



Version Control		
Version	Date Amended	Summary of amendments
DOAC Initiation and monitoring LES specification incl DVT final 30.6.2021	April 2022	Funding updated for 22-23
DOAC Initiation and monitoring LES specification incl DVT final 30.6.2021	May 2023	Fees amended

## LOCAL ENHANCED SERVICE SPECIFICATION FOR THE INITIATION AND ONGOING PRESCRIBING OF DIRECT ORAL ANTICOAGULANTS (DOACs)

### Introduction

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification for the initiation and ongoing prescribing of DOACs, outlines the more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services.

No part of the specification by commission, omission or implication defines or redefines essential or additional services.

### Background

The DOACs – Apixaban, Dabigatran, Edoxaban and Rivaroxaban – are alternatives to warfarin for a number of indications. These include (but are not limited to):

- Prevention of stroke and systemic embolism in patients with Non-Valvular Atrial Fibrillation (NVAf)
- Treatment of an acute Venous Thrombo Embolism (VTE)
- Prevention of recurrent VTE.

Unlike warfarin, treatment with DOACs does not necessitate routine coagulation (INR) monitoring. However routine monitoring of the patient's renal function and FBC is recommended.

Significant drug-drug interactions may occur with DOACs, so care must be exercised when initiating a new medication or stopping any existing medication.

Many of the causes of poor compliance with warfarin may also result in non-compliance with DOACs. Non-compliance is therefore not a reason to switch anti-coagulant treatments. Poor compliance with DOACs is likely to be associated with increased risk of bleeding or thrombosis. Non-compliance should trigger review of the appropriateness of continuing with treatment.

Practitioners should refer to current guidelines in selecting the best anti-coagulant for the patient.

Further details on choice of oral anti-coagulant, contraindications, pre-treatment testing and ongoing monitoring, advice on switching between oral anti-coagulants, and known interactions can be found in the links at the end of this document.

### **Overall Aim**

The local enhanced service for the initiation and ongoing prescribing of DOACs is designed to provide a safe, effective and convenient service within primary care to patients requiring DOAC therapy for an agreed indication or condition provided that it is not contraindicated.

### **Overall Objectives**

- Provide an accessible DOAC initiation and ongoing prescribing service for the indications of:
  1. Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAf)
  2. Emergency treatment of suspected Deep Vein Thrombosis (DVT) in primary care, when the secondary care DVT clinic is closed (Out of Hours)
- Provide a safe and effective service by following the guidelines set out in this document
- To promote and offer locally based services within the primary care setting which are convenient to the patient

### **Service Outline**

- **Geographic coverage/boundaries**

This local enhanced service (LES) is aimed at practices contracted by Cardiff and Vale UHB wishing to provide or that are already providing anti-coagulation enhanced services to their own patients as well as those wishing to provide a service to patients who are registered with other practices contracted by Cardiff and Vale UHB
- **Location(s) of Service Delivery**

The service will be provided from the practice premises, including branch surgeries, health centres and outreach clinics as appropriate

- **Referral criteria and sources**
  - The service will be available to patients who require initiation and ongoing prescribing of DOAC
  - Those wishing to provide a service to patients who are registered with other practices contracted by Cardiff and Vale UHB must already be providing a DOAC initiation enhanced service and have in place auditable processes and written procedures to ensure timely responses to referrals and effective reporting back to the referring practice

## **Service Delivery**

This local enhanced service will fund:

- **Pre-therapy face-to-face assessment and counselling of patients prior to commencement of treatment** (for AF or suspected DVT)
  - Assessment should include assessment and documentation of the patients' need for anticoagulation therapy, and their score for bleeding risk on oral anticoagulation if indication is stroke reduction in AF. This is to ensure that, at initial diagnosis, an appropriate review of the patient's health is carried out including checks for potential complications and all clinical information related to the LES is appropriately recorded in the patient's own GP-held lifelong record
  - Counselling should ensure that all newly diagnosed patients and/or their carers and support staff (when appropriate) receive appropriate information on the management and prevention of secondary complications of their condition. This should include the provision of printed patient information, plus a **patient alert card** (available within the medication packet or via the manufacturer's website, for use in emergency situations)
- **Initiation of DOAC therapy for AF**
- OR
- **Conversion of anticoagulation therapy to a DOAC for AF**
- OR
- **Emergency Initiation of DOAC for suspected DVT when the acute DVT service is closed**
- **Annual patient review** if indication is stroke reduction in AF to include: appropriateness of continued anticoagulation; re-assessment of bleeding risk using the **HAS-BLED** tool for AF and a full person to person (face to face strongly recommended) review of all current medication.
- **The development and maintenance of a register of patients commenced on DOAC:** Practices should be able to produce an up-to-date register of all patients receiving DOACs, indicating patient name and date of birth (For those

patients whose indication for DOAC is Atrial Fibrillation, the register is available via Stop a Stroke audit plus module).

- **Call and recall:** to ensure that systematic call and recall of patients on this register is taking place in general practice.
- **Professional links:** to work together with other professionals when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained.
- **Referral policies:** when appropriate, to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist.
- **Record-keeping:** to maintain adequate records of the performance and result of the service provided, incorporating appropriate known information, as appropriate. This should include the number of bleeding episodes requiring hospital admission and deaths caused by anti-coagulants.
- **Audit:** to carry out an annual clinical audit of the care of patients including untoward incidents. The audit should include information on the following:
  - number of patients being initiated and the reason for initiating DOAC rather than warfarin (patient unable to tolerate or inability to maintain within therapeutic range, or acute use for suspected DVT)
  - brief details as to arrangements for each of the aspects highlighted above
  - details of training and education relevant to the anti-coagulation monitoring service received by practitioners and staff
  - details of the standards used for the control of anti-coagulation

The practice should submit a copy of the audit to the UHB on request, as per *Details of Service Monitoring, Evaluation and Review* requirements.

- **Training:** each practice must ensure that all staff involved in providing any aspect of care under this scheme has the necessary training and skills to do so.

*No sub-contractors will provide any element of this Service unless agreed in writing by the UHB prior to the sub-contractor starting work.*

## **Requirements for prescribing**

### **Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAf)**

- **Initiation / Switching from Warfarin**
  - Patients with an existing diagnosis of AF can be identified using the Stop a Stroke Module in Audit+
  - The rationale for the decision to initiate anticoagulation therapy and for the choice of anticoagulant must be documented
  - No more than 6 weeks prior to initiation of anti-coagulation treatment, patient's risk of stroke must be assessed and their **CHA<sub>2</sub>DS<sub>2</sub>VASc** score

- documented. Their bleeding risk must also be assessed and documented, using the **ORBIT** or **HAS-BLED** tool.
- Patients must be educated with regard to risks and compliance and informed consent to treatment obtained and documented, using a patient decision tool as appropriate
  - No more than 6 weeks prior to initiation of Apixaban, Dabigatran, Edoxaban and Rivaroxaban *for repeat prescribing*, the following baseline tests must be undertaken and the results reviewed:
    - Blood pressure
    - Body weight
    - Full blood count
    - Clotting screen (PT and APTT)
    - Urea & electrolytes
    - Creatinine clearance (Cockcroft Gault)
    - Liver function
  - **Ongoing prescribing and monitoring**
    - No less than 10 months and no more than 14 months following initiation of a DOAC for stroke reduction in NVAF, and thereafter on an annual basis, the patient must be reviewed and the findings documented. This must include:
      - appropriateness of continued anticoagulation
      - re-assessment of bleeding risk using the **HAS-BLED / ORBIT** tool
      - appropriate blood monitoring
      - full person to person medication review. (Face to face preferable).
    - Patients who fail to attend for review must be recalled three times and each recall attempt and subsequent decisions and action clearly documented in the patient's clinical record. If, after three recall contacts, the patient still does not attend for review, withdrawal of treatment should be considered.
    - Either of following *review* codes to be used:

8BT3 anticoagulant medication review

6A9 atrial fibrillation annual review

## **Emergency Treatment of suspected Deep Vein Thrombosis (DVT)**

- **Initiation of DOAC for suspected DVT is only applicable in urgent primary care setting for a maximum of 4 days (see pathway).**
  - Patients commenced on DOAC for DVT should be referred to DVT clinic on next working day as per [pathway](#) for further investigation, management and long term prescribing of DOAC.
  - Apixaban 10mg twice daily is the only DOAC on Cardiff and Vale formulary for this indication
- **Ongoing Prescribing and Monitoring in Primary Care**
  - **Primary Care NOT to initiate *long term anticoagulation for VTE.*** All patients with confirmed DVT should receive a minimum of 3 months of anticoagulation commenced *and prescribed* by secondary care.
  - **Read code to be used:**

<b>#8CMWA    On Deep Vein Thrombosis Care Pathway</b>
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## **Client Group Served / Eligibility / Access Criteria**

The Service Provider must ensure that the service offered is accessible to all, sensitive and respecting all areas of Race, Economics, Gender, Age, Religion, Disability and Sexual Orientation. Appropriate arrangements should be made for non-English speaking patients and to provide the same high level of service to those requiring interpreter services.

## **Quality Targets and Continual Improvement**

- The practice must ensure that they contribute to the wider patient safety agenda including, but not exclusively, the control of infection agenda and the identification, reporting and investigation of incidents and complaints. *This must be reported within 72 hours of the information becoming known to the practitioner.* This includes all emergency admissions or deaths of any patient covered by this service, where such admission or death is due to haemorrhage. This is in addition to a practitioner's statutory obligations. Please refer to the [Primary Care Clinical Governance/incident reporting pages](#) of the UHB intranet for the most up-to-date guidance on reporting requirements.
- All suspected Adverse Drug Reactions (ADRs) should be reported, as well as all serious ADRs to the DOACs and warfarin. ADRs should be reported directly to the MHRA via the Yellow Card Scheme, using the electronic form at [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) or cards available at the back of the BNF
- Participation in clinical audit and implementation of changes arising from audits should take place. The service should be able to demonstrate learning and improvement across the quality agenda and in response to local and/or national policy guidance.

- It is the responsibility of the Practice to:
  - Continually improve the quality of service delivery, e.g. in response to audit (undertaking and completing the audit cycle), user and staff feedback (complaints, compliments, suggestions) and incidents.
  - Continually review and be aware of relevant new and emerging guidance and recommendations and take the appropriate steps to assess and improve services to achieve current best practice.
  - Ensure that appropriate professional standards are maintained updated and validated through clinical supervision and provision of relevant training to support reflective practice and CPD.
  - During the term of this specification, fully co-operate in reviewing and improving/redesigning services at the request of the UHB, to include improving quality and performance monitoring.

### **Details of Service Monitoring, Evaluation and Review**

The practice will be required to undertake an annual audit as agreed in advance with the UHB and provide the monitoring data to the UHB Primary Care team for annual review of the LES. This information will inform service planning and allow for identification and/or sharing of good practice and/or areas for improvement where the service outline has not been met.

### **Untoward Events**

It is a condition of participation in this Local Enhanced Service that (in addition to their statutory obligations) doctors/practices will give notification to the UHB via the significant events reporting process, of all emergency admissions or harm/potential harm to patients under this service, where such events may be due to administration/usage of the drug(s) in question or attributable to the relevant underlying medical condition. Notification should be given within 72 hours of the information becoming known to the doctor/practice and the standard incident reporting process/form should be used. (Please refer to the [UHB Intranet Clinical Governance pages](#) to link to the correct form and the most up-to-date guidance on reporting).

### **Clinical and Corporate Governance**

Service Providers must ensure that they adhere to all relevant legislation and best practice.

### **Accreditation**

UHBs are responsible for ensuring that enhanced services are delivered by professionals who are properly qualified to do the job and accreditation of the service should be based upon consideration of the enhanced service specification. This Local Enhanced Service has been classified as requiring **General Accreditation**.

An Enhanced Service that requires General Accreditation is defined as a named GP who has the necessary skills and experience to carry out a contracted specific service or procedure. It provides a means whereby **accredited persons will be responsible and accountable** for the delivery of the enhanced service on behalf of the practice. This enhanced service does not have to be delivered by the accredited GP however where components of the service are delivered by somebody other than the accredited GP, the accredited GP is responsible for ensuring that the appropriate skills are available to deliver the service safely.

### **Costs**

Each practice contracted to provide this service will receive the following payment for the provision of the DOAC LES as detailed under service delivery above:

- **Initial patient assessment and counselling plus DOAC initiation for AF** (including switch from warfarin) - £114.78 per patient (one-off payment)
- **Initial patient assessment and single episode of DOAC use for suspected DVT out of DVT Clinic hours** - £114.78 per patient (one-off payment)

**plus**

- **Annual review and re-assessment for patients on regular DOAC for AF** - £36.52 per patient (annual payment).

The annual review and re-assessment fee will still be payable in instances where the patient has failed to respond to three recall contacts and has not attended for review, provided that the contact attempts and subsequent decisions and actions are clearly documented in the patient's clinical record.

The annual review fee will be payable in instances where initiation has been carried out by another provider (e.g. hospital services or another GP).

However, if a patient has been initiated on a DOAC in secondary care and this needs to be continued in primary care, but there is insufficient evidence of pre-initiation investigation and counselling from the secondary care source, then the initial assessment will need to be undertaken in Primary Care and the assessment fee claimed.

The annual review fee will be payable in instances where a patient has already been initiated on DOAC therapy within the GP practice prior to the implementation of this LES.

## **Useful Read codes**

#38G3	HAS-BLED score for bleeding risk
#38DE0	CHA2DS2vasc score
# 8BT3	Anticoagulation medication review
#6A9	AF annual review
#8IH1	Novel Oral Anticoagulant Declined
#8I3d	Anticoagulation Declined
#9kg..	Deep Vein Thrombosis – Enhanced Services Administration
#8CMWA	On Deep Vein Thrombosis Care Pathway
#8HTm.	Referral to Deep Vein Thrombosis Clinic
#1JH..	Suspected Deep Vein Thrombosis

## **Claiming**

Practices are required to make claims in accordance with NWSSP claiming cycle guidelines. Claims must be submitted within 6 months from the end of the quarter in which the vaccine/drug/service was delivered, to ensure payment.

### **End of Financial Year**

Practices should endeavour to submit claims for the January – March quarter at the earliest convenience and in line with the claiming cycle provided by NWSSP. Any claims for this quarter submitted after the 15<sup>th</sup> of June will require approval from the UHB. These claims are also subject to a six- month deadline for submission, after which they will not be paid.

### **Termination Period**

Should the practice wish to cease providing the Enhanced Service, it will be required to provide 3 months' notice in writing to the Health Board. Should the practice wish to suspend providing the Enhanced Service it should contact the Health Board for guidance prior to any action being taken.

If, for any reason, a practice terminates/suspends the Enhanced Service and, if claims have been made during the current financial year, any reporting/auditing requirements outlined in the specification must still be submitted upon request.

### **General Medical Practice Indemnity (GMPI)**

This Enhanced Service is covered by the scheme for General Medical Practice Indemnity (GMPI) which falls under the GMS Contract Wales.

This scheme relates to potential or actual clinical negligence claims arising from incidents on or after 1 April 2019, and captures all General Medical Practice (GP practice) staff undertaking NHS 'primary medical services' as defined in The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019.

The GMPI will include clinical negligence liabilities for NHS work arising from the activities of all GP practice staff, including: GP partners; salaried GPs; locum GPs, if

on the All Wales Locum Register; Practice Pharmacists; Practice Nurses; Practice Healthcare assistants; and any other member of staff providing clinical services. GP trainees and trainee nursing students delivering general medical services will also be covered.

The GMPI will also cover any healthcare professionals providing the delivery of NHS Primary Care through Primary Care cluster arrangements and any vicarious liability to practices where a cluster-based health professional is providing direct care to the practice's registered patients.

## **Appendix**

The hyperlinks below will take you directly to these documents on the C&V UHB Intranet (hover over the link and use "control+click"). Alternatively, they can be accessed via the Enhanced Services heading within the Primary Care pages of the intranet.

### **Appendix 1: Pathways**

[AF Anticoagulation pathway](#)

[Pathway for Suspected DVT outside DVT Clinic Hours](#)

[Out of DVT Clinic hours referral and patient information sheet-](#)

### **Appendix 2: Information on Risk Scores and Calculators**

<https://ahajournals.org/doi/full/10.1161/circulationaha.111.060061>

[https://qxmd.com/calculate/calculator\\_106/bleeding-risk-in-atrial-fibrillation-has-bleed-score](https://qxmd.com/calculate/calculator_106/bleeding-risk-in-atrial-fibrillation-has-bleed-score)

[ORBIT bleeding risk score - MDCalc](#)

[Wells' Criteria for DVT - MDCalc](#)

[Creatinine Clearance \(Cockcroft-Gault Equation\) - MDCalc](#)

### **Appendix 3: Guidance documents**

- a) **Prevention of stroke and systemic embolism in atrial fibrillation  
Prescriber support document  
Updated in accordance with NICE Guideline 196 (27th April 2021)**

[Prevention of stroke and systemic embolism in atrial fibrillation - Prescriber support document](#)

b) Examples of patient alert/information cards are available on-line, e.g.:

- Apixaban alert card <https://www.medicines.org.uk/emc/rmm/112/Document>
- Dabigatran alert card <https://www.medicines.org.uk/emc/rmm/401/Document>
- Edoxaban alert card <https://www.medicines.org.uk/emc/rmm/227/Document>
- Rivaroxaban alert card [patient-alert-card-Xarelto-Rivaroxaban.pdf](#)

c) Cardiff and Vale UHB Anticoagulation Pages

[http://nww.cardiffandvale.wales.nhs.uk/portal/page?\\_pageid=253,141518901,253\\_141518902&\\_dad=portal&\\_schema=PORTAL](http://nww.cardiffandvale.wales.nhs.uk/portal/page?_pageid=253,141518901,253_141518902&_dad=portal&_schema=PORTAL)

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