INITIATION AND MONITORING OF DIRECT ORAL ANTICOAGULANTS (DOACs) FOR LICENSED INDICATIONS

LOCAL ENHANCED SERVICE SPECIFICATION

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/or monitoring 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

Direct Oral Anticoagulants (DOACs) – dabigatran etexilate, apixaban, rivaroxaban and edoxaban – are an alternative to warfarin in the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAF), in the prophylaxis of recurrent deep-vein thrombosis (DVT), recurrent pulmonary embolism (PE) and for prophylaxis of atherothrombotic events in adults with coronary artery disease or symptomatic peripheral artery disease.

> For patients with Mechanical Heart Valves, DOACs are not indicated in the prevention of systemic embolism in patients with Atrial Fibrillation.
>
> Please read Patient Safety Alert PSA014/October 2021 - Inappropriate anticoagulation of patients with a mechanical heart valve patient (Appendix 1).

Unlike warfarin, treatment with DOACs does not necessitate routine coagulation (international normalised ratio [INR]) monitoring. However, significant drug-drug interactions may occur with DOACs, and dosing is related to renal function. Unlike warfarin, there is no specific antidote for all DOACs – currently there is no specific antidote for edoxaban.

Many of the causes of poor adherence with warfarin may also result in non-adherence with DOACs. Non-adherence is therefore not a reason to switch anticoagulant treatments. Poor adherence with DOACs is likely to be associated with increased risk of bleeding or thrombosis. Non-adherence should trigger review of the appropriateness of continuing with treatment. Practitioners should refer to current Health Board guidelines[1,2] in selecting the best anticoagulant for the patient.

[1] Medicines Management - HDUHB NOAC choices for AF v1.1 Final Aug 2019.pdf - All Documents (sharepoint.com)
[2] Medicines Management - NOAC prescr bing guide update Nov17interimupdatefinal v4 2.pdf - All Documents (sharepoint.com)

Further details on choice of oral anticoagulant; contraindications; pre-treatment testing and ongoing monitoring; advice on switching between oral anticoagulants and known interactions can be found in this document:

http://www.swmit.nhs.uk/media/2240/swmitrtdc-oac-comparison-2015-version-21.pdf

Overall Aim

This Local Enhanced Service for the initiation and monitoring of DOACs is designed to provide a safe, effective and convenient service within primary care to patients requiring DOAC therapy for an agreed licensed indication or condition provided that it is not contraindicated.

Overall Objectives

The Objectives of this service are to:

- Provide an accessible DOAC initiation and monitoring service via a DOAC Local Enhanced Service within general practice for recognised licensed indications and conditions.
- Provide a safe and effective service:
    - The rationale for the decision to initiate anticoagulation therapy and for the choice of anti-coagulant must be documented.
    - No more than 6 weeks prior to initiation of anticoagulation treatment, an assessment of each patient's risks (including bleeding risk) must be documented. In patients with AF, this must include their **CHA_2DS_2VASc** and **HAS-BLED or ORBIT** scores. Patient/carer discussion regarding risk vs benefits of treatment, importance of adherence should be documented within the clinic notes prior to initiation. Informed consent to treatment must be obtained and documented prior to initiation, using a patient decision tool as appropriate.[3,4]
    - **Three months** prior to initiation of any DOAC the following tests must be undertaken and the results reviewed:
        - Baseline clotting screen including aPTT,
        - Urea & electrolytes including serum creatinine
        - Liver function including AST/ALT, Bilirubin
        - Full blood count including Hb and platelets
        - Blood pressure – Address uncontrolled hypertension (systolic >160mmHg increases bleed risk)
        - Creatinine clearance – refer to latest individual Summary of Product Characteristics (SPCs)

[3] https://www.nice.org.uk/guidance/ng196/resources/atrial-fibrillation-diagnosis-and-management-pdf-66142085507269
[4] https://awttc.nhs.wales/files/guidelines-and-pils/all-wales-advice-on-oral-anticoagulation-for-non-valvular-atrial-f brillation-feb-2022-pdf/

- No more than 6 weeks prior to initiation of apixaban and edoxaban, the same tests must be undertaken with the addition of body weight being documented[5].
- Concurrent medications:
    - Antiplatelets: review course length and indication NSAIDs: bleeding risks.
    - Selective serotonin re-uptake inhibitors/Selective norephinephrine re-uptake inhibitors, possible increased bleeding risk. Strong inhibitors of both cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp)
    - Check for interactions - Refer to SPCs, BNF, Liverpool HIV Drug Interaction Checker
    - Consider ability of patient to swallow oral medications- crushable/liquid options
- **Follow up review**: No less than 10 months and thereafter on an Annual basis following initiation of a DOAC and thereafter on an annual basis, the patient must be reviewed and the findings documented. This must include: appropriateness of continued anti-coagulation; a review of compliance; re-assessment of bleeding risk (e.g. HAS-BLED or ORBIT tool for AF) and a full medication review. Where possible, this medication review should be face to face, but virtual reviews are suitable in some circumstances. An assessment of renal function is indicated.
- **Annual Return**: On an annual basis (by 30th September each year), GP practices will be required to run a search to identify all patients who have a mechanical heart valve and compare this with a list which will be provided by the Cardiology Team to reconcile (in both directions) of any differences in patients identified.
- 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.

- 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 Hywel Dda University Health Board wishing to provide or that are already providing anticoagulation 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 Hywel Dda University Health Board.

Referral criteria and sources

The service will be available to patients who require **DOAC therapy** for all licensed indications provided that it is not contraindicated.

Those wishing to provide a service to patients who are registered with other practices contracted by Hywel Dda University Health Board 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.

Exclusion criteria

Patients who are not suitable for DOAC treatment; patients who are at risk of excessive bleeding (e.g. following HAS-BLED or ORBIT assessment), and patients who are assessed as at risk of non-adherence following pre-treatment education and counselling will be excluded from the service.

For patients with Mechanical Heart Valves, DOACs are not indicated in the prevention of systemic embolism in patients with Atrial Fibrillation, and the annual return (Appendix 4) must be completed. Please read Patient Safety Alert PSA014/October 2021 - Inappropriate anticoagulation of patients with a mechanical heart valve patient (Appendix 1).

Service Delivery

This local enhanced service will fund:

- Pre-therapy face-to-face assessment and counselling of patients prior to commencement of treatment. Assessment should include assessment and documentation of the patients' need for anticoagulation therapy and their bleeding risk on oral anticoagulation. 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, for use in emergency situations. Examples of patient alert/information cards are available on-line, e.g:

  http://www.atrialfibrillation.org.uk/files/file/Publications/AFA%20Anticoagulation%20Alert%20Card.pdf

- Individual management plan: To prepare with the patient an individual management plan, to include the diagnosis and planned duration of treatment.

- **Initiation** of DOAC therapy for NVAF in line with current Hywel Dda University Health Board guidance.

  OR

  Conversion of anti-coagulation therapy from warfarin to a DOAC, where deemed appropriate and in-line with current Hywel Dda University Health Board guidance

- Where a patient is initiated in secondary care but the GP has not been supplied by secondary care with the information to be confident that the appropriate assessment, bloods, counselling etc. have been undertaken to allow the GP to prescribe safely, the practice is able to repeat the appropriate tests and patient initiation and claim accordingly.
- Annual patient review, to include: appropriateness of continued anticoagulation; a review of compliance; re-assessment of bleeding risk (e.g. **HAS-BLED or ORBIT** tool in AF) and a full review of all current medication. Virtual medication reviews are permitted, but face to face consultations may be suitable in some circumstances. Assessment of renal function is indicated as dose adjustment may be required with declining renal function.
- The development and maintenance of a register of patients commenced on DOACs: Practices should be able to produce an up-to-date register of all patients receiving DOACs, indicating patient name and date of birth.
- 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 anticoagulants.
- 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 e.g. TTR).
    - brief details as to arrangements for each of the aspects highlighted above.
    - details of training and education relevant to the anticoagulation monitoring service received by practitioners and staff.
    - details of the standards used for the control of anticoagulation.

- Other relevant clinical audits as requested

The practice should submit a copy of the audit to the Health Board on request.

- Annual Return: Each practice must submit an Annual Return
- 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 Health Board prior to the sub-contractor starting work.

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.

Rivaroxaban is currently under "Additional Monitoring" by the European Medicines Agency. All suspected Adverse Drug Reactions (ADRs) should be reported, as well as all serious ADRs to dabigatran etexilate, apixaban, edoxoban and warfarin. ADRs should be reported directly to the MHRA via the Yellow Card Scheme, using reporting software within the prescribing system, the Yellow Card app, the electronic form at 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 no patient with a mechanical heart valve is prescribed a DOAC and if identified, patients are urgently switched to warfarin and referred to Cardiology
- 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 Health Board, 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 Health Board and provide the monitoring data to the Health Board 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 Health Board 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 should be used.

Clinical and Corporate Governance

Service Providers must ensure that they adhere to all relevant legislation and best practice. The following Read codes should be used:

Essential Read codes

8BT3 Anticoagulant Medication Review
or
6A9 Atrial Fibrillation Annual Review

Supplementary Read Codes

66QD Anticoagulation monitoring in primary care
8B611NOAC prophylaxis
38G3 HASBLED
8I2u NOAC Contra-indicated
8IH1 NOAC declined
8I7V NOAC not tolerated
66c1 Anti-coagulation stopped

Accreditation

Hywel Dda University Health Board is 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. Any registered health care professional involved in the assessment and counselling of DOACs must be appropriately trained.

Necessary skills suggested for accreditation:

- Details of experience
- Modules https://bjcardio.co.uk/category/anticoagulation-learning/ Free of charge
- Other relevant CPD modules

Costs

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

Initiation
Initial patient assessment and counselling plus DOAC initiation for NVAF - [redacted] per patient (one-off payment) paid a month in arrears.

In the absence of clear written details of the results of the initial patient assessment and counselling undertaken by any secondary care initiation, to enable the GP to prescribe safely for the patient the practice is able to claim [redacted] per patient for initiation (as above) to allow the initial assessment and counselling to be undertaken again in primary care.

(This Secondary Care information must be available when the GP is first expected to prescribe the DOAC.)

Review
Annual review and re-assessment - [redacted] per patient (annual payment) paid at the end of the financial year. The following criteria will apply to this payment:

- The annual service is to include:
    - a review of the appropriateness of continued anticoagulation;
    - a review of compliance;
    - re-assessment of bleeding risk (e.g. **HAS-BLED or ORBIT** tool in AF);
    - a face-to-face or virtual review of all current medication; and
    - an assessment of renal function within the last three months.
- 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).
- 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.

Claims can be made on submission of the number of patients initiated/annually reviewed to Contractor Payments, NWSSP. For initiation claims, every effort should be made by the contractor to submit regular claims, except at year-end when the following will apply:

Claims for previous (financial) year's activity will only be accepted up to the first week of July following the year of provision. Claims made after this date will only be considered in extenuating circumstances and in these cases payment will be totally at the discretion of HDUHB.

Practices should ensure that claims are properly recorded and kept on file and that each such claim has a clear audit trail for Post Payment Verification (PPV) reasons.

APPENDIX 1

Patient Safety Alert PSA014 / October 2021
Inappropriate anticoagulation of patients with a mechanical heart valve
(Inappropriate anticoagulation of patients with a mechanical heart valve (nhs.wales)

APPENDIX 2
CHA_2DS_2VASc, HASBLED and ORBIT score documents

http://circ.ahajournals.org/content/126/7/860

https://qxmd.com/calculate/calculator_106/bleeding-risk-in-atrial-fibrillation-has-bled-score

https://qxmd.com/calculate/calculator_41/cha2ds2-vasc-score-for-af

https://www.mdcalc.com/calc/10227/orbit-bleeding-risk-score-atrial-fibrillation

Overview | Atrial fibrillation: diagnosis and management | Guidance | NICE

APPENDIX 3
Guidance documents

a) Common Questions and Answers on the Practical Use of Oral Anti-coagulants in Non-Valvular Atrial Fibrillation (January 2016)

http://www.swmit.nhs.uk/media/2240/swmitrtdc-oac-comparison-2015-version-21.pdf

b) Atrial Fibrillation: Diagnosis and Management - NICE NG196 (2021)
https://www.nice.org.uk/guidance/ng196

c) All Wales Advice on Oral Anticoagulation for Non-valvular Atrial Fibrillation (AWMSG 2022)

https://awttc.nhs.wales/files/guidelines-and-pils/all-wales-advice-on-oral-anticoagulation-for-non-valvular-atrial-fibrillation-feb-2022-pdf/

d) 2021 European Heart Rhythm Association Practical Guide on the Use of Non-Vitamin k Antagonist Oral Anticoagulants in Patients with Atrial Fibrillation – EHRA (2021)

https://academic.oup.com/europace/article/23/10/1612/6247378#.Y1-_s319828.link

e) Rivaroxaban for the treatment of DVT and prevention of recurrent DVT and PE – NICE TA261

https://www.nice.org.uk/guidance/ta261

f) Dabigatran etexilate for the treatment and secondary prevention of DVT and/or PE – NICE TA327

https://www.nice.org.uk/guidance/ta327

g) Apixaban for the treatment and secondary prevention of DVT and/or PE – NICE TA341

https://www.nice.org.uk/guidance/ta341

h) Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation – NICE TA355

https://www.nice.org.uk/guidance/ta355

i) Inappropriate anticoagulation of patients with a mechanical heart valve. Patient Safety Alert: PSA014 October 2021

https://du.nhs.wales/files/alerts/psa014-mechanical-heart-valve/

j) A guide to NOAC treatment choices in non-valvular AF – HDUHB (2019)

Medicines Management – HDUHB NOAC choices for AF v1.1 Final Aug 2019 – (sharepoint.com)

k) Prescribing Decision Support Aid for the non-vitamin K oral anticoagulants (NOACs) in the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation - HDUHB (2017)

Medicines Management - NOAC prescribing guide update Nov17interimupdatefinal v4 2.pdf - All Documents (sharepoint.com)

APPENDIX 4

Annual Return

Each year the practice should complete the annual return via the link below by 30th September.
https://forms.office.com/e/GA5KW9MW7k