Kent and Medway ICB Position Statement and Risk Mitigation Principles for Anticoagulant Prescribing in nvAF

Position Statement(s)

1. Direct Oral Anticoagulants (DOACs) are recommended as first line treatment over Vitamin K antagonists (warfarin) for treatment in newly initiated patients with non-valvular atrial fibrillation (NVAF) as per NICE NG196 .

2. Generic Apixaban or generic Rivaroxaban (joint best value) are recommended as first line (preferred) DOACs in newly diagnosed patients with NVAF, unless contraindicated, not tolerated or clinically inappropriate.

3. If the highest ranked best value DOAC is contraindicated or not clinically appropriate for the specific patient then, subject to the criteria specified in the relevant NICE technology appraisal guidance, clinicians should then consider the next highest ranked DOAC and so on until an appropriate treatment is identified. See Table below.

4. Patients on warfarin for NVAF should be encouraged to switch to a DOAC (with generic Apixaban or Rivaroxaban as preferred DOACs) during a discussion at their next routine appointment unless a DOAC is contraindicated, not tolerated or clinically inappropriate.

5. The ICB recommends that the effectiveness of anticoagulation should be considered for every patient as part of their standard review.

6. Where consideration is being given to changing between DOACs, take into account the specific risks of moving from a once-a-day treatment to a twice-a-day treatment (or vice-versa) and implement appropriate safeguards to ensure patients take the alternative drug correctly. Risk mitigation principles (as outlined in this document) should be followed if patients on other DOAC treatments or warfarin are considered for a switch to Apixaban or Rivaroxaban.

7. Ensure all patients prescribed DOACs have had a review of treatment and dose within the past 12 months.

Background to the Position Statement

In December 2021, NHS England & Improvement (NHSE&I) announced a secured national procurement agreement with three of the four manufacturers of DOACs, this framework was aimed at securing the best value DOACs for NVAF treatment and stroke prevention across England.

A Task and Finish Group of Kent and Medway clinicians (including cardiologists, haematologists, stroke specialists and GPs) was set up with representation from the 4 Kent and Medway Acute Trusts and Health & Care Partnerships (HCPs). Following wider Kent and Medway multi-stakeholder consultation, evidence and recommendations were presented to the Kent and Medway Policy Recommendations and Guidelines Committee (PRGC) for further deliberation prior to final recommendations by the JPC and Clinical Cabinet. A position statement was ratified which stated

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that Edoxaban was recommended as first line (preferred) DOAC in newly diagnosed patients with NVAF, unless contraindicated, not tolerated or clinically inappropriate.

On 6th September 2024 NHSE published updated commissioning recommendations (here), which replace those published in January 2024 to replace the Operational Note published in January 2022 (PAR1279). The Kent and Medway position statement and risk mitigation principles document has been revised in response to these commissioning recommendations.

The table below provides the available DOACs ranked from highest to lowest best value:

Overall rank	**DOAC**	
1 (Joint best value)	Generic rivaroxaban Generic apixaban	Best value once a day treatment Best value twice a day treatment
2	Edoxaban	
3	Branded rivaroxaban	
4	Dabigatran	
5	Branded apixaban	

Risk Mitigation Principles

The Kent and Medway ICB strongly recommends the following risk mitigation principles are followed if considering anticoagulant treatment changes:

1. DOAC to best value DOAC Switch (for NVAF patients only)

a) It is recommended that clinicians/practices without previous experience of using Apixaban or Rivaroxaban prioritise initiation of new patients. The ICB recommends that the effectiveness of anticoagulation should be considered for every patient as part of their standard review.

NICE Guidance (NG196 1.6.16 published 27 April 2021) states that "For people who are taking an anticoagulant, review the need for anticoagulation and the quality of anticoagulation (taking into account MHRA advice on direct-acting oral anticoagulants about bleeding risk and the need to monitor renal function in patients with renal impairment) at least annually, or more frequently if clinically relevant events occur affecting anticoagulation or bleeding risk".

b) Clear rationale for any changes to anticoagulant medication during a hospital stay must be included in discharge documentation.

c) Switches may be considered during routine patient reviews which should include an assessment of bleeding risk (using ORBIT or HASBLED score) and creatinine clearance − When considering a patient's bleeding risk, it should also be considered that there is currently no licensed reversal agent for Edoxaban; andexanet alfa is not a direct reversal agent and is unlicensed for use, but does offer some effectivity. − Patients should be well advised of the risks and be able to make an informed shared decision to switch.

d) Creatinine clearance must be used as the measure of renal function; do not use estimated glomerular filtration rate (eGFR).

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e) Please see the SmPC for dosing information Home - electronic medicines compendium (emc) .

f) Patients with a creatinine clearance <15ml/min should not be on a DOAC - these patients should receive warfarin.

g) It is recommended that patients with a prior cardiac event are not prioritised for a switch from one DOAC to another unless on the recommendation of a relevant specialist.

h) Additional caution and counselling is recommended if changing patients from a once a day DOAC to a twice-a-day preparation or vice versa.

i) Ensure that the patient knows when to start the new DOAC i.e. after they have finished their current DOAC supply at the time of the next dose.

j) Ensure patient is counselled and given a DOAC booklet and alert card and sign-posted to suitable online resources. Consider a referral to the New Medicines Service / Discharge Medicines Service.

k) The above principles should be considered in conjunction with the Apixaban SmPC , Rivaroxaban SmPC and the Kent and Medway DOAC Monitoring Guidance (here) .

l) Additional advice for switching between DOACs:

- Please follow the guidance in, the individual drug's **SmPC** when: assessing patients for switch suitability
- Document clearly in the consultation notes if a DOAC switch has been carried out
- Carry out the usual follow up and monitoring needed for the patient
- It is suggested that the switching conversation should always be part of a shared decision-making conversation between the patient and the clinician.
- For patients who decide to switch**, take off** the current DOAC from the patients' medication list and then add the new DOAC to the medication list. And ensure a reason is documented for stopping the drug.
- To avoid medicine wastage, patients should finish their current DOAC supplies before starting the new DOAC unless there is a clinical reason not to do so e.g. if dose optimisation is required.
- **Ensure you have up to date renal function and actual body weight to calculate creatinine clearance for dosing.**
- Ensure that there is no more than one anticoagulant on the patient's current medication list. A combination of Warfarin and a DOAC, DOACs of multiple strengths or two or more different DOACs are examples of more than one anticoagulant. Please remember to check the acute, repeat, variable repeat and hospital only drug categories of the current medication list. It is good practice to carry out periodic audits to ensure that there is no more than one anticoagulant on the patient's current medication list.
- For patients on antiplatelet therapy, seek specialist advice before initiating DOACs, switching between DOACs or changing DOAC doses.

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- Ensure the patient has a clear understanding of the instructions given, complete counselling checklist for DOACs, provide anticoagulant alert cards, patient information on DOACs and document the discussion clearly in the consultation notes. Include the patient's carer in the conversation wherever feasible.
- In the 'pharmacy message' section of the electronic prescription, clearly communicate that a formulary change/ has occurred, request for **NMS** (new medicine service) and warn against inadvertent dispensing/handing out of old anticoagulant prescriptions still in the system.
- Double check with the patient if they had an anticoagulant dispensed following a recent hospital discharge or if they have medications in a dossette box. Discuss all dossette box patients with their community pharmacist.
- Care home patients will require extra care. This may involve a conversation with care home manager/nurse to outline the formulary change and/or dose optimisation.
- Take a holistic approach. Consider co-morbidities as well as interacting medications including P-gp inducers/inhibitors which may require DOAC dose adjustments or specialist input. The patient's weight, serum creatinine, age or comorbidities may necessitate a DOAC dose adjustment, please see the individual DOAC SPC for suitability criteria and detailed information.
- When reviewing patients on DOACs take care to follow the recommendations in the relevant SmPC.
- Seek specialist advice if weight 120Kg or BMI >40kg/m2

Useful Links

Drug SPCs

NICE Clinical Knowledge Summaries Anticoagulation – Oral (NICE CKS)

NICE (NG196) Atrial Fibrillation Diagnosis and Management

BNF British National formulary

Patient resources:

https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/drug-cabinet/novel-anticoagulants

https://www.stroke.org.uk/professionals/atrial-fibrillation-information-and-resources

2. Warfarin to DOAC Switch

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See Microsoft Word - FINAL guidance on safe switching of warfarin to DOAC COVID-19 Mar 2020 (rpharms.com) .

See SmPC (Home - electronic medicines compendium (emc)) and risk materials associated with SmPc on EMC -prescriber guide

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