### Edoxaban Switch Programme - Frequently Asked Questions

#### What should I tell patients?

- There is a national initiative to use edoxaban in preference to other direct oral anticoagulants (DOACs) as it offers some advantages:
  - ✓ it is a ONCE daily dose,
  - ✓ it can be taken on a full or empty stomach
  - ✓ has the lowest cost to the NHS and savings will be used to directly help people with atrial fibrillation
- Local clinical experts are supporting the use of edoxaban
- All newly diagnosed patients with non-valvular atrial fibrillation (NV-AF) will be started on edoxaban as 1st choice unless not clinically appropriate
- Existing patients already on a rivaroxaban, dabigatran, apixaban for NV-AF are to be reviewed and considered for switch to edoxaban

#### Is edoxaban as good as the other DOACs?

- Yes, the evidence is that it is as effective as warfarin and the other DOACs. It is licensed for this indication and has been recommended by NICE NG 196 Atrial fibrillation: diagnosis and management
- Local clinicians from cardiology, stroke, vascular medicine and haematology are all supportive of this guidance on the basis of current evidence

#### Will we need to do a further switch if the price of other DOACs falls?

- Current pricing arrangements (known as national framework agreements) are in place to 31 March 2024, with the option for NHS England and NHS Improvement to extend to 31 March 2025.
- A further switch will only be considered if clinical evidence emerges that another DOAC is more effective and/or safer than edoxaban or in the unlikely event of a very significant price change of an equivalent product
- Based upon the latest patent expiry dates, the DOACs that are currently prescribed for more than 96% of patients nationally will remain patent protected until at least 2026

#### Which patients should NOT be SWITCHED from apixaban, rivaroxaban or dabigatran TO edoxaban?

- Diagnosis other than NV-AF
- High creatinine clearance (CrCl) see SmPC for details. Due to a trend towards decreasing efficacy with increasing creatinine clearance for edoxaban vs well managed warfarin, edoxaban should only be used in patients with NVAF and high CrCl after a careful evaluation of the individual thromboembolic and bleeding risk. Seek advice from haematology
- BMI >40 kg/m² or weight >120kg, seek advice from haematology as to most appropriate DOAC or anticoagulant
• Patients with NV-AF who require intervention for acute coronary syndrome may be discharged on a combination of anticoagulant and one or more antiplatelets based on current evidence

• Note there is no reversal agent for edoxaban

**How do I switch patients to edoxaban?**

• If patients meet the criteria for switching and have agreed to the switch, they should be issued with a prescription for edoxaban; see dosing and monitoring advice below and in SmPC
• They should be advised to use up the supply of existing DOAC before switching to edoxaban. They should switch to edoxaban the day after they use up their existing supply.
• If they are switching from apixaban they should take both the morning and evening dose on the day before switching to edoxaban. Further details on switching in local AF guidelines (available shortly)
• Edoxaban should be taken once daily. The precise time of day is not important, neither is the timing in relation to food. The patient should decide the most convenient time of day for them. It is important to take edoxaban every day
• Community pharmacists are being informed of this change and will be supplied with all the relevant support materials

**Consider seeking specialist advice for those with a CrCl <30ml/min**

• DOACs increases the risk of bleeding and can cause serious, potentially fatal, bleeds [MHRA June 2020](#)
• Exposure to DOACs is increased in patients with renal impairment and it is therefore important that patients receive an appropriate dose depending on renal function. Calculate CrCl to determine renal function for dosing of DOACs. Estimated glomerular filtration rate (eGFR) can overestimate renal function and increase the risk of bleeding events (see [Drug Safety Update](#)).
• Patients with a CrCl<30ml/min require a dose reduction if edoxaban is being considered
• Patients with a creatinine clearance<15ml/min should not be on a DOAC. These patients should receive warfarin

**What happens if renal function changes?**

• If renal function decreases significantly then the DOAC dose may need to be reviewed.
• For edoxaban the important value for review of treatment is 50ml/min which should trigger a dose reduction to 30mg once daily [SmPC](#)
• Edoxaban, and other DOACs are not recommended if the creatinine clearance is <15ml/min. These patients should receive warfarin if there is a clinical indication for long-term anticoagulation
• Alternatively, if a reduced dose of a DOAC has been started during an acute impairment of renal function, then the dose will need to be reviewed if renal function subsequently improves
**Do I need to use the Cockcroft-Gault equation to estimate renal function or can I use eGFR?**

- The Cockcroft-Gault equation is recommended by the manufacturers of all DOACs for calculating creatinine clearance (CrCl) when prescribing these agents. eGFR should not be used.
- If patient is underweight, normal weight or overweight (BMI <30 kg/m^2) use actual body weight.
- If patient is obese or morbidly obese (BMI≥30kg/m^2) use adjusted body weight: Adjusted body weight = Ideal body weight + 0.4 x (actual body weight – ideal body weight).

**How often do I need to check weight and renal function?**

- At initiation of treatment or when switching DOACs. Both weight and renal function should have been confirmed within the last 6 months.
- Once the patient has been reviewed and confirmed to be on the appropriate dose of edoxaban monitor:
  - 3 monthly if expected decline in renal function.
  - 6 monthly if frail or ≥ 75 years.
  - Annually if no significant changes in weight, CrCl > 60ml/min, Age <75 years.
  - If needed during intercurrent condition that may impact renal or liver function. Dose may need to be modified.
  - If CrCl <60 mL/minute, the frequency of monitoring (in months) can be guided by the CrCl divided by 10. Eg 3 monthly if CrCl is 30 mL/minute.
  - See local DOAC Clinical decision aid or AF guidelines for further details (available shortly).

- For new patients and those switching to edoxaban, the dose should be reduced to 30mg once daily if the creatinine clearance is <50ml/min or if the patient weighs ≤ 60kg SmPC.
- Caution when prescribing any other new medicines which may interact with edoxaban and require the dose of edoxaban to be reduced to 30mg once daily - ciclosporin, dronedarone, erythromycin or ketoconazole see SmPC for further details.

**What about patients with liver disease?**

- **Edoxaban**, **rivaroxaban** and **apixaban** are contraindicated in patients with hepatic disease associated with coagulopathy and clinically relevant bleeding risk.
- **Dabigatran** is contraindicated in hepatic impairment or liver disease expected to have any impact on survival.
- See relevant SmPCs for information on mild to moderate hepatic disease with DOACs.
- Prior to initiating edoxaban, liver function testing should be performed.
- Patients with elevated liver enzymes ALT or AST > 2 x upper limit of normal (ULN) or total bilirubin ≥ 1.5 x ULN, were excluded in clinical studies. Therefore, edoxaban should be used with caution in this population. Edoxaban should be used with caution in patients with mild to moderate hepatic impairment see SmPC for further details.
Annual monitoring of liver function is recommended if treatment continues beyond one year. More frequently if intercurrent condition that may impact liver function

What happens if a patient has more than one reason to be on a DOAC?

- There are several reasons why a patient might be taking a DOAC either for a fixed period of time or for the long-term
- All DOACs are licenced and approved by NICE for stroke prevention in NV-AF and treatment of a DVT/PE. Some DOACs are also used for thromboprophylaxis following joint replacement. This switch programme is focussing on patients receiving a DOAC for stroke prevention in NV-AF. If a patient is on a long-term DOAC for another indication this should be discussed with the relevant specialist before switching.
- For a diagnosis of DVT/PE without AF, rivaroxaban remains the first choice
- The use of edoxaban to treat DVT/PE requires initial treatment with heparin for 5 days and for this reason is not considered a suitable first choice for this indication at the outset of treatment.
- If a patient has NV-AF and is already established on rivaroxaban for DVT/PE it would be appropriate to consider them for a switch to edoxaban

What drugs interact with edoxaban and what should I do about them?

- See SmPC Lixiana for full details
- Co-administration of edoxaban with other anticoagulants is contraindicated due to increased risk of bleeding
- Edoxaban 30 mg once daily must be administered during concomitant use with the following P-gp ciclosporin, dronedarone, ketoconazole or erythromycin
- SSRIs/SNRIs: As with other anticoagulants the possibility may exist that patient is at increased risk of bleeding in case of concomitant use with SSRIs or SNRIs due to their reported effect on platelets
- Co-administration with NSAIDs, steroids and antiplatelet see advisory guidance on initiating PPIs
- As with other anticoagulants, the risk of bleeding is increased if edoxaban is used in combination with one or more antiplatelet drugs. This combination is clinically appropriate in certain circumstances, but this should only be done on the advice of a specialist and a clear treatment plan describing the intended duration of treatment

Can edoxaban go into a patient compliance device?

- There are no known issues with using edoxaban in a compliance device.
- Compliance devices should only be requested for patients following an assessment by a pharmacist

How can patients feedback if they wish to raise concerns or make a complaint?

- Any patient feedback or complaints can be routed through:
  - local practice procedures or
  - CCG Patient Advice and Liaison Services (PALS).
    - Email weccg.comments@nhs.net
    - Phone: 01992 566122 lines are open 10am to 4pm, Monday to Friday (excluding bank holidays).
    - PALS team, Building 4, NHS West Essex Clinical Commissioning Group, The Plain, Spencer Close, Epping, CM16 6TN
    - Online

Edoxaban switch FAQs approved west Essex MOPB April 2022, review April 2025, or before if new guidance is published