SCHEDULE 2 – THE SERVICES

A. Service Specifications (B1)

Service Specification No.	03_CVDS_36
Service	Community DVT Service
Commissioner Lead	CVDS CCP
Provider Lead	
Period	01/12/2014 – 31/03/2016
Date of Review	October 2015

1. Population Needs

1.1 National/local context and evidence base

Evidence base

Venous thromboembolic (VTE) diseases cover a spectrum ranging from asymptomatic deep vein thrombosis (DVT) to fatal pulmonary embolism (PE). They are the result of a blood clot forming in a vein. If the blood clot dislodges and travels to the lungs, this can lead to a potentially fatal PE. Even if blood clots are non-fatal, they can still result in long-term illness, including venous ulceration and development of a post-thrombotic limb and have a significant impact on quality of life.

Major risk factors for blood clots include cancer and thrombophilia, an inherited or acquired disorder in which the blood is prone to clot abnormally. Other risk factors include a history of DVT, age over 50 years, recent surgery/serious injury, IV drug use, obesity, prolonged travel, acute medical illness, immobility and pregnancy. NHS England has identified VTE prevention as a national patient safety priority and previously CQUIN measures required acute Trusts to audit DVT/PE occurring within 90 days of a secondary care episode.

There are on average 850,000 reported thromboembolic patient episodes per year in England and two thirds of these are DVT. Nationally it is estimated that two thirds of patients with suspected DVT present in primary care and of these only 12-20% will have a positive diagnosis.

Whilst a confirmed DVT is accepted to require urgent medical attention, 85% of presenting cases are not medical emergencies and the development of clinical probability tools and near patient testing devices mean that DVT assessment and treatment can be safely provided in settings other than hospitals.

NICE Guidance published in June 2012 provides key recommendations in the diagnosis of and management of DVT. The recommendations for diagnosis include:

- Clinical assessment and 2 level Wells Score
- D-dimer testing for patients with Wells Score <2 (low probability of DVT)
- Proximal leg vein ultrasound scan for patients with Wells score >2 (high probability of DVT) or a positive D-dimer.
- Interim anticoagulation with Low Molecular Weight Heparin (LMWH) for patients who cannot have a proximal leg vein ultrasound scan (USS) within 4 hours and the ultrasound to be performed within 24 hours.
- Repeat ultrasound scan 6–8 days later if negative for all patients with a positive D-dimer test.

The recommendations for the treatment of confirmed DVT are:

- Appropriate anticoagulation therapy
- Below-knee graduated compression stockings if clinically appropriate
- Consider investigations for cancer for patients diagnosed with unprovoked DVT and thrombophilia screening for patients aged < 45years if clinically indicated.

Further NICE guidance was published in July 2013 recommending Rivaroxaban as a treatment option for DVT with further licencing of additional NOAC drugs anticipated in late 2014.

1.2 Local context

Data collected from current Dorset service providers suggests a prevalence of between 3 and 4.5 patients per thousand presenting annually in primary care with suspected DVT. This equates to approximately 2,300 to 3,500 patients annually for the population of Dorset. Based on these estimations the prevalence annually by GP locality is provided below:

GP Locality	GP list size 30/09/2013	Predicted number of patients	
		3 per 1000 population	4.5 per 1000 population
Bournemouth North	65,152	195	293
Central Bournemouth	64,711	194	291
Christchurch	54,153	162	244
Dorset West	40,938	123	184
East Bournemouth	59,550	179	268
East Dorset	70,342	211	317
Mid Dorset	42,606	128	192
North Dorset	86,121	258	388
Poole Bay	71,944	216	324
Poole Central	61,560	185	277
Poole North	52,045	156	234
Purbeck	33,413	100	150
Weymouth & Portland	74,181	223	334
Grand Total	**776,716**	**2,330**	**3,495**

Available activity data suggests that approximately 50% of patients who initially present with symptoms suggestive of DVT will require diagnostic ultrasound to obtain a definitive diagnosis and 20% of the total presenting patients will have a confirmed DVT.

For planning purposes the annual DVT activity in primary care is outlined in the table below. These activity assumptions may be cautiously high in that the West GP's have

suggested approximately 30% of patients are referred for ultrasound with only 12-15% of the total presenting patients having a confirmed DVT.

Suspected DVT - Annual Activity Assumptions	3/1000 Population	4.5/1000 population
Total presenting patients	2,330	3,495
Number requiring ultrasound scan(50%)	1,165	1,748
Number of confirmed DVT (20%)	466	699

In Dorset, DVT services are community and GP practice based in the predominantly rural west and north of the County and secondary care based in the urban conurbations of Bournemouth and Poole in the east. The table below outlines DVT service provision for patients who present in primary care in each locality in Dorset:

GP Localities	Service provider
Bournemouth, Poole, East Dorset and Purbeck	Secondary care –Royal Bournemouth Hospital(RBH) and Poole Hospital (PHT)
Mid, West and North Dorset , Purbeck (1 Practice only)	GP practices
Weymouth and Portland	Weymouth Walk-in centre

Dorset CCG needs to ensure these services meet current NICE guidelines and patient outcomes and costs are consistent and offer value for money across Dorset. A review of current services was therefore undertaken by the Cardiovascular Clinical Commissioning Programme (CVD CCP) to understand the pathways for patients that present in primary care with suspected DVT and how these services could be enhanced or redesigned to provide optimal care for this patient group. The review has informed the development of this service specification which covers the DVT pathway from investigation and diagnosis through to anticoagulation therapy to therapeutic range, follow-up and VTE audit. This is in line with Dorset CCG and patient aspirations to provide access to community services across the County with appropriate specialist support when required.

Anticoagulation services are an integral part of the DVT pathway. In Dorset, these are currently provided by acute Trusts in the east of the County and by individual GP practices and Dorset Health Care NHS Foundation Trust (DHUFT) in the west. A review will also be undertaken by the CVD CCP to ensure these services are safe, accessible and convenient for patients to support the care closer to home principle.

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 that would be expected are:

- equitable access to DVT services across Dorset that offer value for money in and clinically appropriate locations that take account of staff skills and patient safety;
- patients seen, diagnosed and treated in line with NICE guidance;
- effective interface between DVT and associated community and specialist services;
- a reduction in referrals, attendances and admissions to hospitals with associated cost savings;
- a reduction in hospital provoked DVT through effective VTE audit;
- care as close to home as possible with positive patient experience.

3. Scope

3.1 Aims and objectives of service

The aim of this service specification is to provide comprehensive outpatient services for the diagnosis and management of patients presenting in primary care with suspected DVT.

The objectives of the service are:

- to provide 7 days a week access to DVT services in an out-patient setting;
- to provide services that meet the needs of the local population taking account of the geographical locations of each GP locality;
- to provide DVT services in line with NICE guidance including waiting times;
- to reduce inappropriate referrals through effective clinical assessment and identification of patients with suspected DVT in primary care;
- to ensure that patients are seen diagnosed and treated in a clinically safe and appropriate location that takes account of clinical risk and complexity;
- to provide safe and effective anticoagulation treatment with appropriate specialist support when required;
- to ensure that patients receive appropriate follow- up if clinically indicated;
- to promote collaborative working between all providers of DVT and related

services including anticoagulation, radiology and community IV services;
- to provide DVT services that are supported by robust clinical governance arrangements;
- to reduce the incidence of hospital provoked DVT through robust VTE audit;
- to collect data in a standardised format that allows transparent analysis of patient outcomes, satisfaction and cost benefits;
- to provide patient centred care with appropriate verbal and written information for patients at all stages of the care pathway;
- to provide high quality patient experience.

The key principles for delivery of this service specification are:
- effective clinical risk assessment including Wells Score in primary care as part of GP core business;
- predominantly nurse led services with appropriate clinical supervision;
- 7 days a week access to community based services between 8am and 6pm;
- designated specialist DVT services to provide clinical support to community services and manage high risk/complex patients:
- locally agreed clinical guidelines and clinical exclusion criteria for the management of patients in a community setting;
- access to DVT assessment for housebound patients in their own home prior to referral for ultrasound if required;
- same day access to standardised 'point of care' (POC) or laboratory based D-dimer testing for all patients;
- implementation of appropriately licenced New Oral Anticoagulants (NOAC) as the preferred option for prophylactic and therapeutic treatment of DVT if clinically appropriate;
- 7 day GP direct access to ultrasound with 75% of scans performed within 24 hours and 100% performed within 48 hours of the patient presenting with suspected DVT;
- whole leg ultrasound to reduce the need for repeat investigation if the first scan is negative;
- referral to specified community IV services when a differential diagnosis of cellulitis is confirmed that requires administration of intravenous antibiotics;
- appropriate referral to secondary care specialists for patients requiring cancer investigation following unprovoked DVT or where there are clinical indications to undertake thrombophilia screening;
- reporting of provoked DVT within 90 days of hospital episode to the relevant acute Trust for Root Cause Analysis (RCA).
- a lead specialist service with responsibility for training, production of standardized patient information and links to VTE audit for ongoing learning across the County.

3.2 Service description/care pathway

The DVT service has been divided into 3 Tiers which reflect the level of DVT management and care that would be offered by the provider. It is anticipated that providers may include individual GP practices, locality or community clinics,

community hospitals and local acute trusts who may offer one or more Tiers of the service depending on staff skills and resources and the demographic of the local population.

DVT services will be predominately nurse led with appropriate clinical supervision and will be offered in outpatient venues and locations which meet the needs of the local population.

Tier 1 Community DVT – Daytime service
Weekday Community DVT services will be available from 8am to 6pm, 5 days a week

Locations may include GP practices, community hospitals/clinics or within local Acute Trust premises.

Providers offering a weekday service only (e.g. GP practices) will link with a specified out-of-hours Tier 1 Community DVT service within the GP locality to provide 7 days per week access for all patients as close to home as possible.

Tier 1 Community DVT – Out-of –hours service
Out-of hours DVT services will be available within each GP locality to support the delivery of 7 day access in an out-patient setting for all patients presenting in primary care.
Providers may include GP Out-of-Hours services and Emergency Care Practitioners (ECPs) who would follow the same DVT model of care but deliver the front end of the pathway through to booking of ultrasound and then refer the patient to a specified daytime DVT service for follow-up and ongoing management. (To be detailed in separate service specification)

Tier 2 Specialist DVT services
All Tier 1 DVT services will be supported by designated Tier 2 Specialist services to provide access for high risk and complex patients who are deemed clinically unsuitable to be safely managed in a community service.

It is anticipated that these services will be provided by Acute Trusts with a designated Consultant lead.

Specialist providers will also offer clinical support to community services including:
- general advice and guidance
- specialist support with anticoagulation management if required
- a point of referral to coordinate follow-up investigation for cancer and thrombophilia screening

Tier 3 Lead Specialist DVT Service
Dorset CCG is seeking one specialist service to act as lead for the County. The lead Specialist service will:
- oversee staff training and development across all Tier 1 DVT providers in Dorset to ensure that services remain safe and effective and in line with current best

practice;
- develop patient information for use in Tier 1 services;
- provide a key link to VTE audits between Tier 1 DVT services and relevant Acute Trusts to ensure that outcomes are shared to promote ongoing learning and a reduction in hospital acquired VTE;
- foster relationships across all key stakeholders.

Referral Sources

Referrals into the DVT service will be primarily received from GP practices and GP out-of-hours services.

This service specification does not specifically cover patients who present in secondary care general outpatients including orthopaedics and oncology, A&E departments and minor injury units although it is anticipated that care pathways for these patients will be developed over time to support timely care as close to home as possible.

Referral Route

All patients presenting in primary care with suspected DVT will be fully assessed to determine the appropriate care pathway for the patient and exclude other diagnoses prior to referral to a DVT service. This assessment will include:

1. Medical history and risk assessment
2. Physical examination
3. 2 level Wells Clinical Probability Score (see Appendix C)
4. Baseline renal and liver function

Patients presenting in GP practices that do not provide a DVT service will be referred to a specified DVT service within the GP locality.

Scope of Service

On receipt of a referral the DVT service will review the information against the agreed clinical guidelines and care pathway and a same day appointment arranged for all patients within 4 hours of receipt of the referral.

The diagnostic elements of the DVT service will include:

- undertaking standardized POC or lab based D-dimer testing for all patients with both low and high probability of DVT;
- initiation of prophylactic anticoagulation in accordance with the agreed Dorset CCG guidelines;
- arranging an ultrasound with the designated local provider and reviewing and acting upon the result.

Where a diagnosis of DVT is confirmed the service will include:

- initiation of therapeutic anticoagulation in accordance with the agreed Dorset CCG guidelines;
- provision of Class 2 knee length compression stockings in accordance with NICE guidelines;
- referral to specialist service for cancer investigations or thrombophilia screening if clinically indicated;
- reporting of DVT occurring within 90 days of admission to the relevant specialist in secondary care;
- Referral to local anticoagulation services for patients requiring long term anticoagulation beyond 3 months post DVT event.

Providers will ensure that the patient receives follow-up by the GP for alternative diagnosis if DVT diagnosis is negative. This may include referral to community IV services for antibiotic treatment if a differential diagnosis of cellulitis is confirmed.

High risk or complex patients deemed unsuitable for management in a Tier 1 service will be immediately redirected by phone to the designated Tier 2 Specialist service and the referrer and patient informed.

Patient information

DVT services should be patient focused and as such patients/carers and GPs should:

- know how to access the service;
- are provided with good quality information at each step of their pathway of care for diagnosis, management and treatment of their condition;
- have clear advice and information with contact details should their condition worsen;
- ensure that information is reinforced using the appropriate media including patient information and advice sheets.

Skills of Staff

The service shall have an appropriate staffing structure in terms of skill, experience and numbers and shall be delivered by appropriately qualified and trained individuals.

The provider will ensure that all clinical staff meet the CPD requirements of their professional and regulatory bodies, that they are competent to deliver the service and that their skills are regularly updated.

Clinicians carrying out the DVT Service work should demonstrate a continuing sustained level of activity, conduct regular audits, be appraised on what they do and take part in necessary supportive educational activities.

The provider will ensure that clinicians have access to appropriate supervision, mentorship and advice.

Performance and Activity Monitoring

The provider must ensure an appropriate record of activity is developed and maintained for audit and payment purposes and which meets the requirements of this service specification.

The provider will submit quarterly activity data to NHS Dorset CCG in respect of this service within 1 calendar month following the end of each quarter during the year.

3.3 Any acceptance and exclusion criteria and thresholds

DVT services will be accessible to all patients aged 18 years and over who are registered with Dorset CCP GP practices and meet the clinical guidelines.
These guidelines are to be agreed and will determine the criteria for which patients should be excluded from a community based level 1 service and will need referral to the specialist Level 2 service.
These exclusion criteria may include:

- Suspected PE
- Pregnant patient
- Groin pain
- Significant colour change of affected limb
- Involvement of whole leg

In addition, there will be some patients who will be excluded from community anticoagulation initiation, (e.g. intravenous drug users, patients with clotting disorders etc.)

The above list is not exhaustive and individual cases may be considered by GP for exclusion depending on clinical circumstances

3.4 Interdependence with other services/providers

All DVT services will work in a collaborative way to provide safe and effective care for patients and ensure smooth transfer between services when appropriate. Providers will effectively interface with other key services to deliver the DVT pathway including:

- Radiology
- Anticoagulation services
- Community IV services

Other key stakeholders will include:

- GP practices
- GP Out-of -Hours services
- Secondary care
- Service users
- Commissioners
- South West Ambulance Service

Relevant networks
Dorset CVD CCP
Dorset CCG Medicines Advisory Committee

1. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

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

NICE TA261- Rivaroxaban for the treatment of deep vein thrombosis and prevention of recurrent deep vein thrombosis and pulmonary embolism(July 2012)

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

Anticoagulation and Prescribing
The provider is responsible for safe systems for prescribing and medicines management as required for CQC outcome 9. Prescribing is the responsibility of the provider, and the provider is responsible for ensuring they have access to appropriately qualified medical or non-medical prescribers. The CCG will not provide PGDs or funding for training of non-medical prescribers to enable delivery of this service.

The provider will comply with the safety aspects of prescribing LMWH as detailed in NPSA compliance checklist – see Appendix A.

POC testing and Quality Assurance
All staff undertaking POC D-dimer testing must be adequately trained on the procedure, use of the equipment and interpretation of results.

The provider will be responsible for ensuring that POC D-dimer testing equipment is properly maintained and calibrated, and a record of patient identity, date and operator must be kept to create an audit trail. It is good practice also to be able to track the time of testing and lot number of test strip used for each patient should the need arise.

Cleaning procedures recommended by the manufacturer should be adhered to and health and safety standards should be followed at all times.

The Provider shall follow a prescribed Internal Quality Control (IQC) process in accordance with manufacturer's instructions to ensure that equipment is calibrated correctly and working accurately at all times.

4.3 Applicable local standards

The provider will comply with Dorset CCG Medicines Advisory Committee guidance for shared care guidance on prescribing of Rivaroxaban – see Appendix B.

2. Applicable quality requirements and CQUIN goals

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

The provider shall carry out bi-annual quality audits of the service. The results shall be reported to Dorset CCG. See Contract Reporting Requirements spreadsheet.

Providers will complete patient satisfaction surveys at least annually – to be agreed with the commissioner in terms of questions and sample size.

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

None

3. Location of Provider Premises

The Provider's Premises are located at:

4. Individual Service User Placement