SCHEDULE 2 – THE SERVICES

A. Service Specifications (B1)

Service Specification No.	03_CVDS_43
Service	Primary Care Anticoagulation Service
Commissioner Lead	CVDS CCP
Provider Lead	
Period	01/04/2015 – 31/03/2017
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

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.

- Prevalence rate in primary care is 1.2%, which equates to just over 600,000 patients in England and 9,000 patients registered with Dorset GPs have AF
- 12,500 strokes per year are thought to be directly attributable to AF.
- The estimated total cost of maintaining one patient on warfarin for one year, including monitoring, is £383.
- The cost per stroke due to AF is estimated to be £11,900 in the first year after stroke occurrence.
- NICE estimate that approximately 40% of patients in whom warfarin is indicated are not receiving it, amounting to some 166,000 patients nationally.
- The average cost of social care in final year of life for person with AF is £3,410 (Unit costs of health and social care 2013,PSSRU)

The lifetime risk of developing AF is one in four after the age of 40 with some 70% of cases occurring in individuals aged 65 -85 years. AF is the second largest cause of Stroke and causes one in five strokes – one in three after the age of 80. Strokes caused by AF lead to more permanent disability and cost 1.5 % more than other causes of Stroke. The diagnosis of AF rises with age with numbers set to double by 2050.

The most commonly used anticoagulant in the UK is Warfarin. Treatment with Warfarin is usually long term and patients require regular education and monitoring for drug adherence and avoidance of side effects. The number of patients on permanent anticoagulant therapy has increased rapidly over the last few years as a result of NICE guidance on the treatment of patients with AF (CG180). This has

created a greater demand on hospitals for monitoring purposes.

Monitoring of Warfarin therapy in a primary care setting has shown to lead to quicker stabilisation of the patient and maintenance of therapeutic range. It has also shown to improve patient education, compliance and overall patient satisfaction.

Since 2008 a range of new oral anticoagulants (NOACs) have been available for use in AF. NICE appraisals of each NOAC have recommended they be made available as options to treat non-valvular AF when certain criteria are met. Further NICE guidance recommends NOACs as a treatment option in DVT and PE. The biggest advantage of NOACs is the absence of need for INR monitoring although patients still require education and ongoing monitoring of adherence. NICE approval has seen rapid growth in the use of NOACs and this is expected to continue as prescription in a range of indications becomes more commonplace.

Local context

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.
The table below shows the number of active patients being seen in DHC anticoagulation clinics in West Dorset which have increased by 4% since April 2014:

DHC Clinic location	Total active patients at November 2014/15
Bridport Hospital	417
Wareham Hospital	195
Dorchester:	
Frederick Treves	423
Crossways Surgery	16
Market Pharmacy	173
Weymouth:	
Littlemoor Health Centre	391
Wyke Regis Health Centre	143
Lane House Surgery	92
Southill Church/Westhaven Hospital	105
Cross Road Surgery	137
Chickerall Surgery	86
Royal Crescent and Preston Road Surgery	125
Weymouth Community Hospital	153
Housebound patients	347
Patient Self Testing	15
Dosing only for GP practices	28
Total active patients	**2846**

The following table shows the current number of active patients seen by GP anticoagulation services which has increased by 6% since April 2014. The available data does not identify housebound patients or those who are self-testing from the

total number of active patients.

GP practice	Active patients at Quarter 2, 2014/15
Gillingham Medical Practice	239
Bere Regis Surgery	96
Sandford Surgery	43
Providence Surgery	64
Corfe Castle Surgery	44
Swanage Medical Centre	344
Wellbridge Practice	133
Broadmayne Surgery	40
Cerne Abbas Surgery	100
Milton Abbas Medical Practice	74
Puddletown Surgery	86
Apples Medical Centre	143
Bute House Surgery	142
Eagle House Practice	144
New Land Surgery	155
Stalbridge Surgery	123
Sturminster Newton Medical Centre	244
Whitecliff Group Practice	355
Yetminster Health Centre	98
Barton House Medical Practice	167
Charmouth Medical Practice	72
Lyme Bay Medical Practice	62
Lyme Regis Medical Centre	99
Maiden Newton & Tunnel Rd Surgeries	171
Portesham Surgery	85
Royal Manor Health Care	286
Total active patients	**3609**

There is likely to be a 5% growth in activity in future.

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

The key outcomes of this service are:

- standardised, safe and clinically affective management of patients receiving Warfarin or NOAC 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 Warfarin and other vitamin K antagonists;
- to maximise drug compliance and minimise risks for people on anticoagulation therapy including NOACs.

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 CCG approved (INR star or DAWN) Computerised Decision Support Software (CDSS) to support Warfarin dosing;

- 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 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;

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 patients who do not meet the clinical criteria for anticoagulation monitoring in primary care;
- provide INR testing from venous samples;

Clinical Acceptance Criteria

Patients will be accepted in primary care anticoagulation services for:

- slow warfarin initiation and ongoing management for AF;
- ongoing management following two stable INR results in therapeutic range;
- education and assessment of compliance on commencement of NOAC.

Clinical Exclusions

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 2 INR's in therapeutic range are achieved
- patients with poor control – consistently unstable INR results despite the full support of the community anticoagulation management;

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.

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 e.g. for AF;
- via the GP or secondary care clinician following commencement of NOAC;
- After hospital induction of Warfarin for ongoing maintenance. Patients will normally be transferred from hospital care when stabilised with a minimum of two consecutive INRs in TTR;
- via a DVT service for ongoing monitoring of Warfarin after initiation and at least 2 consecutive INRs in TTR;
- on-going monitoring of new-to-area patients who are already established on Warfarin.

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 i.e. poor compliance and/or unstable INR control and refer back to the GP to consider alternatives;
- to provide education to patients on NOAC 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 NOACs 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;
- ensure there are processes in place to monitor adverse incidents and significant events e.g. 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.

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 (e.g. 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. Training should include:

- 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;
- the new oral anticoagulants

3.3 Any acceptance and exclusion criteria and thresholds

The provider will offer an anticoagulation service to patients aged 16 years and over who are registered with Dorset CCG GPs within the agreed localities.

Patient will be accepted by primary care anticoagulation services in line with the locally agreed clinical acceptance criteria and exclusions in 3.1

3.4 Interdependence with other services/providers

Primary care anticoagulation services will work in a collaborative way with relevant specialists, and departments in secondary care including:

- Haematologists
- Cardiologists
- Pathology
- Pharmacy
- Emergency Departments

Other key stakeholders will include:

- GP practices
- DVT service providers
- District nurses
- Nursing homes
- Community Pharmacy
- Commissioners
- Services users

Relevant networks

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

- Dorset Anticoagulation Treatment Group
- Dorset CCG Medicines Advisory Committee and Cardiology Working Group
- Dorset CCG Long Term Conditions, Frail Elderly and End of Life Working Group

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

NICE CG180 Atrial Fibrillation: The management of Atrial Fibrillation June 2014

CG144 - Venous Thromboembolic diseases: the management of venous thromboembolic diseases and the role of thrombophilia testing (NICE 2012).

NICE Patient Decision Aid - Atrial fibrillation: medicines to help reduce your risk of a stroke –what are the options?

NICE Quality Standard 29 - Diagnosis and management of venous thromboembolic diseases.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. 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
BCSH Guidelines on oral anticoagulation with warfarin – fourth Edition 2011

4.3 Applicable local standards

5. Applicable Quality Requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

None

6. Location of Provider Premises

6.1 The Provider's Premises are located at:

As defined within the main contract.

7. Individual Service User Placement