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. Apixaban (generic) is recommended as first line (preferred) DOAC in newly diagnosed patients with NVAF, unless contraindicated, not tolerated or clinically inappropriate.

3. If the highest ranked best value DOAC (generic apixaban) 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 (edoxaban) 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 as preferred DOAC) 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, and is not advocating switch programmes for moving patients from one DOAC to another.

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.

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

Approved by: IMOC
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Review Date: April 2026

In January 2024 NHSE&I published "Operational note: Commissioning recommendations for national procurement for Direct-acting Oral Anticoagulant(s) (DOACs)" (here) which replaces 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	Notes
1 (Best value)	**generic apixaban**	**Best value twice a day treatment**
2	**Edoxaban (Lixiana®)**	**Best value once a day treatment**
3	Rivaroxaban (Xarelto®)	
4	Dabigatran (Pradaxa®)	
5	Eliquis® (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 Apixaban Switch (for NVAF patients only)

a) It is recommended that clinicians/practices without previous experience of using Apixaban prioritise initiation of new patients in the interim (3-6 months) before implementing a switch programme. The ICB recommends that the effectiveness of anticoagulation should be considered for every patient as part of their standard review, and is not advocating switch programmes.

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).

e) Please see the SmPC for dosing information for Apixaban.

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

The recommended dose of apixaban is 5 mg taken orally twice daily.

Dose reduction

The recommended dose of apixaban is 2.5 mg taken orally twice daily in patients with NVAF and at least two of the following characteristics: age ≥ 80 years, body weight ≤ 60 kg, or serum creatinine ≥ 1.5 mg/dL (133 micromole/L). Therapy should be continued long-term.

In patients with severe renal impairment (creatinine clearance 15-29 mL/min), when used for the prevention of stroke and systemic embolism in patients with NVAF, patients should receive the lower dose of apixaban 2.5 mg twice daily.

Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE (VTEt)

Dosing advice for Apixaban differs from that in NVAF. Please refer to SmPC (here)

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 Apixaban which is a twice-a-day preparation.

i) Ensure that the patient knows when to start Apixaban 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 and the

Kent and Medway DOAC Monitoring Guidance (here) .

2. Warfarin to Apixaban (or other DOAC) Switch

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