Service Specifications

Service Specification No.	FINAL – June 2023
Service	Direct Acting Oral Anticoagulation (DOAC) Management
Commissioner Lead	NHS Lincolnshire Integrated Care Board (ICB)
Period	1st April 2023 – 31st March 2024
Date of Review	June 2023

1. Population Needs

1.1 Context

- Anticoagulation needs are not restricted to patients with Atrial Fibrillation (AF). The burden of venous thromboembolic disease (VTE) is also significant for ICBs. Whilst many episodes of VTE have an identifiable cause, a significant number are either spontaneous or recurrent and will result in a need for lifelong anticoagulation. DOACs provide an excellent and highly effective treatment option for the majority of VTE patients.
- It is estimated that 1.4 million people in England have AF. This is equal to 2.5% of the population
- AF prevalence is higher in men than in women, 2.9% versus 2.0%.
- AF prevalence increases with age; 2.8% of the total estimated AF in the population is likely to occur in people aged under 45, 16.6% in people aged 45-65 and 80.5% in people aged over 65.

Studies indicate that one in twenty of those untreated patients are likely to have a stroke every year and that 66% of these can be avoided by anticoagulation. Strokes occurring as a result of Atrial Fibrillation are generally the most disabling strokes a person can have. 20% of people having an AF stroke will die acutely and a further 60% will suffer permanent disability as a result of the AF stroke.

There are a number of people who require anticoagulation but have not been identified. It is estimated that the current diagnosed UK prevalence rate is 1.9% which equates to as many as 425,000 people in the UK that may have undiagnosed atrial fibrillation (AF). It is estimated that in Lincolnshire there are around 6,600 people with undiagnosed AF (0.85%). Undiagnosed AF rates are much higher in the older population. Reference: https://www.gov.uk/government/publications/atrial-fibrillation-prevalence-estimates-for-local-populations

For Lincolnshire ICB the estimated AF prevalence is 2.8% (2021-22). At GP level for Lincolnshire this ranges from 1.4% to 4.9%.

As of 1 January 2023, the Lincolnshire population was 813,240. The estimated number of patients therefore who will need access to anticoagulation based on likely prevalence of 3.1% is approximately 25,210. Guidance from the National Institute for Clinical Excellence (NICE) and from the Quality and Outcomes Framework (QOF) means that the number of patients requiring this care is likely to continue to increase. PACEF (Prescribing and Clinical Effectiveness Forum) have considered a range of key opinion leaders in terms of developments in AF. These include the All Party Select Committee on AF (GRASP-AF), East Midlands Cardiac and Stroke Network and European Society of Cardiology. National data from the GRASP-AF initiative reports that 8.5% of AF patients at high risk of stroke are receiving no treatment, 35% are on aspirin and 56.9% are receiving an oral anticoagulant.

It should be noted that NICE now advise that Aspirin monotherapy alone is not offered to patients with AF for stroke prevention as anticoagulants present no greater safety risk than Aspirin and evidence has shown that Aspirin has minimal efficacy in stroke prevention in atrial fibrillation.

1.2 Local Context

Lincolnshire's Integrated Care System and Integrated Care Board

The NHS Lincolnshire Integrated Care System (ICS) was created on 1 July 2022 following an amendment of the Health and Social Care Act 2006.

The ICS is a partnership that brings together providers and commissioners of NHS services across Lincolnshire with local authorities and other local partners (such as the voluntary sector), to collectively plan health and care services to meet the needs of their population.

The 4 aims of the ICS are:

- improve outcomes in population health and healthcare
- tackle inequalities in outcomes, experience, and access
- enhance productivity and value for money
- help the NHS support broader social and economic development

NHS Lincolnshire Integrated Care Board (ICB) is the statutory body within Lincolnshire ICS responsible for the provision of health services, in accordance with the Health and Care Act 2022.

Lincolnshire ICB will use its resources and powers to collaboratively tackle complex challenges, including:

- improving the health of children and young people
- supporting people to stay well and independent
- acting sooner to help those with preventable conditions
- supporting those with long-term conditions or mental health issues
- caring for those with multiple needs as the population ages
- getting the best from collective resources so people get care as quickly as possible

Lincolnshire ICB statistics

- Lincolnshire ICB has 82 practices
- The total registered population is 813,240 (as of January 2023)
- The registered population live in 7 different lower tier Local Authorities
- As of 2021, the male average life expectancy in Lincolnshire (78.3 years) is slightly lower than the national average (78.7 years). The average Lincolnshire life expectancy for females is 82.8 years, which is the same as the national average
- The 2021 overall premature mortality rate in Lincolnshire (deaths <75 years per 100,000) is 366.3, which is slightly higher than the national figure of 363.4
- The average level of deprivation in England as of 2019 was 21.7. Lincolnshire ICB as a whole is slightly less deprived than this, at 20.2. However, there are pockets of deprivation across the county that are within the national 20% most deprived areas (mainly around coastal and inner urban areas)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	X
Domain 2	Enhancing quality of life for people with long-term conditions	X
Domain 3	Helping people to recover from episodes of ill-health or following injury	X
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	X

2.2 Local defined outcomes

The commissioned service will be delivered within a primary care setting and must be easy to access for all patients. Uniformity of standards and procedures are necessary to provide a high-quality service for patients who are mobile and able to attend a monitoring appointment and also for patients who are temporarily in the area, as well as for patients that are housebound[1] and require domiciliary care.

DOACs are covered within this service specification. Guidance is contained https://cks.nice.org.uk/anticoagulation-oral and further guidance is in this specification.

The service must:

- Ensure that where appropriate and where indicated, patients are initiated onto oral anticoagulation therapy in a secondary or primary care setting at the earliest opportunity and monitoring and maintenance takes place, where possible, within a primary care setting
- Provide adequate capacity in the community to meet the current and rising demand for anticoagulation monitoring. Services to be based at the patient's own registered practice or as locally as practicable and communicating effectively with the patient's own registered practice.
- Ensure a quality approach to monitoring and correct dosing of patients
- Ensure that maintenance of patients is properly controlled; the need for continuation of therapy is reviewed regularly, the dose changed, or therapy discontinued as appropriate.

3. Scope

Background

The management of patients requiring oral anticoagulation therapy includes:

- Stroke prevention in non-valvular atrial fibrillation
- Treatment of thromboembolic disease
- Prevention of recurrent thromboembolic disease
- Prevention of thromboembolism post-hip and knee surgery (use of DOAC varies for this indication)

Increasingly patients are initiated on or changed to a direct oral anticoagulant (DOAC), currently these are Edoxaban, Dabigatran, Rivaroxaban and Apixaban. Guidance relating to management of patients taking DOAC medication can be found: (Appendix A & B)

Reference: https://cks.nice.org.uk/anticoagulation-oral

Note: Warfarin therapy (rather than DOAC use) is indicated specifically with the following conditions:

- Stroke prevention in valvular atrial fibrillation in connection with patients who have moderate to severe mitral stenosis
- Stroke prevention in valvular atrial fibrillation in connection with patients with mechanical prosthetic heart valves (European Society of Cardiology Guidelines) -note each valve type has specific management guidelines and is an evolving picture
  Reference: https://www.escardio.org/Search?q=prosthetic+valves
- The management of Ventricular wall thrombus & ventricular aneurysms (DOAC have significantly poor outcomes and are contra-indicted in the treatment of mural thrombosis)

3.1 Aims and objectives of the service

To provide a safe, effective and accessible initiation, stabilisation, monitoring and dosing of Direct-Acting Oral Anticoagulation (DOAC) Management service in a community setting for patients.

[1] Definition of Housebound – *"A patient is deemed to be housebound when they are unable to leave their home environment through a physical or psychological illness. A patient is not considered housebound if he or she is able to leave their home with minimal assistance. For example unassisted/assisted visit to the doctor, dentist, hairdresser, supermarket, social events. Some patients may not be housebound permanently but rather are housebound temporarily as a consequence of an episode of illness."*

To ensure a seamless service for patients aged 16 and over, registered to a GP practice in Lincolnshire who have been initiated on DOAC therapy in primary care and where appropriate, patients initiated in secondary care in line with National Guidance.

*Please note that if patients present to the service who are **under 16 or an obstetric** patient, they should be discussed and reviewed on a case-by-case basis, this review should include the provider, supervising Consultant (paediatrician or obstetrician) with a view to reaching a decision as to where and how that patient is to be treated (see exclusions below).*

The service will minimise the potential adverse effects of DOAC therapy by providing patients with appropriate monitoring while continuing to maximise the effective benefits of such treatment.

The service will have equitable access, ensuring that patients are treated with dignity and respect, are fully informed about their care and are able to make decisions about their care in partnership with healthcare professionals.

The key objectives are as follows:

- To provide standardised and clinically effective management to patients receiving DOAC therapy whilst minimising the risks associated with this method of anticoagulation, following nationally recognised and clinical safe standards.
- To initiate DOAC therapy for suitable patients (may have been initiated in secondary care setting).
- To produce optimum management.
- To educate patients in understanding their treatment, in terms of their condition requiring DOAC therapy.
- To maintain a register of all patients receiving DOAC therapy and have a treatment plan for each patient that is reviewed on a regular basis.
- To review the need for continuation of therapy at each visit.
- To identify and manage appropriately, patients with specific needs i.e. poor compliance, non-attendees. This includes the updating of electronic patient clinical records to reflect each review.
- To optimise care to patients receiving DOAC therapy in terms of accessibility, continuity of care and treatment and waiting times.
- To ensure complete and accurate documentation of the clinical process.
- To respond appropriately and in a timely way following notification of changes in co-prescribed medication and to ensure this is communicated effectively to the patient as well as clinicians involved in the patient's care.
- To undertake an annual review and update of the protocol referred to in section 4.3.4.
- Consider the impact of patient choice (patient satisfaction questionnaire annually e.g. accessibility, waiting time, confidence in staff ability and continuity of care).

3.2 Service description/care pathway

This specification refers to DOAC therapy being delivered in primary care. Providers will monitor DOAC use in line with national guidelines and will also initiate patients onto DOAC therapy where appropriate including the continuation of initiation started in secondary care.

3.2.1 Service requirements: DOAC therapy monitoring

This service does not include diagnosis of VTE or AF, or commencement of low molecular weight heparin therapy where that is appropriate.

Service providers are expected to follow guidance set out in the protocol for DOAC use which sets out minimum requirements. This is included in *Appendix A*.

The service provider is expected to provide the following service:

- Initiation
- Regular monitoring and follow-up

- Planned discontinuation
- Adjustment for in-practice procedures (surgeons must specify their own requirements for procedures in hospital)
- Treatment of temporary resident patients
- Liaison with cardiology regarding treatment before and after cardioversion

3.2.2 Referral into the Anticoagulation DOAC Service:

No formal referral into the service is required however providers need to ensure that where a patient has been commenced on treatment by secondary care, or new patients have joined the practice, they will be added to the register of DOAC patients.

Where necessary the provider will be expected to initiate and continue the management of DOAC therapy.

3.2.3 Anticoagulation – choice of treatment

DOACs:

There are a number of newer direct oral anticoagulants (DOACs) available which require less monitoring than warfarin; however standardised management and monitoring is still required. The decision on which agent is appropriate for a patient is made in line with current local and national guidance (see section below) and following an informed discussion as to anticoagulant options.

If *considering* or *offering* anticoagulation, options include either Warfarin or a DOAC (Edoxaban, Dabigatran Rivaroxaban and Apixaban). The clinician should discuss the options for anticoagulation with the patient and base the choice on their clinical features, preferences and bleeding risk.

Discussing anticoagulant treatment options with patients will help them make an informed decision using patient decision aids (PDAs).

Following an AF diagnosis, the patient will need to make an informed decision regarding whether to commence anticoagulation or not. In most cases the decision to start immediate anticoagulation is not necessary. The patient should be given a few days to reflect and to talk over with family, friends or healthcare professional before making their decision.

Following the diagnosis of a Ventricular Tachycardia (VT) the decision to anticoagulate is largely academic and patients should be provided with appropriate and timely treatment in the form of Low-molecular Weight Heparin (LMWH), DOAC or Warfarin depending on the clinical situation. The significant risk of clot extension and embolism must be stressed to the patient and any decision not to anticoagulate clearly documented.

NICE have produced patient decision aids to support patients and clinicians in choosing between the recommended options for stroke prevention in AF. All the options for anticoagulation should be considered and the advantages and disadvantages of the different treatments available should be discussed with the patient before choosing a particular drug. If the patient does not wish to commence anticoagulation; the decision should be documented following discussion with the patient using the PDA's and patient information produced by NICE: https://www.nice.org.uk/guidance/ng196

Key points: DOACs

- ✓ No requirement for INR monitoring.
- ✓ Some DOACs provide immediate anticoagulant effect (time to peak effect ranges from 1-4 hours).
- ✓ DOACs currently have no known food interactions.
- ✓ Reduced risk of intracerebral bleeds versus Warfarin

For all patients being considered for treatment with DOACs use the Cockcroft and Gault formula to

calculate the Creatinine Clearance.

Key points: Warfarin (*Vitamin K Antagonist*) (See local anticoagulation guidance for further information)

- ✓ Warfarin has been prescribed for more than 50 years and is a Vitamin K Antagonist medication.
- ✓ Warfarin remains an established and cost effective option for anticoagulation in patients.
- ✓ Reduced risk of Gastrointestinal (GI) bleed compared to DOAC – Dabigatran, Edoxaban and Rivaroxaban.
- ✓ Patients with AF and moderate to severe mitral stenosis, including mechanical valve replacement should be treated **only** with Warfarin **not** a DOAC.
- ✓ Unlike DOACs, Warfarin should be considered in those patients with mechanical heart valves, and for AF with moderate to severe mitral stenosis and/or hepatic impairment
- ✓ The benefits of DOACs over Warfarin declines as the Time in Therapeutic Range (TTR) on Warfarin increases.
- ✓ INR gives clinicians a guide to patient compliance.
- ✓ Effective and familiar use of antidote with vitamin K should a severe bleed occur whilst being treated.
- ✓ All DOACs are licensed for prevention of stroke in non-valvular atrial fibrillation plus at least one additional risk factor. Warfarin can be used with no additional risk factors.
- ✓ Clearance of Warfarin is not affected by renal function.
- ✓ Clinicians may choose to use Warfarin in patients for whom the ability to readily and objectively monitor the extent of anticoagulation is paramount.
- ✓ For patients with poor adherence, the long time to onset and offset of action, may be advantageous as the anticoagulant effect of Warfarin will persist for days after the last dose.

Reports of calciphylaxis, a very rare but serious condition causing vascular calcification and skin necrosis have been reported to the MHRA. The mortality rate is high. Patients should consult their doctor if they develop a painful skin rash. See MHRA, July 2016 for further details.

The service provider will provide information on a range of relevant issues to enable patients to fully understand their treatment. Patients will receive appropriate verbal and written information at the start of their therapy and when necessary throughout the course of their treatment. It is important that the healthcare practitioner who first provides this information records in the patient's healthcare record that this information has been supplied. The provider should emphasise and explain to each patient the importance of carrying an alert card and presenting this when attending clinical appointments, including Accident and Emergency attendance, dental reviews.

Defined areas of responsibility will be mutually agreed locally between the service provider and the Commissioner to ensure the best possible coverage of the DOAC service throughout the area.

All patient's, whether housebound or clinic attendees, will have a regular review, at a frequency determined by assessed clinical need. Note that regular review of the anticoagulation aspect of a patient's management may not require face to face consultation with a GP; regular monitoring of creatinine clearance, full blood counts & liver function with evidence in the form of an administrative consultation entry showing the next interval for monitoring & comments relevant to ongoing management will suffice. Staff taking blood for DOAC reviews should be encouraged to enquire into tolerance, side effects and compliance.

The service provider will have in place a system for referring patients promptly onto acute services and relevant support agencies when their clinical condition / circumstances warrant it: i.e. if they have signs or symptoms of major bleeding or thromboembolism. These services will include, but are not limited to, the Accident and Emergency Department and local Acute Ambulatory Care Unit.

3.2.1 Data Collection and Record Keeping

The Service Provider will develop and maintain an up-to-date register of all patients for whom they provide a DOAC service. Service Providers will ensure that an up-to-date systematic call and recall system is in place.

Providers should record all the required information detailed on the Minimum Data Set (MDS) which will inform a quarterly report. The required reporting template can be found in Schedule 6A of the contract

It is recommended that the practice use the following codes when recording the delivery of this enhanced service.

Procedure	READ codes	SNOWMED codes
Anticoagulation monitoring enhanced services administration	XaK9m	166271000000109

The computerised decision support software such as INR Star provides a useful additional record facility for DOAC patients; providers are encouraged but not required to utilise these systems as they provide excellent recall and audit tools and are continuously improving their provision for DOAC patients.

The DOAC Provider will be responsible for maintaining each patient's electronic record and ensuring it is updated following each clinical contact.

The information recorded will include:

- Medical Condition leading to requirement for treatment
- Date of Initiation
- The dose of DOAC medication
- The date of the next review appointment
- Information from the prescriber where appropriate
- Patient specific unusual events
- Expected duration of treatment Stop date (if known) e.g., for DVT/ PE

All staff are required to protect personal data in accordance with the requirements of the UK General Data Protection Regulations. 'Personal data' means data relating to a living individual who can be identified from data or other information in the possession of Lincolnshire ICBs or the provider organisation. Staff must not make unauthorised access to, modification to or copy computer material in breach of the Computer Misuse Act 1990. If there is any doubt about staff obligations under any of this legislation the Commissioner must be contacted for clarification.

3.2.2 Reporting and Audit

The service provider will undertake an annual audit and review of the service provided including all quality aspects. The results will be compiled and sent to the Commissioner. Circumstances may arise when a more frequent review is deemed necessary. A review meeting may be required and any reasonable requests for information must be complied with.

The service provider will use the audit results to inform local actions to improve the safe use of anticoagulants.

3.3 Any acceptance and exclusion criteria and thresholds

3.3.1 Population covered and Acceptance

Patients must be temporarily or permanently registered with a General Practice within the geographical boundary of Lincolnshire ICB, and who fit the criteria below will be eligible for care under this service.

The management of patients requiring DOAC therapy includes:

- Stroke prevention in non-valvular atrial fibrillation
- Treatment of thromboembolic disease
- Prevention of recurrent thromboembolic disease
- Prevention of thromboembolism post-hip and knee surgery (use of DOAC varies for this indication)

3.3.2 Exclusions

- Patients who are pregnant
- Patients under 16 years of age
- Patients allergic to or unable to tolerate DOAC therapy or where this is contraindicated
- Those at risk of a major bleed should have their particular cases discussed with a specialist in anticoagulant care after which, by agreement, they may be excluded from this service.

Current Nice guidance recommends using the ORBIT bleeding risk score rather than HAS-BLED. ORBIT is not incorporated into SystmOne but can be accessed via an external link below:

ORBIT Bleeding Risk Score for Atrial Fibrillation - MDCalc

3.4 Interdependence with other services/providers

The provider is expected to work across the Lincolnshire Health System.

Providers are expected to cooperate and share information with others involved in a patients care, treatment and support while having regard to the patients' rights to confidentiality.

3.5 Days/hours of operation

The service must be available during the following core hours:

Monday – Friday, 08:00 to 18:30, excluding bank holidays.

The service provider must ensure the hours are appropriate to the needs of the service and patients and that over a weekly period, both morning and afternoon appointments are available.

4. Applicable Service Standards

4.1 Applicable National Standards (e.g., NICE)

The Provider shall comply with all of the NHS Standard Contract requirements appropriate to the service.

National Standards

- National Service Framework for Coronary Heart Disease National_Service_Framework_for_Coronary_Heart_Disease.pdf (publishing.service.gov.uk)
- NICE Clinical Guideline 196 on 'Atrial Fibrillation: management' https://www.nice.org.uk/guidance/ng196
- NICE Clinical Knowledge Summaries 'Anticoagulation – Oral https://cks.nice.org.uk/anticoagulation-oral
- NICE Quality standard QS93 https://www.nice.org.uk/guidance/qs93
- Venous thromboembolism overview - NICE Pathways
- British Committee for Standards in Haematology (1998, updated 2011). Guidelines on oral anticoagulation: third edition. *British Journal of Haematology,* **101**, 374-387.
- Patient Safety Alerts – Actions that can make anticoagulant therapy safer. Available online at: https://www.gov.uk/report-problem-medicine-medical-device

Venous thromboembolism

- NICE Interactive Flowchart on VTE https://pathways.nice.org.uk/pathways/venous-thromboembolism
- NICE Quality Standard Q3 for Venous thromboembolism in adults: reducing the risk in hospital https://www.nice.org.uk/guidance/QS3
- NICE Quality Standard QS201 (Aug 2021) for Venous thromboembolism in adults: diagnosis and management https://www.nice.org.uk/guidance/qs201 NICE
- NICE Technology Appraisal TA287 - Rivaroxaban for treating pulmonary embolism and preventing recurrent venous thromboembolism https://www.nice.org.uk/guidance/TA287
- NICE Technology Appraisal TA157 - Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults https://www.nice.org.uk/guidance/ta157/chapter/1-guidance

Other

- NICE Interactive Flowchart on Stroke https://pathways.nice.org.uk/pathways/stroke
- NICE Clinical Guideline CG76 - Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence https://www.nice.org.uk/guidance/cg76

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g., Royal Colleges)

See 4.3.5 Accreditation and Training

4.3 Applicable local standards

4.3.1 Facilities

Providers must have policies in place that comply with current national guidelines. Safe and suitable facilities should be available for the administration of DOAC drugs and include:

- Infection control
- Disposal of clinical waste
- Provision of an appropriate room fitted with a couch and adequate space and equipment for resuscitation.
- Provision of sterile surgical equipment and other consumables

This may include home administration.

4.3.2 Equipment

No specific equipment is required.

4.3.3 Staffing

The staff providing the service must have access to a named clinician who is trained, competent, confident and available to offer support and advice to provide this service.

The Service Provider must identify a Service Manager or Lead Clinician, who is responsible for:

- Managing the operational aspects of the service
- Managing all staff
- Ensuring that all staff involved in the service are appropriately trained and competent to provide the specified service
- Ensuring the continued development of the service and staff involved in delivering the care
- Ensuring service contingency plans are developed and in readiness for implementation should the need arise.
- Evaluating the efficacy of the service through the systematic monitoring of quality indicators, thereby ensuring the service meets the requirements of the patients

- Reviewing in conjunction with the Clinical Lead, and where appropriate, updating procedures and clinical protocols for DOAC services to ensure that they reflect safe practice.
- Overseeing, in conjunction with the Clinical Lead, the audit of the DOAC services
- Ensuring that the audit results are used to inform local action to improve the safe use of DOAC medications and sharing the results with the Commissioner Contract lead on an annual basis.
- Ensuring that all equipment is safe and appropriately maintained, that national and local safety alerts are acted on; software licenses maintained; and systems in place to assure the appropriate management of data in line with the statutory Information Governance responsibilities.
- Delivering as requested the contract monitoring reports outlined within this specification to the contract lead of Lincolnshire ICB.

4.3.4 Protocol

Providers must be able to evidence to commissioners that they have an approved protocol in place.

4.3.5 Accreditation and Training

Staff involved in the delivery of this service should be appropriately trained and have appropriate competencies to enable them to undertake their duties safely.

The commissioner, in collaboration with providers, should ensure that this training includes, but is not be limited to, the following:

- Regular masterclass training and mandatory biannual training (annually is encouraged).
- Speakers of local or national recognition with expertise in issues relating to VTE, AF and other clinical conditions for which DOACS are indicated.
- Knowledge of changing NICE/SIGN/BHS or other international guidance (Europe/US) and updated evidence.
- Guidance on changes to commercial software support for DOAC management i.e., INR STAR may be invited to "showcase" products or advise on updates.
- Contribution to mandated audits and potential for research in collaboration with local medical schools etc.

Specifically, the provider must ensure that all staff who prescribe; adjust dosage; dispense, prepare, administer, monitor, and discharge patients on DOAC therapy have attained the necessary competencies outlined by NICE. See competencies related to:

- Maintaining anticoagulant therapy
- Managing anticoagulants in patients requiring dental surgery
- Dispensing medications
- Reviewing the safety and effectiveness of a DOAC service.
- Initiating anticoagulant therapy with DOACs

It is expected that all GP providers will comply with regular training requirements such as:
- Sharps

This list is not exhaustive.

5. Applicable quality requirements and CQUIN goals

5.1 Practices which take part in the scheme must demonstrate that service provision is of high quality, evidence based, safe and effective, with robust governance systems and safeguards in place, staff have received appropriate training and equipment is maintained to the highest standard. Practices may be required to provide commissioners with assurance that services provided are within the criteria of the contract general conditions, service conditions and particulars.

The Service Provider will notify the ICB Quality Services Team, Cross O'Cliff Court, Bracebridge Heath, Lincoln, LN4 2HN directly or by email licb.clinicalriskincidents@nhs.net of all serious incidents. These must be reported by the service provider within one working day of the information becoming known to them.

The service provider will participate in a review of any serious incidents notified to the Head of Quality Services and demonstrate that any learning from the incident is acted upon to minimise future risk.

5.2 CQUIN goals will not be applied.

6. Location of Provider Premises

It is the obligation of the provider to secure premises for service delivery. The provider has the opportunity to use their own practice facilities or negotiate use of a neighbouring GP practice facility or access current NHS accommodation in Lincolnshire managed and accessed through NHS Property Services (to include premises owned by Lincolnshire Community Health Services, United Lincolnshire Hospital Trust and certain GP practices). Location of service must provide ease of access for patients.

7. Individual Service User Placement

N/A

PLEASE NOTE: - these Appendices will be constantly reviewed and updated. Providers should access the most current version of Appendices A&B at the policies and guidance page below -

Lincolnshire Prescribing and Clinical Effectiveness

Appendix A (May 2022)

DOAC Management – Suggested Clinical Protocol for Clinicians

1. **Initiation & Follow up**

   Although there is no need for regular blood tests to monitor the international normalized ratio (INR), people taking DOACs require careful assessment prior to commencement of treatment and regular follow up and monitoring.

   - Baseline clotting screen, renal and liver function tests, and a full blood count should be performed at the start of treatment. This must include an assessment of creatinine clearance – most GP systems have in-built calculators or they are readily available on line. The use of eGFR alone for monitoring is not adequate, particularly where renal function is already shown to be compromised or declining.

   - All patients should have an initial 3 month review, by a clinician, confirming compliance & review of potential side effects; bloods for FBC, U&E, and LFT are required with current BP & weight to enable creatinine clearance to be calculated
     - Assess compliance to treatment and to reinforce advice regarding the importance of a regular dosing schedule.
     - Enquire about the presence of any adverse effects such as bleeding.
     - Assess for the presence of thromboembolic events (e.g. symptoms of stroke, or breathlessness, which may suggest a pulmonary embolism).
     - Ask the person if they have been taking any other medicines, including any bought over-the-counter.

   - Once treatment has started, repeat the renal and liver function tests and the full blood count at least annually.

   - Monitoring intervals must be tailored to individual patients; For the majority 6-12 month intervals may be acceptable, for the elderly or where renal function is declining or already compromised 3-6 monthly should be considered
     - If renal function has declined, review treatment, as treatment may need to be stopped or a lower dose may be required.
     - If there is an unexplained fall in haemoglobin and/or haematocrit, occult bleeding may be present. DOACs can cause bleeding from any site.
     - DOACs are contraindicated for people who have hepatic disease associated with coagulopathy and clinically relevant bleeding risk, including people who have cirrhosis with Child-Pugh B (moderate impairment) or C (severe impairment).

   - Repeat renal function tests:
     - Every six months if the person has a creatinine clearance (CrCl) between 30–60 mL/min.
     - Every three months if the person has a CrCl of 15–30 mL/min.

   - Renal and liver function tests should be performed more often if there is an intercurrent illness that may impact renal or hepatic function

1.1 Specific drug notes as specified in current guidance:

Edoxaban:

- For the prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation (NVAF), the recommended dose of Edoxaban is 60 mg once daily.

- **For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults, the recommended dose of Edoxaban is 60 mg once daily following initial use of parenteral anticoagulation for at least 5 days.**

- Reduce the dose of Edoxaban to 30 mg once daily if one or more of the following are present:
    - Moderate or severe renal impairment (creatinine clearance [CrCl] 15–50 mL/min).
    - Body weight of 60 kg or less.
    - The person is receiving concomitant treatment with any of following P-glycoprotein (P-gp) inhibitors: ciclosporin, dronedarone, erythromycin, or ketoconazole.

- For people with renal impairment:
    - Do not prescribe Edoxaban if creatinine clearance (CrCl) is less than 15 mL/minute.
    - If CrCl is 15–50 mL/min, reduce the dose to 30 mg once daily.

Dabigatran:

- For the prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation (NVAF), the recommended dose is 150 mg twice a day.

    - Reduce the dose to 110 mg twice a day if the person is:
        - Elderly (over 80 years).
        - At high risk of bleeding.
        - Receiving concomitant treatment with verapamil or amiodarone.

- **For the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults the recommended dose is 150 mg twice daily BUT ONLY COMMENCED AFTER AT LEAST 5 DAYS OF PARENTERAL ANTICOAGULANT**

    - Reduce the dose to 110 mg twice a day if the person is:
        - Elderly (over 80 years).
        - Receiving concomitant treatment with verapamil or amiodarone.

- For the prevention of venous thromboembolism (VTE)

  In people who have undergone hip or knee replacement surgery:
    - The recommended dose is 220 mg once daily (treatment should be initiated within 1-4 hours of completed surgery with 110 mg and continued with 220 mg once daily thereafter).

      However, the dose should be reduced to 150 mg once daily (treatment should be initiated within 1-4 hours of completed surgery with 75 mg and continued with 150 mg once daily thereafter) for people:
        - With moderate renal impairment (creatinine clearance (CrCl) 30-50 mL/min).
        - Receiving concomitant treatment with verapamil or amiodarone.
        - Aged 75 or above.

  For people with renal impairment:

- Do not prescribe dabigatran to anyone with a creatinine clearance (CrCl) of less than 30 mL/minute.

- If the person has a CrCl between 30–50 ml/min, consider decreasing the dose to 110 mg twice a day, based on the person's thromboembolic risk and risk of bleeding.
- No dose adjustment is necessary in people with mild renal impairment (CrCl 50–80 mL/min).

Rivaroxaban:

- For the prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation (NVAF),
  - The dose of rivaroxaban is 20 mg once daily.

- **FOR THE TREATMENT AND PROPHYLAXIS OF DEEP VEIN THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) AND THE PROPHYLAXIS OF RECURRENT DVT AND PE:**
  - **PRESCRIBE 15 MG TWICE DAILY FOR THE FIRST THREE WEEKS, FOLLOWED THEREAFTER BY 20 MG ONCE DAILY.**

- For the prevention of venous thromboembolism (VTE) in people who have undergone hip or knee replacement surgery,
  - The recommended dose is 10 mg once daily (treatment should be initiated within 6-10 hours of completed surgery).

- For the prophylaxis of atherothrombotic events in adults following an acute coronary syndrome (ACS) or with coronary artery disease,
  - Prescribe 2.5 mg twice daily (in combination with aspirin or with aspirin plus clopidogrel or ticlopidine).

- For with symptomatic peripheral artery disease at high risk of ischaemic events,
  - Prescribe 2.5 mg twice daily (in combination with aspirin or with aspirin plus clopidogrel or ticlopidine).

- For people with renal impairment:
  - Do not prescribe rivaroxaban if creatinine clearance (CrCl) is less than 15 mL/minute.
  - For prophylaxis of atherothrombotic events in ACS or prophylaxis of venous thromboembolism following knee or hip replacement surgery:
    - Use with caution if CrCl is 15–29 mL/minute.
  - For treatment of DVT or PE and prophylaxis of recurrent DVT and PE in a person with CrCl 15–49 mL/minute:
    - Prescribe 15 mg twice daily for the first three weeks, then 20 mg once daily (but consider reducing to 15 mg once daily if risk of bleeding outweighs risk of recurrent DVT or PE).
  - For prophylaxis of stroke and systemic embolism in a person with AF:
    - Reduce dose to 15 mg once daily if CrCl is 15–49 mL/minute.
    - Use with caution if the person is also taking drugs that increase the plasma concentration of rivaroxaban

Apixaban:

- For the prophylaxis of stroke and systemic embolism in non-valvular atrial fibrillation (NVAF), the usual dose of Apixaban is 5 mg twice a day.

  - Reduce the dose to 2.5 mg twice daily if the person has at least two of the following characteristics:
    - Age 80 years or over.
    - Body weight 60 kg or less.

        - Serum creatinine 1.5 mg/dL (133 micromol/L) or more.

- **For the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) the recommended dose is:**
    - **10 mg twice daily for the first 7 days (maximum daily dose of 20 mg) followed by 5 mg twice daily (maximum daily dose of 10 mg).**

- **For the prevention of recurrent DVT and PE in adults (following completion of 6 months of treatment for DVT or PE) the recommended dose is 2.5 mg twice daily (maximum daily dose of 5 mg).**

- For the prevention of venous thromboembolism (VTE) in people who have undergone hip or knee replacement surgery, the recommended dose is 2.5 mg twice daily to be started 12–24 hours after surgery.

- For people with renal impairment:
    - Do not prescribe Apixaban if creatinine clearance (CrCl) is less than 15 mL/minute.
    - If CrCl is 15–29 mL/min, the following recommendations apply:
    - For prophylaxis of recurrent DVT or PE, and treatment of DVT or PE, use Apixaban with caution.
    - For prophylaxis of stroke and systemic embolism in a person with NVAF, reduce the dose to 2.5 mg twice daily if CrCl is 15–29 mL/minute, or if serum creatinine is 133 micromol/L or greater and the person is 80 years of age or over or weighs 60 kg or less.
    - No dose adjustment is necessary in people with mild or moderate renal impairment

2. **Duration of treatment:**
    - For people with non-valvular atrial fibrillation, treatment duration is usually long-term.

    - For people with deep vein thrombosis (DVT) and pulmonary embolism (PE), the duration of treatment will vary for each individual, depending on a variety of factors. Usual recommendation:
        - Short-term treatment (3 months) for people with transient risk factors such as recent surgery and trauma.
        - Long-term treatment for people with permanent risk factors or idiopathic (unprovoked) DVT or PE.

Decision regarding the duration of treatment are out with the scope of this guidance. Managing clinicians should refer to published guidance (NICE/ SIGN/BHS) for decision support, advice and risk prediction tools.

Appendix B (May 2022)

TABLE OF COMPARISON CURRENT DOAC

	Dabigatran (Pradaxa)	**Rivoroxaban (Xarelto)**	**Apixaban (Eliquis)**	**Edoxaban (Lixiana)**
Action	Direct thrombin inhibitor	Direct Factor Xa inhibitor	Direct Factor Xa inhibitor	Direct Factor Xa inhibitor
Dose in AF	Two strengths (110 & 150mg), both given twice a day 75 yr: 150mg >80: 110mg 75-80: clinicians discretion If on verapamil use lower dose	20mg once daily Reduced dose if Creatinine Clearance <50	5mg Twice daily Reduced dose if Creatinine Clearance <30 If at least 2 of the following reduce to 2.5 bd >80yrs, <60Kg , Cr>133	60mg once daily Reduce to 30mg if: Creatinine Clearance 15-50, <60Kg, or, erythromycin, ketoconazole, dronedarone or ciclosporin
VTE prevention post surgery	220mg once daily post knee 10 days 4-5 weeks post hip	10mg once daily for 2 weeks post knee & 5 weeks post hip	2.5mg twice daily for 10-14d post knee & 32-38d post hip	Currently not licensed
VTE Treatment	**150mg BD but after at least 5d of parenteral anticoagulation**	**15mg twice daily for 3 weeks then 20mg daily**	**10mg twice daily for 7 days then 5mg twice daily**	**60mg daily following at least 5 days of parenteral**
Converting from warfarin	Stop warfarin – start Dabigatran when INR <2	Stop warfarin Start when INR<3 (in AF) or 2.5 (vte)	Stop warfarin Start when INR <2	Stop warfarin Start when INR<2.5
Converting to warfarin	Complicated – see guidance	Continue Rivaroxaban until INR >2	Continue Apixaban until INR >2	Complicated see guidance
Before surgery	Take advice – exact management depends on: • Bleeding risk of procedure – surgeons responsibility • Risk of stroke or VTE (our responsibility to inform surgeon • Renal function Simple procedures probably 24 – 48 hours stop is all that is required – guidance for more complicated & bridging decisions must come from hospital			
Renal impairment	Creatinine Clearance 30-50 Prophylaxis VTE after surgery – 150mg od if high risk – could consider 110 bd Creatinine Clearance <30 – do not use	Creatinine Clearance 15-30 AF 15mg od VTE treatment/prophylaxis same initial dose but consider 15mg daily	Creatinine Clearance 15-30 AF reduce to 2.5mg BD <15 – do not use	Creatinine Clearance 15-30 30mg once daily <15 do not use
Liver disease	Avoid in severe disease or any coagulopathy	Contraindicated if any coagulopathy	Use with caution Avoid if severe disease or any coagulopathy	Contraindicated if any coagulopathy

<table>
<tr><td>Common side effects</td><td>Nausea, diarrhoea, dyspepsia & abdominal pain are common

Anaemia & bleeding</td><td>Nausea& abnormal LFTs are common

Anaemia & bleeding</td><td>Nausea

Anaemia & bleeding</td><td>Nausea & abnormal LFTs are common

Anaemia & bleeding</td></tr>
<tr><td>Interactions</td><td colspan="4">Many (but fewer than warfarin)

Do not use with NSAIDS
Increased risk when used with Amiodarone, fluconazole, phenytoin & rifampicin
No increased bleeding with
Atorvastatin
Diltiazem
Digoxin
Verapamil
Dronedranone
Erythromycin or clarithromycin
Ciclosporin
Ketoconazole or itraconazole</td></tr>
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