SCHEDULE 2 – THE SERVICES
A. Service Specifications

Service Specification No.	**03-CVDS-0043 v2**
Service	**Primary and Community Care Anticoagulation Service**
Commissioner Lead	**Primary and Community Care Commissioning and Contracting**
Provider Lead	**Primary and Community Care**
Period	**From 01/04/2023** *(v1 Primary Care Anticoagulation Service 01/04/2015 – 31/03/2023)*
Date of Review	***This service specification should be reviewed every 2 years unless new guidance or legislation dictates a review any sooner.***

1. Population Needs

1.1 National/local context and evidence base

Anticoagulant medication is used to prevent or treat thromboembolism predominantly in patients with atrial fibrillation (AF), deep vein thrombosis (DVT), pulmonary embolism (PE) and prosthetic heart valve.

Recognition and treatment of AF is of particular importance as strokes due to AF are eminently preventable. Atrial Fibrillation is the most common heart rhythm disorder, affecting approximately 2% of the adult population and estimates suggest prevalence is increasing. If left untreated it is a significant risk factor for stroke and is estimated, it is responsible for approximately 20% of all of strokes.

The NHS Long Term Plan commits to the prevention of 150,000 strokes, heart attacks and dementia cases by 2029 through the earlier detection and treatment of CVD risk factors. The latest figures regarding AF and anticoagulation can be found on the DiiS.

The NICE guidance for AF Management and Diagnosis (NG196) can be found below in 4.1

There are two main types of oral anticoagulants: Vitamin K antagonists (VKAs) and direct oral anticoagulants (DOACs).

Warfarin, the most used VKA, is a coumarin derivative that act by inhibiting vitamin K depending clotting factors in addition to the anticoagulant proteins. Warfarin has been used for decades as an anticoagulant. Warfarin is licensed for prophylaxis of embolization in rheumatic heart disease and atrial fibrillation, prophylaxis after insertion of prosthetic heart valve, prophylaxis and treatment of venous thrombosis and PE and transient ischaemic attacks (TIAs).

DOACs (apixaban, dabigatran edoxaban and rivaroxaban) are anticoagulants with a novel mode of action: apixaban, edoxaban and rivaroxaban are direct and reversible inhibitors of factor Xa. Dabigatran is a reversible inhibitor of free thrombin, fibrin bound thrombin and thrombin-induced platelet aggregation. Apixaban, dabigatran edoxaban and rivaroxaban may be prescribed instead of warfarin for prevention stoke and systemic embolism in adults with non-valvular AF with at least one risk factor such as heart failure, hypertension, previous stroke or TIAs, 75 years or older or diabetes mellitus. In addition, these group of drugs are also licenced for treatment of, and prevention of recurrence of DVT and PEs.

DOACs do not require regular international normalised ratio (INR) monitoring. Although regular follow up is required to review treatment, assess for adverse effects such as bleeding and thromboembolic events and provide advice and information.
The provision of anticoagulation services varies across Dorset. In the East of the County services are based in secondary care. In the west and north of the County services are predominantly provided in primary care either by GP practices or by Dorset Health Care (DHC) who run nurse-led clinics in several locations.

2.

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

The key outcomes of this service are:

- standardised, safe and clinically affective management of patients receiving Warfarin or DOAC therapy
- optimal patient concordance with 65% of INR's of therapeutic range (TTR) following the initial induction period on Warfarin
- collaborative working between primary and secondary care services
- reduced anticoagulation related ED attendances and admissions with associated cost savings
- efficiency and value for money
- positive patient/user experience

3. Scope

3.1 Aims and objectives of service

The aims of the service are:

- to provide standardised and clinically effective anticoagulation management in primary care for patients receiving DOACS, Warfarin and other vitamin K antagonists
- to maximise drug compliance and minimise risks for people on anticoagulation therapy

The key objectives will be:

- to work to locally agreed clinical acceptance/exclusion criteria for managing patients in a primary care service (see in 3.3)
- to work to local policies and procedures including management of patients undergoing elective procedures including DC cardioversion, dental procedures and surgery
- to be able to access to specialist advice and guidance for primary care services to support the management of complex patients

- to work to agreed pathways for referring patients to secondary care specialist anticoagulation services if clinically indicated
- to take over the management of patients that are discharged from secondary care services if clinically appropriate with adequate, timely, standardised discharge information
- to work to an agreed local pathway for management of out-of-range INR and timely access to Vitamin K if required
- to consistently use NHS Dorset approved (INR star or DAWN) Computerised Decision Support Software (CDSS) to support Warfarin dosing to assess, where appropriate, bleeding risk using NICE recommended screening tools.
- to ensure that patients are given standardised high-quality information about anticoagulants to enable them to be fully involved in decisions about their care and improve compliance to prescribe appropriate treatment for each indication from the Dorset formulary. Where more than treatment is suitable, the agent with lowest acquisition cost is prescribed.
- to apply standardised Quality Assurance procedures for 'Point of Care' (POC)) INR testing
- to assess service performance by applying meaningful outcome measures including use of PRIMIS AF GRASP and the Warfarin Patient Safety Tool
- to access formalised training programmes and annual updates at an appropriate level for all healthcare professionals working in primary care anticoagulation services
- to work to agreed pathways for referring to secondary care specialist anticoagulation services for advice if clinically indicated
- to access formalised training programmes and competency assessment and ensure access to annual updates at an appropriate level for all healthcare professionals working in primary care anticoagulation services
- Ensure anticoagulant dose management is provided by trained health care professionals
- Primary care anticoagulation services will be predominantly nurse led by a trained nurse who has undergone training and supervision
- The nurse led anticoagulant service will have appropriate clinical supervision

3.2 Service description/care pathway

Primary care anticoagulation services will be provided in GP practices or community clinics in convenient locations to provide equitable access for patients and support the care closer to home principle.

The service will be available on working days for 52 weeks of the year with plans for cover of leave (both anticipated and unanticipated) and succession planning for staff turnover. Clinics will be held at times that reflect patients' needs and preferences whenever possible taking account of the general service requirements.

Primary care anticoagulation services will be predominantly nurse led with appropriate clinical supervision.

INR blood tests will be predominantly undertaken using a POC device.

Provision for housebound patients will include POC INR testing by appropriately trained district nurses with subsequent Warfarin dosing and advice by the appropriate primary care anticoagulation service.

Primary care anticoagulation services will be supported by secondary care services to:

- provide clinical advice and guidance to support the management of complex patients
- manage clinically critical patients

- provide INR testing from venous samples

Referral Routes

Patients can be referred to primary care anticoagulation services through several different routes:

- via a GP or secondary care clinician for low dose Warfarin induction not requiring heparin cover eg. for AF
- via the GP or secondary care clinician for commencement of DOAC
- After hospital induction of anticoagulation for ongoing maintenance. Patients on warfarin will normally be transferred from hospital care when stabilised and no longer need daily INRs
- via a DVT service for ongoing monitoring of Warfarin after initiation
- on-going monitoring of new-to-area patients who are already established on Anticoagulation

Care Pathway

The key elements of care pathway are:

- to initiate warfarin for suitable patients in line with locally agreed clinical guidelines in 3.3
- prepare treatment plan with each patient which gives the diagnosis, planned duration and therapeutic range to be obtained and review annually or as clinically appropriate
- to undertake INR tests at the frequency and length of time between tests that is clinically appropriate based on individual patient clinical need and INR stability; (the maximum recommended length of time allowed between INR tests is 12 weeks (BCSH Guidelines 1998) with the exception of mechanical heart valves where the maximum recommended length of time is 8weeks)
- to undertake Warfarin dosing supported by the CDSS that has been approved by NHS Dorset CCG (INR star or DAWN) and make the patient record inactive/dormant on the CDSS when treatment is stopped
- to educate patients in understanding their treatment, in terms of their condition, target range for INR, the effects of over and under anticoagulation, bleeding risks, diet, lifestyle and drug interactions
- to provide patients with appropriate supporting written information when necessary throughout the course of their treatment
- to review and stop anticoagulation when planned duration of treatment is completed or refer back to GP for review of treatment plan as clinically appropriate
- to identify patients with specific needs ie. poor compliance and/or unstable INR control and consider alternatives
- to provide education to patients on DOAC and assurance of drug compliance on commencement and at 6 months following commencement of treatment
- to provide education to patients on DOAC in understanding their treatment, in terms of their condition, the need to take their drug as prescribed, the risks of over and under anticoagulation, bleeding risks (continuing monitoring of DOAC as NICE guidelines as detailed in 4.1), availability of reversal, diet, lifestyle and drug interactions and assurance of drug compliance on commencement and at 6 months following commencement of treatment

In delivering the service the provider will:

- maintain a register of all patients receiving Warfarin and DOACs and ensure that adequate information is entered into the life-long patient record including any significant events
- ensure that patients are managed in clinically safe and appropriate locations that take account of clinical risk and complexity
- follow clear referral pathways between primary care, specialist services and vice versa
- Act promptly to patients with bleeding problems and/or INR > 8
- Patients who have Mechanical Heart Valves and INR<1.8 or patients within 4 weeks of DVT or PE should be considered for Enoxaparin (Inhixa®) cover.
- ensure there are processes in place to monitor adverse incidents and significant events eg. admissions to secondary care with bleeds associated to anticoagulation therapy
- ensure on-going review of procedures and clinical protocols to ensure they reflect safe practice
- link with secondary care Anticoagulation Treatment Group through a designated primary care representative to take forward developments, issues, concerns and any adverse incidents related to anticoagulation.

Consideration should be given to the epidemiology of the conditions the patient has/or is being treated/assessed for and steps should be in place to ensure that areas of risk are managed due to ethnicity and health inequalities. This could also include opportunistic screening for associated diseases they may be at risk from.

Administrative Processes

The service will have efficient processes in place to deal with all administration including a bookings and appointments system and suitable processes to handle and manage variations in demand (eg. seasonality)

The service will have procedures in place to follow up and/or recall patients as appropriate and to manage patients who do not attend or cancel appointments.

Quality Assurance

The service will undertake appropriate Internal Quality Control (IQC) and External Quality Assurance (EQA) of POC INR testing equipment and staff in line with the locally agreed Anticoagulation Quality Control Policy Appendix 1.

Patient Information

The service will provide both verbal and written information in a timely manner and in a format which is understood and appropriate for the individual needs of the patient.

The information provided will support patients to:

- enable patients to be fully informed about their condition and treatment plan
- reduce the risks associated with anticoagulation therapy
- promote patient compliance and effectiveness of treatment

All patients on Warfarin treatment will be provided with the NPSA Oral Anticoagulation Therapy Pack including the yellow book.

All patients on anticoagulation therapy including both Warfarin and NOACs will be provided with a Yellow Anticoagulation Alert Card and advised to carry it at all times.

Staff Training

Anticoagulation services will only be managed by appropriately trained healthcare professional that have the training skills and competencies to meet the requirements of their role.

Staff that are involved in making decisions about Warfarin dosage must have undergone a robust education and training programme. Staff must be appropriately and suitably trained which must include:

- Anticoagulant mode of action; indications for use; side effects and interactions
- Physiology of the clotting cascade
- AF and VTE and rationale for use of anticoagulation
- Warfarin mode of action; indications for use; side effects and interactions
- Principles of POC testing; INRs and quality assurance
- guidelines for management of anticoagulation; protocols (including bridging), and referral criteria;
- instruction on use of CDSS software; audit procedures;

3.3 Population Covered

As stated below in 3.4

3.4 Any acceptance and exclusion criteria.

The provider will offer an anticoagulation service to patients aged 16 years and over who are registered with NHS Dorset GPs within the agreed localities.
Patients will be accepted in primary care anticoagulation services for:

- Slow warfarin initiation and ongoing management for AF
- Ongoing management of patients on anticoagulation
- Initiation, education and follow up assessment after commencement of DOACs
- Transfer of patients on warfarin onto a DOAC if clinically appropriate

The following clinical criteria would exclude patients from primary care anticoagulation services:

- Patients requiring rapid programme of Warfarin initiation post heart valve surgery, stroke, DVT or PE until daily INRs are no longer required

These exclusions are not exhaustive, and it is anticipated that the provider will apply clinical judgement in referring patients to secondary care specialist services appropriately.

3.5 Interdependence with other services/providers

Primary care anticoagulation services will work in a collaborative way with relevant specialists, and departments in secondary care including:
Pathology
Pharmacy
Haematologists
Cardiologists
Emergency Departments
Secondary care specialist services

Other key stakeholders will include:

GP practices
DVT service providers
District nurses
Nursing Homes
Community Pharmacy
Commissioners
Services users
Relevant networks

Relevant Networks
Primary care anticoagulation services will link with the following local networks and groups including:

NHS Dorset Medicines Management
NHS Dorset Cardiology Oversight Group
NHS Dorset Primary Care Commissioning and Contracting

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

NICE CG180 Atrial Fibrillation: The management of Atrial Fibrillation June 2014
This has been replaced with NG196 which was published on 27 April 21 as below
Atrial Fibrillation/ Diagnosis and Management/Guidance / NICE

CG144 - Venous Thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing (NICE 2012). Replace with NG158
Venus thromboembolic disease / diagnosis / management and thrombophilia testing / guidance / NICE

NICE Patient Decision Aid - Atrial fibrillation: medicines to help reduce your risk of a stroke –what are the options?
Anticoagulants/Prescribing Information/Atrial Fibrillation/CKS/NICE
https://bnf.nice.org.uk/treatment-summaries/oral-anticoagulants/

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

National Patient Safety Alert 18 – Actions that can make anticoagulation safer
MRHA guidelines – Management and use of IVD point of care test devices
Management and use of IVD point of care test devices – GOV.UK (www.gov.uk)

BCSH Guidelines on oral anticoagulation with warfarin – fourth Edition 2011
Guidelines on oral anticoagulation with warfarin – fourth edition (wiley.com)

4.3 Applicable local standards

5. Location of Provider Premises

The Provider's Premises are located at:

As defined within the main contract

6. Applicable Personalised Care Requirements

6.1 Applicable requirements, by reference to Schedule 2M where appropriate