

## Direct Oral Anticoagulant (DOAC) Initiation Guidance for Non- Valvular Atrial Fibrillation (AF) & Guidance for Healthcare Professionals (HCPs) Monitoring DOACs Prescribed in all Indications

This template guidance relates to **AF patients ONLY at initiation**: Please refer <u>any other indications</u> for anticoagulation initiation to specialist anticoagulation services.

Monitoring guidance on page 2 applies to all indications for DOAC therapy.

#### Which Patients? Assess need and offer anticoagulation for:

- Non-Valvular AF/Atrial Flutter
- CHA2DS2-VASc ≥2 (consider ≥1 for men)
- A cardioversion/ablation procedure when advised by a cardiology specialist (*started regardless of CHA2DS2-VASc score*. *If the score is 0, patients do not require long term anticoagulation following the procedure*)

#### <sup>2</sup> Contraindications? Do not treat: refer patient to specialist services when

- Known intolerance to anticoagulation/previous serious bleed (consider a lesion or condition that is a significant risk for major bleeding e.g. current or recent gastrointestinal ulceration, known or suspected oesophageal varices)
- Hepatic disease associated with coagulopathy
- Mechanical heart valve
- Transcatheter aortic valve implantation within last 3/12
- Mitral valve replacement or repair within last 3/12
- Known moderate to severe mitral stenosis (valvular AF)
- Active or underlying cancer
- Pregnant/breastfeeding or planning a pregnancy
- Triple positive antiphospholipid syndrome (APLS)

#### 3 Assess for initiation of DOAC

Parameter	Action	When to refer (or advice & guidance)
Actual Weight	Measured within the last year	<50kg or >120kg
Creatinine	Refer to Calculating Renal Function	When CrCl <30ml/min
Clearance (CrCl)	DO NOT USE eGFR or /ideal body weight for CrCl	(If CrCl <15ml/min requires a warfarin referral)
	Review medications that affect renal function if	Dialysis patients
	CrCl reduced: See <u>Guidelines for Medicines</u>	If CrCl >95ml/min (edoxaban is cautioned- use
	Optimisation in Patients with Acute Kidney Injury	alternative DOAC)
Review blood	Check	Full blood count (FBC): Hb low with no identifiable
results within	U&Es: serum creatinine (Cr)	cause, Platelets <100
the last month	FBC: haemoglobin (Hb), platelets	Liver function tests (LFTs) >2 x ULN, Bilirubin >1.5
	LFTs: AST/ALT, Bilirubin	ULN
	Baseline clotting screen	Abnormal clotting screen
Bleeding risk	Modify risk factors to reduce bleeding risk	Gastrointestinal/genitourinary bleed within 3/12
<u>HASBLED</u> score		Intracranial haemorrhage within last 6/12
		Severe menorrhagia
		Known bleeding disorders
		Known liver cirrhosis
Alcohol consumption	Aim < 8 units per week	Known liver cirrhosis
Blood Pressure	Address uncontrolled hypertension- systolic BP	
(BP) mmHg	>160mmHg increases bleed risk	
Concurrent	Antiplatelets: review course length and indication	Dual Antiplatelet Therapy (DAPT)
medications	NSAIDs: bleeding risk	Antiplatelet co- prescribing should be avoided
	Check for interactions -Refer to SPCs BNF, HIV Drug	(unless advised by a specialist)
	Interaction Checker	Contraindications
	Consider ability of patient to swallow oral	Interactions
	medications- crushable/liquid options for AC	Ask pharmacist for advice

#### Choose DOAC (consider patient preference and lifestyle- adapt dosing as below): see appendix 1 for counselling

SPC hyperlinks:	<b>Edoxaban</b>	Rivaroxaban	<u>Apixaban</u>	<u>Dabigatran</u>
Standard dose	60mg OD	20mg OD (with	5mg BD	150mg BD
		food)		
Reduced dose	30mg OD	15mg OD (with	2.5mg BD	110mg BD
		food)		
Criteria for reduced	≥ 1 of	CrCl 15-49ml/min	≥ 2 of;	<ul> <li>Age ≥ 80 yrs</li> </ul>
dose	<ul> <li>weight ≤ 60kg</li> </ul>		<ul> <li>Age ≥ 80yrs</li> </ul>	On verapamil
	CrCl 15-50ml/min		<ul> <li>weight ≤ 60kg</li> </ul>	Consider for
	<ul> <li>On ciclosporin,</li> </ul>		<ul> <li>Cr ≥ 133μmol/L</li> </ul>	<ul> <li>Reflux/gastritis</li> </ul>
	dronedarone,		OR	o Age 75-80 yrs
	erythromycin,		CrCl 15-29ml/min	o CrCl 30-50ml/min
	ketoconazole			o "Bleed risk"
Contra-indicated	CrCl <15ml/min	CrCl <15ml/min	CrCl <15ml/min	CrCl <30ml/min
	(caution CrCl			
	>95ml/min)			
Compliance aid?	Compatible	Compatible	Compatible	Not compatible

#### Monitoring: For patients who DNA for monitoring, refer to practice repeat prescribing protocol

First Review	Then MINIMUM YEARLY review  (more frequent renal, liver and haemoglobin monitoring if CrCl <60ml/min, age over 75 years and/or frail- see table 6 below)	
ideally after 1 month of therapy)		
<ul> <li>Check for side effects (refer to SPC for each DOAC- table 4) – seek advice and guidance from haematology clinic if present/a concern</li> <li>Check for bruising/bleeding – refer for further investigation according to local pathways as indicated (DOAC FAQs)</li> <li>U&amp;Es and FBC- as specified by initiating clinic/secondary care and/or if indicated by a change to clinical state: Check CrCl (and review DOAC dosing- see table 4)</li> <li>Check medication adherence- refer to community pharmacist for NMS (New Medicines Service) and further support (refer to DOAC counselling checklist-appendix 1)</li> <li>Schedule repeat prescriptions and reviews</li> </ul>	<ul> <li>Age – check if DOAC dosage adjustment is required (see table 4)</li> <li>Weight - check if DOAC dosage adjustment is required (see table 4)</li> <li>FBC - investigate any Hb drop without an identifiable cause and if platelets &lt;100</li> <li>LFTs – seek advice and guidance from haematology clinic if Bilirubin &gt;1.5 ULN, AST/ALT &gt;2 x ULN</li> <li>U&amp;Es and CrCl (as per table below)- check if DOAC dosage adjustment is required</li> <li>Interacting/new medications- check if may effect DOAC dosing and set a review/course length date (seek advice from pharmacist as indicated)</li> </ul>	

### Renal function monitoring frequency: (see also guidance Calculating Renal Function)

Creatinine Clearance (CrCl) range (ml/min)	How often to check renal function?
<15	All DOACs contraindicated, refer to specialist (to consider warfarin)
15 to 30	3 monthly, consider referral to specialist (dabigatran contraindicated)
30 to 60 and/or aged >75 years and/or frail±	6 monthly
All patients aged > 75 years and/or frail	6 monthly
>60	12 monthly

# **Appendix 1: DOAC in AF Counselling Checklist for healthcare professionals (HCP)**

Apixaban (Eliquis®), Dabigatran (Pradaxa®), Edoxaban (Lixiana®), Rivaroxaban (Xarelto®)

DOAC Agent Counselled: .....

<b>Counselling points</b> (tailor specifics to your patient and record any queries or concerns in medical notes)	HCP Sign:
Explanation of an anticoagulant (increases clotting time and reduces risk of clot formation) and	
explanation of atrial fibrillation (including stroke risk reduction)	l
<b>Differences between DOAC and warfarin</b> (if applicable for patients converting from warfarin to DOAC	
therapy <u>or</u> offering choice of anticoagulation agent)	ı
No routine INR monitoring	ı
Fixed dosing	ı
<ul> <li>No dietary restrictions and alcohol intake permitted (within national guidelines)</li> </ul>	ı
Fewer drug interactions	ı
Name of drug: generic & brand name	
Explanation of dose: strength & frequency	<u> </u>
Duration of therapy: lifelong (unless risk:benefit of anticoagulation changes)	<u>.                                    </u>
To take with food (dabigatran and rivaroxaban). Not required for apixaban or edoxaban	
Missed doses: Message is to "take the dose as soon as you remember and then at the same time each	
day". For further information:	1
Apixaban and dabigatran can be taken within 6 hours of missed dose, otherwise omit the	ı
missed dose	1
• Edoxaban and rivaroxaban can be taken within 12 hours of missed dose, otherwise omit the	ı
missed dose	ı
Extra doses taken: obtain advice immediately from pharmacist/GP/NHS Direct (111)	
Importance of adherence: short half-life and associated risk of stroke and/or thrombosis if non-	
compliant	ı
Common and serious side-effects and who/when to refer: symptoms of bleeding/unexplained	
bruising. Avoidance of contact sports	ı
<ul> <li>Single/self-terminating bleeding episode – routine appointment with GP/pharmacist</li> </ul>	ı
<ul> <li>Prolonged/recurrent/severe bleeding/head injury – A&amp;E</li> </ul>	ı
Major bleeds managed/reversed by supportive measures and Prothrombin Complex Concentrate (PCC).	l
Antidotes: Idarucizumab for dabigatran (NICE TA)	İ
Drug interactions and concomitant medication: avoid NSAID's. Always check with pharmacist	<u> </u>
regarding OTC/herbal/complimentary medicines	ı
Inform all healthcare professionals of DOAC therapy: GP, nurse, dentist, pharmacist i.e. prior to	
surgery	ı
Pregnancy and breastfeeding: potential risk to foetus – obtain medical advice as soon as possible if	
pregnant/considering pregnancy. Avoid in breastfeeding	
<b>Storage:</b> dabigatran <u>must</u> be kept in original packaging – moisture sensitive. All other DOAC's suitable for medication compliance aids if required	l
Follow-up appointments, blood tests, and repeat prescriptions: where and when	
Record here:	ı
Issue relevant patient information AF booklet/leaflet and anticoagulant patient alert card	. <u> </u>
(For AC alert card supplies- email: pcse.supplies-leeds@nhs.net)	1
Give patient opportunity to ask questions and encourage follow up with community pharmacist	<del></del>
(NMS – New Medicine Service)	1
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