SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	**03_CVDS_0036 v2**
Service	**Community DVT Service**
Commissioner Lead	**Primary and Community Care**
Provider Lead	**Primary Care and Community Care**
Period	**From 01/04/2023** *(v1 01/12/2014 – 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

The term venous thromboembolism (VTE) comprises deep vein thrombosis (DVT) and pulmonary embolism (PE). Failure to diagnose and treat VTE promptly can result in fatal PE. Although advances have occurred in the diagnosis and management of acute VTE, it remains an important cause of morbidity and mortality. The NHS Outcomes Framework indicator for hospital-associated thrombosis (HAT) covering the period 2018/19 suggests a rate of death attributed to HAT of 57 per 100,000 adult hospital admissions, equating to thousands of deaths.[1] Because of its wide variation in presentation, PE is frequently missed—autopsy studies suggest that PE was suspected in less than half of fatal cases.

NICE Guideline (NG) 158 on *Venous thromboembolic diseases: diagnosis, management and thrombophilia testing*, published in March 2020, updates and replaces NICE Clinical Guideline 144 (published in 2012, last updated 2015). It covers adults with suspected or confirmed DVT or PE. It does not cover children or young people aged under 18 years, or pregnant women.

Since the publication of the original guideline, direct-acting oral anticoagulants (DOACs), such as apixaban and rivaroxaban, have become an established part of the oral anticoagulation landscape for the management of VTE. All four licensed DOACs are recommended for the acute treatment and secondary prevention of VTE through the NICE Single Technology Appraisal (STA) process.

NICE has produced three helpful visual summaries covering the diagnostic pathways for DVT and PE and recommendations on the use of anticoagulation (see Figures 1–3). In addition, a useful resource impact report has been developed to support considerations around cost pressures and savings in the implementation of NG158.

Diagnosis and initial management of VTE

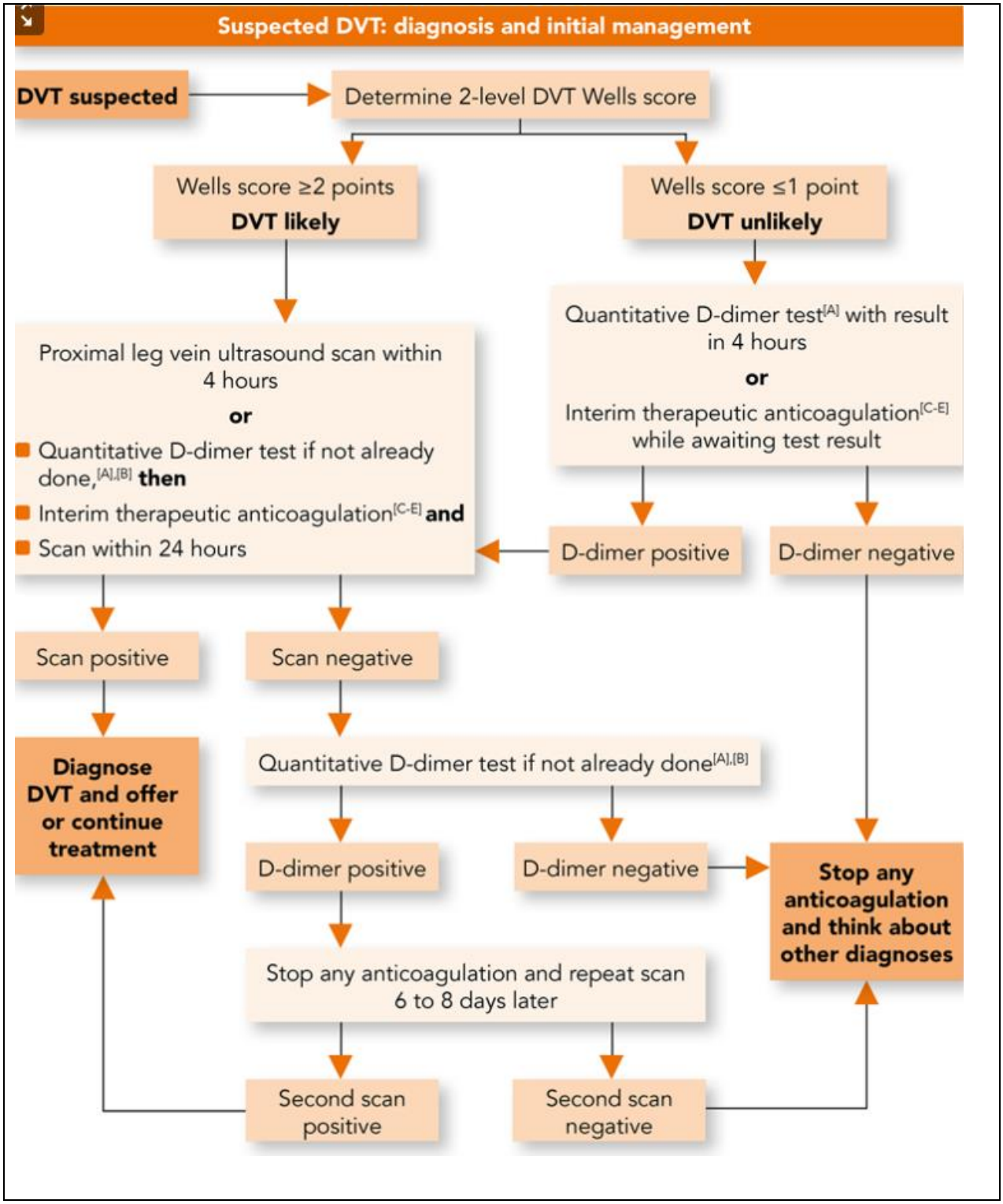
The diagnostic pathway in NG158 includes new recommendations on the use of point-of-care and age-adjusted D-dimer tests and the use of the PE rule-out criteria (PERC). In terms of

management, the key change is the recommendation to use DOACs in most cases, including in people with cancer.

Please note that not all of the treatments discussed in this article currently (May 2020) have UK marketing authorisation for the indications mentioned; see notes to the recommendations in NG158. The prescriber should follow relevant professional guidance, taking full responsibility for all clinical decisions. Informed consent should be obtained and documented. See the General Medical Council's guidance on *Good practice in prescribing and managing medicines and devices* for further information.

Diagnostic pathway for DVT

For people presenting with signs or symptoms of DVT, the guideline continues to recommend an assessment of their general medical history followed by a physical examination to exclude other causes (see Figure 1). NICE continues to recommend the 2-level DVT Wells score to estimate the clinical probability of DVT when an event has not been ruled out by general medical history and physical examination. A DVT Wells score of ≥2 is predictive of DVT and termed 'DVT likely'. Such patients should be offered a proximal leg vein compression ultrasound scan (CUS) with the results available within 4 hours if possible.


Suspected DVT: diagnosis and initial management
DVT suspected
Determine 2-level DVT Wells score
Wells score ≥2 points
DVT likely
Wells score ≤1 point
DVT unlikely
Proximal leg vein ultrasound scan within 4 hours
or
Quantitative D-dimer test if not already done,[A],[B] then
Interim therapeutic anticoagulation[C-E] and
Scan within 24 hours
Quantitative D-dimer test[A] with result in 4 hours
or
Interim therapeutic anticoagulation[C-E] while awaiting test result
D-dimer positive
D-dimer negative
Scan positive
Scan negative
Diagnose DVT and offer or continue treatment
Quantitative D-dimer test if not already done[A],[B]
D-dimer positive
D-dimer negative
Stop any anticoagulation and think about other diagnoses
Stop any anticoagulation and repeat scan 6 to 8 days later
Second scan positive
Second scan negative

This is a summary of the recommendations on diagnosis and management from NICE's guideline on venous thromboembolic diseases. See the original guidance at www.nice.org.uk/guidance/NG158.

[A] Laboratory or point-of-care test. Consider age-adjusted threshold for people over 50

[B] Note that only one D-dimer test is needed during diagnosis

[C] Measure baseline blood count, renal and hepatic function, PT and APTT but start anticoagulation before results available and review within 24 hours

[D] If possible, choose an anticoagulant that can be continued if DVT confirmed

[E] Direct-acting anticoagulants and some LMWHs are off label for use in suspected DVT. Follow GMC guidance on prescribing unlicensed medicines

Figure 1: Suspected DVT—diagnosis and initial management

DVT=deep vein thrombosis; PT=prothrombin time; APTT=activated partial thromboplastin time; LMWHs=low molecular weight heparins

DVT imaging should be in line with current national guidelines.

D-dimer testing

Raised D-dimer levels are seen in a number of conditions other than VTE, including postoperatively, or with infection, cancer, inflammation, or trauma; therefore a raised D-dimer level alone is not predictive of VTE. The role of D-dimer testing is to identify those patients where VTE can be ruled out as a diagnosis as the test has a high negative predictive value.

A D-dimer should only be requested.

when the clinical probability of a DVT or PE is deemed 'unlikely' following use of the appropriate 2-level Wells score
for patients with 'likely' DVT when:
diagnostic imaging results will not be available within 4 hours
the initial proximal CUS has not identified DVT, in order to ascertain whether repeat imaging should be done 6–8 days later.

When a CUS cannot be performed within 4 hours, a D-dimer test should be requested and after the test has been done, interim anticoagulation with either a DOAC or a parenteral anticoagulant commenced, unless contraindicated. In this scenario, the recommendation is that scan results should be available no later than 24 hours from request. The D-dimer test should be performed before commencing anticoagulation as anticoagulants can affect the results of the test.

If a re-scan is indicated due to a positive D-dimer, then stopping anticoagulation will improve the likelihood of identifying a DVT that will extend proximally and require anticoagulation treatment. When the proximal CUS and the subsequent D-dimer are both negative, anticoagulation should be stopped and alternative diagnoses should be sought. To ensure that the ordering of D-dimer does not result in undue delay to the DVT diagnostic pathway, NICE now specifies a turnaround time of 4 hours for D-dimer test

results. When this is not possible, interim anticoagulation should be initiated unless contraindicated.

Of particular relevance to primary care, NG158 now states that the use of fully quantitative point of care tests (POCT) for D-dimer should be considered when laboratory facilities are not immediately available and that an age-adjusted D-dimer test threshold should be considered for people aged over 50 years. This approach optimises the timeliness of the diagnostic pathway, improves the accuracy of the D-dimer tests, reduces referrals for imaging, and reduces the need for interim anticoagulation. While some practices will need to purchase D-dimer POCT for the first time, there will be a requirement for other practices to switch from qualitative and semi-quantitative D-dimer tests to the more accurate quantitative tests. The authors suggest that one approach to implementing these NICE recommendations in a cost-efficient manner across a federation could be to arrange the diagnostic pathway so that nominated practices purchase the POCT for use within a federation hub-and-spoke model.

Anticoagulation

In the absence of contraindications, confirmed VTE requires anticoagulation for at least 3 months; in patients with active cancer NICE recommends anticoagulation for 3–6 months.[3] NG158 defines 'active cancer' as: *'Receiving active antimitotic treatment; or diagnosed within the past 6 months; or recurrent or metastatic; or inoperable. Excludes squamous skin cancer and basal cell carcinoma.*

The NICE review of the clinical and cost-effectiveness of the DOACs, compared with low molecular weight heparin (LMWH) in combination with vitamin K antagonist anticoagulants (VKAs), favoured the use of apixaban and rivaroxaban for acute treatment in the first 3 months in most cases, with a strong 'offer' recommendation after taking into account co-morbidities, contraindications, and the person's preferences. If neither apixaban nor rivaroxaban is suitable the alternatives that can be offered are:

LMWH for at least 5 days followed by dabigatran or edoxaban or

LMWH concurrently with a VKA for at least 5 days, or until the INR is at least 2.0 in two consecutive readings, followed by a VKA on its own.

A weaker recommendation (1.4.8) suggests that practitioners 'consider' apixaban in the secondary prevention of unprovoked VTE. The preference for apixaban resulted from some evidence of the favourable bleeding profile of apixaban compared with rivaroxaban for acute treatment and in secondary prevention; however, the committee were not entirely convinced by this evidence as there were too few major bleeding episodes in the trials for them to be confident about the results. Rivaroxaban was marginally less cost effective than apixaban in the acute treatment setting.

The licensing for dabigatran and edoxaban specifies initial treatment with parenteral anticoagulation for at least 5 days before they are started, making them less attractive and less suitable in the ambulatory care setting and more costly than their oral-only counterparts. However, cost-effectiveness is different from budget impact and different localities may benefit from a variety of procurement arrangements with manufacturers, as per recent guidance.

Prescribing considerations

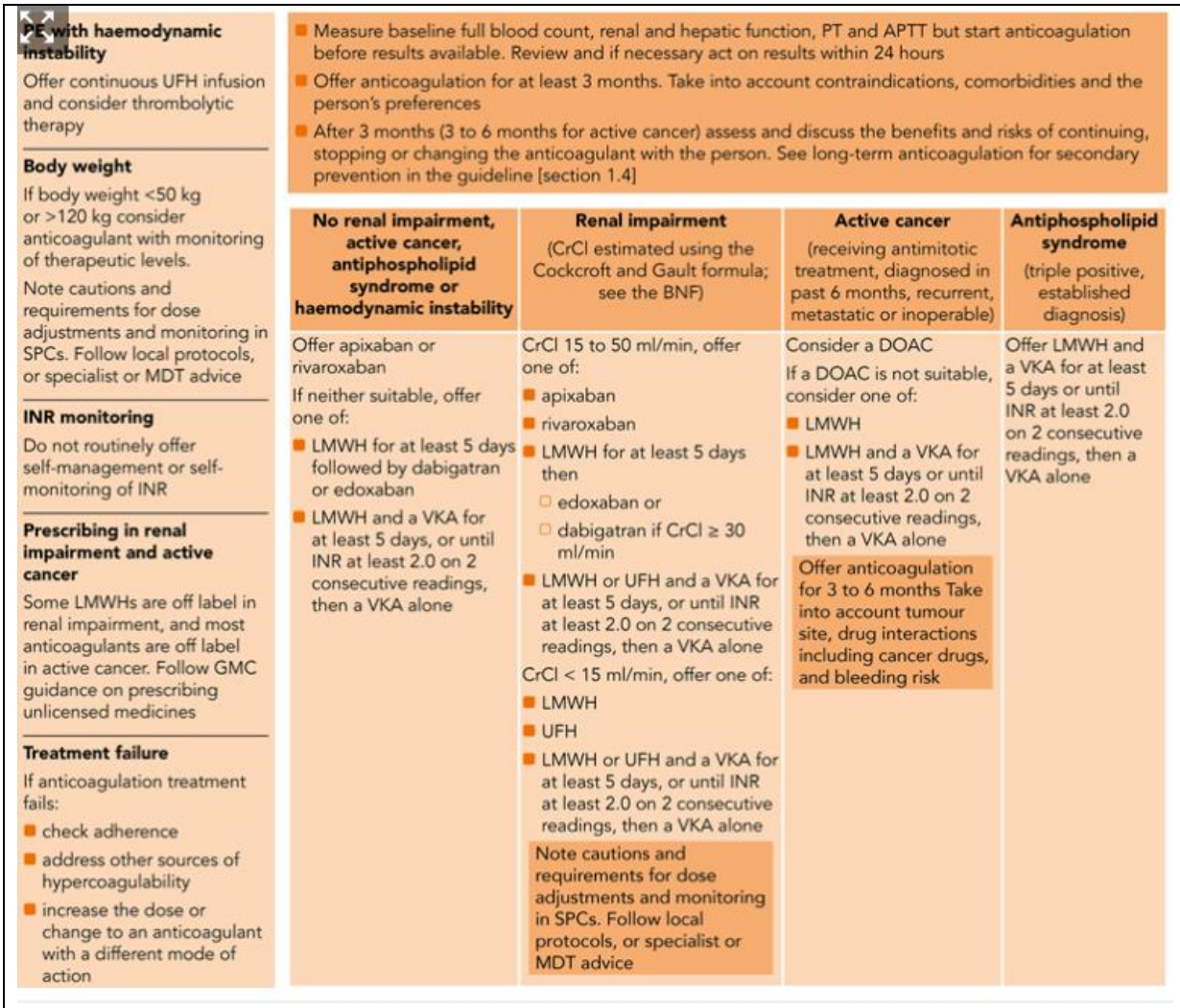
It is important to note that the DOAC oral-only regimens comprise higher initiation doses, which at a specified time point are reduced to the maintenance dose for the remainder of the 3-month treatment course (see the summary of product characteristics [SPC] for individual drugs for full details). Systems must be in place to ensure that patients change dose at the appropriate time and that prescribing and administration errors are avoided so that patients do not receive the wrong dose of medicine. Information about dose changes, adherence to medicine, management of inadvertent overdosing, and actions in the event of missed doses should be covered as part of patient education. In addition, pathways can be designed with follow up at critical time points to ensure that aspects such as dose changes are safely implemented.

NICE advises that interim anticoagulation should, if possible, be commenced with an agent that can be continued if VTE is confirmed, again favouring the use of oral-only DOACs over LMWH preceding DOAC or in combination with VKA. Before oral anticoagulation is started, baseline blood tests should be taken but treatment should not be delayed while results are awaited; instead, results should be reviewed and acted upon within 24 hours as necessary.

In addition, it is important to ensure that a recent body weight measurement is available to support accurate calculation of renal function and appropriate dose selection. The trials of DOACs, their SPCs, and the British National Formulary use creatinine clearance (CrCl) calculated using the Cockcroft and Gault equation rather than estimated glomerular filtration rate (eGFR), which is reported by most pathology services as a measure of renal function.

Anticoagulation for VTE in particular patient groups

The guideline makes separate recommendations on the use of anticoagulation for VTE in: renal impairment, people with cancer, antiphospholipid syndrome, and in people at extremes of weight



PE with haemodynamic instability

Offer continuous UFH infusion and consider thrombolytic therapy

Body weight

If body weight <50 kg or >120 kg consider anticoagulant with monitoring of therapeutic levels.

Note cautions and requirements for dose adjustments and monitoring in SPCs. Follow local protocols, or specialist or MDT advice

INR monitoring

Do not routinely offer self-management or self-monitoring of INR

Prescribing in renal impairment and active cancer

Some LMWHs are off label in renal impairment, and most anticoagulants are off label in active cancer. Follow GMC guidance on prescribing unlicensed medicines

Treatment failure

If anticoagulation treatment fails:

- check adherence
- address other sources of hypercoagulability
- increase the dose or change to an anticoagulant with a different mode of action

- Measure baseline full blood count, renal and hepatic function, PT and APTT but start anticoagulation before results available. Review and if necessary act on results within 24 hours
- Offer anticoagulation for at least 3 months. Take into account contraindications, comorbidities and the person's preferences
- After 3 months (3 to 6 months for active cancer) assess and discuss the benefits and risks of continuing, stopping or changing the anticoagulant with the person. See long-term anticoagulation for secondary prevention in the guideline [section 1.4]

No renal impairment, active cancer, antiphospholipid syndrome or haemodynamic instability	Renal impairment (CrCl estimated using the Cockcroft and Gault formula; see the BNF)	Active cancer (receiving antimitotic treatment, diagnosed in past 6 months, recurrent, metastatic or inoperable)	Antiphospholipid syndrome (triple positive, established diagnosis)
Offer apixaban or rivaroxaban If neither suitable, offer one of: ■ LMWH for at least 5 days followed by dabigatran or edoxaban ■ LMWH and a VKA for at least 5 days, or until INR at least 2.0 on 2 consecutive readings, then a VKA alone	CrCl 15 to 50 ml/min, offer one of: ■ apixaban ■ rivaroxaban ■ LMWH for at least 5 days then □ edoxaban or □ dabigatran if CrCl ≥ 30 ml/min ■ LMWH or UFH and a VKA for at least 5 days, or until INR at least 2.0 on 2 consecutive readings, then a VKA alone CrCl < 15 ml/min, offer one of: ■ LMWH ■ UFH ■ LMWH or UFH and a VKA for at least 5 days, or until INR at least 2.0 on 2 consecutive readings, then a VKA alone Note cautions and requirements for dose adjustments and monitoring in SPCs. Follow local protocols, or specialist or MDT advice	Consider a DOAC If a DOAC is not suitable, consider one of: ■ LMWH ■ LMWH and a VKA for at least 5 days or until INR at least 2.0 on 2 consecutive readings, then a VKA alone Offer anticoagulation for 3 to 6 months Take into account tumour site, drug interactions including cancer drugs, and bleeding risk	Offer LMWH and a VKA for at least 5 days or until INR at least 2.0 on 2 consecutive readings, then a VKA alone

Renal impairment

Renal impairment can result in accumulation of anticoagulant agents, exposing patients to even greater risk of bleeding. Both apixaban and rivaroxaban can be used in renal impairment down to CrCl 15 ml/min and remain options in this patient group (Figure 3).[3] Following at least 5 days of LMWH, edoxaban is also an option, while dabigatran (after LMWH) is not an option for people with more severe renal impairment (estimated CrCl 15 ml/min to 29 ml/min), as stated in its SPC.[18,19] LMWH or unfractionated heparin (UFH) with VKA is also an acceptable option. As well as ensuring CrCl is calculated using up-to-date data it is also important to ensure that the appropriate dose is selected based on parameters including renal function, age, and drug interactions, following guidance in the relevant SPCs. There is evidence that suggests a considerable proportion of patients are receiving less than the SPC-recommended doses of DOACs;[20] this may expose patients to excess risk of a VTE recurrence.

Active cancer

One of the most prominent new recommendations is in the use of anticoagulation in patients with active cancer (see NICE's definition, above). LMWHs are the only licensed anticoagulants for use in active cancer and have traditionally been the anticoagulant of choice in this patient group. However more recent, albeit relatively small, published studies have explored the use of rivaroxaban and edoxaban in patients with cancer and demonstrated non-inferiority to LMWH with respect to VTE recurrence (numerically lower recurrences) but higher

rates of bleeding (particularly gastrointestinal and genitourinary bleeding, mainly in patients with gastrointestinal malignancies).

Taking the comparative clinical efficacy and safety of DOACs together with their considerably lower cost compared with LMWH, DOACs were found to be substantially more cost-effective in patients with active cancer than LMWH. However, given the need for special consideration as to the appropriateness of DOACs for different cancer types and their possible interactions with cancer therapies, as well as the current lack of licensed indication for prescribing DOACs in active cancer, NICE's recommendation is to 'consider' DOACs as first line rather than to 'offer' them.

When DOACs are not considered appropriate, then LMWH alone or LMWH with a VKA are alternatives.

The increased use of DOACs for patients with active cancer will conserve NHS resources, reduce injection burden for patients, and hopefully improve patient experience of anticoagulation treatment.

Antiphospholipid syndrome

In June 2019, the Medicines and Healthcare products Regulatory Agency (MHRA) published a safety alert warning of an increase in VTE recurrence in people diagnosed with triple positive antiphospholipid syndrome taking a DOAC compared with those taking LMWH with VKA such as warfarin. Although people with antiphospholipid syndrome were not included in the guideline evidence review, NG158 reflects the importance of this alert by recommending that people with confirmed VTE and an established diagnosis of triple positive antiphospholipid syndrome are offered LMWH with VKA.

People at extremes of weight

Due to the influence of body weight on the absorption, distribution and elimination of anticoagulants, NICE recommends that consideration should be given to regular monitoring of anticoagulation levels for people with confirmed VTE who weigh less than 50 kg or more than 120 kg to ensure therapeutic anticoagulation.

Risks and benefits of long-term anticoagulation

Traditionally, *provoked VTE*, where the provoking risk factor is no longer present and the clinical course has been uncomplicated, is treated for at least 3 months and the updated NICE guideline still recommends that consideration should be given to stopping anticoagulation after 3 months in this patient group and after 3–6 months in patients with active cancer. When anticoagulation is stopped, patients must be given information about the risk of having another VTE as well as the information outlined under heading 'Information for people having outpatient treatment', above.

For patients with *unprovoked VTE*, consideration should be given to continuing anticoagulation beyond 3 months (beyond 6 months in patients with active cancer). Factors that should be considered when making a decision about whether to continue anticoagulation include the balance between the person's risk of VTE recurrence and their risk of bleeding. The risks and benefits of long-term anticoagulation should be

discussed with the person, and their preferences taken into account. DOACs have a more favourable bleeding profile than VKAs such as warfarin; therefore in most individuals with unprovoked VTE and low bleeding risk, the benefit of continuing anticoagulation now outweighs the risk of a major bleed and NICE recommends that this be explained to people falling within this category.

NICE recommends that a discussion about stopping anticoagulation should take place with people who have unprovoked VTE and a HAS-BLED score of 4 or more, that cannot be modified. For people who decline long-term anticoagulation where the benefits of continued therapy outweigh the risks, the use of aspirin 75 mg or 150 mg daily should be considered.

A review of general health, risk of VTE recurrence, bleeding risk, and treatment preferences should be undertaken at least once a year for patients receiving long-term anticoagulation or aspirin therapy for secondary prevention of VTE.

The 2012 guideline controversially suggested that people with unprovoked VTE undergo screening for cancer, including mammograms and CT imaging. The updated guideline recommends a review of the medical history and baseline blood tests, and a full physical examination only. Now, any further investigations should be offered only if patients have relevant clinical symptoms or signs (see NG12 on suspected cancer). This recommendation will not only reduce costs and imaging appointments but also alleviate the anxiety of patients who would have previously been needlessly referred for imaging.

Treatment failures

In treatment failures the guideline recommends checking adherence to anticoagulation treatment, addressing other potential sources of hypercoagulability, increasing the dose of anticoagulant, or switching to an anticoagulant with a different mode of action.

When anticoagulation is contraindicated

Due to the limited evidence of benefit, the updated guideline recommends that inferior vena cava (IVC) filters should only be used in the context of a clinical trial, or when anticoagulation is contraindicated, or when a PE has occurred despite adequate anticoagulation. Before the IVC filter is fitted, there must be a clear plan in place for removing it at the earliest possible opportunity.

Summary

NICE guideline 158 represents an opportunity for primary care to be more involved in a number of aspects of the management of VTE, including low-risk PE and VTE in patients with active cancer. Moving VTE services out of secondary care into primary care is expected to improve the patient experience and deliver cost savings.

To implement NICE recommendations successfully in primary care, some localities will require pathway redesign to ensure straightforward referral mechanisms as well as availability of slots for imaging scans in their local service, with results available within NICE recommended timeframes. In addition, some will need to invest in quantitative point-of-care D-dimer tests to optimise the timeliness of the pathway. It will be important to agree and clearly define the pathway across primary and secondary care, including who has clinical responsibility for the

patient at different stages of the pathway and in different scenarios, to ensure a safe and timely patient journey.

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 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
- 7 day GP direct referral 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)

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 (eg. 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
NHS Dorset 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. 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 NHS Dorset 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 NHS Dorset 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.

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

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.
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 include opportunistic screening for associated diseases they may be at risk from.

3.3 Population Covered

As stated in 3.4 below

3.4 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, (eg. 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

3.5 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 Cardiology Oversight Group
Dorset ICB Medicines Advisory Committee

3.6 Reporting

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 in respect of this service within 1 calendar month following the end of each quarter during the year.

4. Applicable Service Standards

4.1 Applicable National Standards (eg.NICE)

Venous Thromboembolic diseases: diagnosis, management and thrombophilia testing:

https://www.nice.org.uk/guidance/ng158

4.2 Applicable standards set out in Guidance and/or issued by a competent (eg. 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 as per the Dorset Formulary (link in 4.3)

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 adhere to the Dorset Formulary for the most up to date prescribing information.
https://www.dorsetformulary.nhs.uk/default.asp

5. Applicable quality requirements

5.1 Applicable quality requirements
The provider shall carry out bi-annual quality audits of the service. The results shall be reported to Dorset ICB. 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.