NHS
Kent and Medway
Clinical Commissioning Group

KMCCG Joint Prescribing Committee (JPC) Position Statement and Risk Mitigation Principles for anticoagulant prescribing

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

3. Patients on warfarin should be encouraged to switch to a DOAC (with Edoxaban as preferred DOAC) during a discussion at their next routine appointment unless a DOAC is contraindicated, not tolerated or clinically inappropriate

4. 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 Edoxaban

Background to the Position Statement

In December 2021, NHS England & Improvement (NHSE&I) announced a secured a 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.

All four DOACs (Apixaban, Edoxaban, Rivaroxaban and Dabigatran) are recommended by NICE over warfarin for stroke prevention in patients with NVAF; Annual treatment costs in England are expected to reach over £1 billion a year by 2024 (current yearly spend in Kent and Medway is circa £26M)

The secured cost for Edoxaban within the procurement framework is markedly less than that of any of the other DOACs. For the same spend, it would be possible to treat two patients with Edoxaban over one patient with any of apixaban, dabigatran or rivaroxaban. NHSE&I recommends that where clinically appropriate, Edoxaban should be used first line in patients newly initiated on a DOAC and that patients currently prescribed other DOACs could be switched onto Edoxaban. Besides lowering prescribing costs, projected savings will support funding for initiatives to find undiagnosed NVAF patients, get appropriately diagnosed patients onto treatment and monitor existing patients.
In March 2022, NHSE&I introduced new CVD indicators to the PCN DES specifications aimed at driving anticoagulation treatment for people with NVAF and using Edoxaban as preferred DOAC.

In response to these developments, 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.

Approved by: JPC, KMMOC, Clinical Cabinet
Approval Date: Ratified By Clinical Cabinet June 2022
Review Date: June 2023

Risk Mitigation Principles

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

1. DOAC to Edoxaban Switch (for NVAF patients only)

a) It is recommended that clinicians/practices without previous experience of using Edoxaban prioritise initiation of new patients in the interim (3-6 months) before implementing a switch programme
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) The recommended dose of Edoxaban for patients with a creatinine clearance of ≥ 50ml/min is 60mg once daily. A reduced dose of 30mg once daily is recommended if:
   - Renal function falls below 50ml/min OR
   - Low body weight ≤ 60 kg OR
   - Concomitant use of the following P-glycoprotein (P-gp) inhibitors: ciclosporin, dronedarone, erythromycin, or ketoconazole
f) If creatinine clearance falls to ≤ 30ml/min, a switch to Edoxaban is not recommended without relevant specialist input.
g) Caution is advised in patients with creatinine clearance > 95ml/min- Specialist input may be required.
h) Patients with a creatinine clearance <15ml/min should not be on a DOAC - these patients should receive warfarin
i) It is recommended that patients with a prior cardiac event are not prioritised for a switch to Edoxaban unless on the recommendation of a relevant specialist
j) Additional caution and counselling is recommended if changing patients from a twice a day DOAC to Edoxaban which is a once-a-day preparation.
k) Ensure that the patient knows when to start Edoxaban i.e. after they have finished their current DOAC supply at the time of the next dose
l) The above principles should be considered in conjunction with the Edoxaban SPC and the Kent and Medway DOAC Monitoring Guidance

2. Warfarin to Edoxaban (or other DOAC) Switch

See Guidance for the safe switching of warfarin to direct oral anticoagulants (DOACs) for patients with non-valvular AF