticoagulation therapies
- Initiation of Warfarin for appropriate patients
- Prescription of Warfarin medication and testing strips
- Prescription of injectable anticoagulants in line with bridging plan when patient has their first clinical appointment where required.
- Monitoring, dosing and cessation of Warfarin
- Provision of equivalent service to housebound Warfarin patients
- Patient education
- Documentation and electronic sharing of clinic information with patient's GP practice
- Clinical reviews and reassessments for Warfarin patients in line with local care pathways.
- Liaison with secondary care where required
- Liaison with other health and social care professionals where necessary
- 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
- Reporting and learning from serious incidents.
- Implementing action, where appropriate, on the results of safety and quality monitoring.

5.3 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 a full service risk assessment, in line with NPSA guidance.
- 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 all times that initiation clinics are running. This is to ensure all patients' anticoagulation therapy can be initiated and 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.
- Adhere to policy documents outlined in the SLA monitoring of Warfarin including annual audit review.
- 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.

5.4 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:

- The CCG purchased the initial near patient testing equipment to support GP practices. All subsequent near-patient testing equipment including POCT machines and testing strips for use in anticoagulation clinic or when visiting domiciliary patients must be purchased by the provider.
- 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)

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 if required.

The service provider must undertake internal and external quality assurance as appropriate.

5.5 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 GP systems

5.6 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 visit, the service provider must take all necessary equipment with them to provide the full service at this location.

5.7 Population covered

Patients registered with Mercheford House and Riverside Practice who require initiation of Warfarin and patients registered with Trinity Surgery and Clarkson Surgery, Wisbech who require initiation of Warfarin.

5.8 Clinic Reviews

5.8.1 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.
- 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 patient's GP may be required to fully complete the review in complex cases.
- It is the responsibility of the provider to call warfarin patients for their review.
- All reviews should be fully documented and the patient's GP informed, 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.

5.8.2 Any acceptance and exclusion criteria and thresholds

The fee will be paid for new patients (not registered with the provider practice) who have never had Warfarin. The fee cannot be claimed for restarting after stopping treatment due to a high INR or other management issues.

5.8.3 Interdependence with other services/providers

NHS Acute Trusts, Riverside Practice, Mercheford House Surgery March, Trinity Surgery, Wisbech; Clarkson Surgery Wisbech.

6. Accreditation

Those doctors who have previously provided services similar to this service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the service shall be deemed professionally qualified to do so.

7. Untoward events

It is a condition of participation in this service that practitioners will give notification to the Commissioner clinical governance lead of all emergency admissions or deaths of any patient covered under this service, where such admission or death is or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition. This must be reported within 72 hours of the information becoming known to the practitioner. This is in addition to a practitioner's statutory obligations.

8. Pricing and Payment Arrangements

- Pricing Arrangements

The provider will receive the sum of **£60.60 per patient** for initiation of Warfarin for patients **who are not registered** at their GP practice.

- Payment Arrangements

Practices will be commissioned based on indicative levels of activity using data from the previous years outturn. Practices will receive 6 monthly payments based on the total indicative budget for the year with any adjustments to be made at year end if necessary

9. Activity Reporting

Practices are required to report the number of non registered patients who have received warfarin initiation in the relevant quarter via the Practice Commissioning Statement to capccg.enhancedservices@nhs.net by the 15th day of the following month, following Quarter end.

If Practices require help or advice on clinical recording, coding and reporting, please contact The Primary Care Information team via the following email address: capccg.primarycareinformation@nhs.net

10. Payment Verification

Practices entering into this contract agree to participate fully in the post payment verification/validation process determined by the Commissioner and LMC. Practices should ensure that they keep accurate records to ensure a full and proper audit trail is available and Practices are encouraged to utilise Practice computer systems to enable this condition to be met.

11. Performance

The CCG reserves the right to suspend the commissioning of this service where there are concerns around compliance and patient safety.

12. Safeguarding Adults

It is important that practices protect adults from avoidable harm (as defined in Safeguarding Adults guidelines) including safeguarding training, training on the Mental Capacity Act and Deprivation of Liberty. A Safeguarding lead should be identified in each practice.

13. Care Quality Commission (CQC)

The provider must meet CQC standards and where appropriate be registered with the Care Quality Commission (CQC). The standards and the relevant services are contained in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations 2014.

14. Termination

Should either party wish to terminate this agreement, a minimum period of 3 months notice must be provided in writing.

15. Signatories to the Agreement

Practices wishing to provide this service are required to complete and sign the application form, and return to the Commissioner for consideration.