

Version 5 (Updated April 2025)

DOCUMENT HISTORY:

Version	Date Updated	Main Changes / Comments		
Final Draft	September 2020	Minor changes to wording following comments from ICP MOGs (see under document distribution)		
Final Draft V2	September 2020	Following comments from K&M JPC: Part 1 Ongoing monitoring, Line 9: ' as DOAC may need to be stopped' changed to 'as DOAC dose may need to be reduced or alternative treatment initiated'. Approved by JPC		
Final Draft V3	September 2020	Approved by Kent and Medway Clinical Cabinet		
Version 2 updated May 2021	May 2021	Updated following revisions to NICE Atrial Fibrillation Guidance and NICE CKS Anticoagulation-Oral. Changes to monitoring frequency requirements and recommended bleeding risk tool. Addition of statements re modifiable risk factors and advice if HB dropping. Minor changes to wording. Addition of reference 16.		
Version 3 updated Sep 2021	September 2021	Updated following revisions to NICE Atrial Fibrillation Guidance and NICE CKS Anticoagulation-Oral. Comments from JPC on content of document led to wholesale review (Version4)		
Version 4 update d April 2025	April 2025	Updated following revisions to monitoring guidance for DOACs which has been updated from 6 monthly to 4 monthly for people 75 years or older or those who are frail. This aligns with recommendations from the European Heart Rhythm Association Practical Guide on the Use of Non-Vitamin K Antagonist Oral Anticoagulants in Patients with Atrial Fibrillation (2021). Repetition of NICE CKS and SPS advice on monitoring has been removed and replaced with links to these resources. Title changed to cover DOAC monitoring regardless of indication.		

DOCUMENT DISTRIBUTION

Version	MOG/Clinical Group	Date Agreed	Comments
Draft 3 reformatted	Medway and Swale MOG	Aug 2020	Approved following additional sentence to clarify part 2, point 1, bullet 3.
Draft 3 reformatted	West Kent MOG	Aug 2020	None
Draft 3 reformatted	East Kent MOG (EKPG)	Aug 2020	EKPG- Part 2, point 3, bullet point 6 has been changed from current EK document which gives local advice, to advise to seek specialist advice. Further discussion is required on whether this change is appropriate. PCN and practice pharmacists may need training to be able to provide support. SKC Prescribing Advisor – changes to wording part 2, point 2, bullet 4- "except in situations where a patient's weight is unknown" changed to "in exceptional circumstances where it is



			not possible to obtain a person's weight".
Draft 3 reformatted	DGS MOG	Aug 2020	No comments from MOG. DVH Cardiology Pharmacist – minor changes to wording. "Tests" changed to "requirements" and added meds initiated by 2° and 3° care and check for interactions to part 1 bullet 6.
<u>Version 4 Draft</u> <u>September 2021</u>	Document was sent to key stakeholders (primary and secondary care specialists) across K&M for comment	Sep 2021	Consultant Haematologist Trust Thrombosis Lead (EKUFT) "A drop in HB of >1g/DL rather than any drop otherwise minor fluctuations will get inappropriate investigations. Check for bleeding" Unless there is a clear cut alternative reason for abnormal LFT. Also consider repeat testing in 4 weeks if mildly abnormal. Investigate for causes as appropriate" K&M Cardiovascular Clinical Lead: Would it be worth including indications (including DVT,PE) and when not use (e.g. metallic valve) etc. or is it out of scope here and best left to GPs? No further comments made
	Document was discussed at length at JPC and KMOCC. The wording in the latest draft reflects the discussion at these committees.	Nov 2021	GP stakeholders requested some rewording around FBC point on table 1 (An Hb drop (>1g/dL) should prompt a review and may require further investigation; consider a clinical assessment of the patient) and LFTs (Caution and seek specialist(s) advice as appropriate when results are out of normal range)
Version 5 Draft April 2025			



- 1. Monitoring recommendations for Direct Acting Oral Anticoagulants (DOACS) in primary care
- 2. Assessing Renal Function for dosing of DOACs
 - 1. Monitoring Recommendations of Direct Oral Anticoagulants

For full details of monitoring requirements <u>PRIOR</u> to starting treatment and <u>ONGOING</u>, after treatment has started, please refer to the following resources in the summary table below. The SPS and NICE CKS resources give detailed advice on monitoring requirements and frequency.

Resource Links:	Apixaban	Rivaroxaban	Edoxaban	Dabigatran			
NICE Guidelines (NG196)	Atrial fibrillation: diagnosis and management (for stroke and bleeding risk assessment)						
NICE Guidelines (NG158)	Overview Venous thromboembolic diseases: diagnosis, management and thrombophilia testing Guidance NICE						
SPC (Specific Product Characteristics)	<u>Apixaban SPC</u>	<u>Rivaroxaban SPC</u>	<u>Edoxaban SPC</u>	Dabigatran SPC			
NICE CKS (Anticoagulation) (Includes information on monitoring and switching)	<u>Scenario: Apixaban</u> <u>NICE CKS</u>	<u>Scenario: Rivaroxaban</u> <u>NICE CKS</u>	<u>Scenario: Edoxaban</u> <u>NICE CKS</u>	<u>Scenario: Dabigatran</u> <u>NICE CKS</u>			
BNF (British National Formulary)	<u>Apixaban</u>	<u>Rivaroxaban</u>	<u>Edoxaban</u>	<u>Dabigatran</u>			
SPS (Specialist Pharmacy Service - login required)	Monitoring DOACs (Direct Oral Anticoagulants) To assess bleeding risk, use the <u>ORBIT bleeding risk score</u> because evidence shows that it has a higher accuracy in predicting absolute bleeding risk than other bleeding risk tools (NG196).						
Compliance aid compatibility (As per SPS)	Dabigatran -Not Compatible must be kept in original packaging – moisture sensitive.						

- If renal function has declined, treatment must be reviewed as DOAC dose may need to be reduced or alternative treatment initiated e.g. Warfarin or alternative DOAC. See SPC's for individual anticoagulants (linked in table directly above)
 - 2.

Assessing Renal Function for dosing of DOACs

- a) All DOACs are to some extent, dependent on the kidneys for excretion.
- b) Using a lower dose, when patients do not meet criteria for dose reduction may increase the risk of embolic events and result in potentially preventable strokes in AF. Using a higher dose than indicated by the renal function may increase the risk of bleeding



c) Dosage adjustments for DOACs should be based on creatinine clearance (CrCl) estimated using the Cockcroft-Gault (CG) formula, not eGFR. (use up to date blood tests and body weights). Please ensure you refer to SmPC and BNF for dosing, specific to indications. (*Note: dose of Apixaban in NVAF is determined by serum creatinine, weight, age as well as CrCl-* <u>See BNF</u>)

The MDCalc Tool is recommended for Calculating Creatinine Clearance (CrCl) This can be accessed using the link (here) or it can be downloaded as an app.

- MDCalc recognises the need to adjust bodyweight in obese individuals and will calculate a modified estimate of CrCl with a range that is based on ideal body weight, adjusted body weight and actual bodyweight.
 - d) Measure actual body weight each time CrCl is calculated (The Cockcroft and Gault formula may not be accurate for estimation of CrCl at extremes of bodyweight, especially in obese patients. It is important to remember that the CrCl is an estimate and should not be considered in isolation.
 - e) Do not use eGFR except in exceptional circumstances where it is not possible to obtain a person's weight as studies with DOACs have demonstrated that it overestimates renal clearance in comparison with CrCl. Actual body weight and CrCl was used in all the major DOAC clinical trials.
 - f) In patients at extremes of body weight (<60kg or >120kg) refer to individual drug SPC and seek specialist advice where necessary.
 - g) After a hospital admission or other transition of care, clinicians should aim to review the dose of a DOAC before issuing a first prescription in primary care. This is because renal function can alter during acute admissions, and it may not have been possible to calculate CrCl during admission.

Further Reading

- 1) NICE Guidance: Atrial Fibrillation: Diagnosis and Management (NG196). 27th April 2021
- 2) <u>Recommendations | Venous thromboembolic diseases: diagnosis, management and thrombophilia testing | Guidance | NICE</u>
- 3) NICE CKS Anticoagulation-oral.
- 4) DOACs (Direct Oral Anticoagulants) monitoring SPS Specialist Pharmacy Service The first stop for professional medicines advice
- 5) MHRA. DOACs- Reminder of bleeding risk including availability of reversal agents. 29 June 2020.
- 6) MHRA. Drug Safety Update. Prescribing medicines in renal impairment: using the appropriate estimate of renal function to avoid the risk of adverse drug reactions. 18 October 2019.
- 7) Electronic medicines compendium (summary of product characteristics SPC) for <u>apixaban</u>, <u>dabigatran</u>, <u>edoxaban</u> & <u>rivaroxaban</u>
- 8) British National Formulary (BNF) summaries for <u>apixaban</u>, <u>dabigatran</u>, <u>edoxaban</u> &<u>rivaroxaban</u>
- 9) <u>PrescQIPP</u>. Bulletin 282: anticoagulation (login required)