



Directed Enhanced Service: Oral Anticoagulation with Warfarin

INTRODUCTION

All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification for the provision of warfarin anti-coagulant management outlines the more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

BACKGROUND

Anticoagulation¹ is being used in the management of increasing numbers of patients and conditions including patient's post myocardial infarction, atrial fibrillation (AF), deep vein thrombosis and other disorders. While anticoagulants are very effective drugs in these conditions, they can also have serious side effects, such as severe haemorrhage. Care must be taken to ensure that patients are fully engaged in decisions about their care and informed of the balance of benefits and risks in ways that they are able to understand.

Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital^{2 3}. A Patient Safety Alert was issued in 2007 detailing actions to make anti-coagulant therapy safer.⁴

¹ The administration of anticoagulant drugs to patients who have a high risk for venous thromboembolism: Anticoagulation may be with warfarin or a non-vitamin K antagonist oral anticoagulant (NOAC)

² Pirmohamed M et al. Adverse drug reactions as a cause of admission to hospital. Prospective analysis of 18,820 patients. *BMJ*. 2004; 329: 15-19

³ Howard RL et al. Which drugs cause preventable admissions to hospital? A systematic review. *Br. J. Clin. Pharmacol.* 2007; 63: 136-147

⁴ <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=60105&type=full&servicetype=Attachment>

NICE Guidance was updated in 2014: **Atrial fibrillation: management (CG180)**⁵ including new recommendations for a personalised package of care and information, referral for specialised management, stroke prevention, rate and rhythm control and the management of acute atrial fibrillation.

A range of guidance and resources is also available from the National Patient Safety Agency and the All Wales Medicines Strategy Group⁶

This service specification incorporates the available guidance to support safe local provision of care.

INITIATION AND MANAGEMENT

In non-valvular Atrial Fibrillation the decision about whether to start treatment (with warfarin or a novel oral anticoagulant, *NOAC*) should be made after an informed discussion between the clinician and the person about the risks and benefits.

The options for anticoagulation should be discussed and the choice of treatment should be based on the individual's clinical features and preferences (based on NICE CG180 [2014]).

Discussion of the risks and benefits of treatment should be informed using accredited decision aids such as: -

- www.anticoagulation-dst.co.uk or
- [NICE Patient Decision Aid
https://www.nice.org.uk/guidance/cg180/resources/cg180-atrial-fibrillation-update-patient-decision-aid2](https://www.nice.org.uk/guidance/cg180/resources/cg180-atrial-fibrillation-update-patient-decision-aid2))

A Stroke and bleeding risk assessment must be undertaken (including pre-treatment blood tests: full blood count [FBC], urea and electrolytes, liver function tests, coagulation screen and INR).

Patients with a new diagnosis of non-valvular AF should, where possible, have the initial assessment and discussion regarding anticoagulation in the setting (hospital or GP practice) in which the diagnosis was made.

When a decision to initiate anticoagulation has been agreed, prompt initiation and stabilisation⁷ should also be undertaken in the setting in which the decision was made wherever possible.

If a primary care team does not have appropriate expertise to initiate warfarin it should ensure that referral is made to an appropriate service. Primary care clinicians should provide a baseline assessment, on a locally agreed proforma (such as provided by AWMSG or www.anticoagulation-dst.co.uk), to the service providing

⁵ <http://www.nice.org.uk/guidance/cg180>

⁶ <https://www.awttc.org/advice-role-oral-anticoagulants>

⁷ Stabilisation: Two INR readings in range with confirmation that INR/dosing interval at least 7 days.

initiation and provide additional information or advice to inform on-going management as required to ensure safe care⁸.

Sharing information with other healthcare professionals is important for safe and effective patient care. GPs should provide all relevant information about the patient, including their medical history and current condition.

After a referral has been made the GP should keep the specialist informed of significant changes in the health or care of the patient, particularly if related to the condition for which the specialist is caring. When advice is received from the specialist it should be acted on promptly, and mechanisms to ensure this happens should be in place within the practice. The specialist should be informed when the advice from the specialist has not been followed and the reasons for this should be communicated.

Primary care clinicians taking over the prescribing and management of anticoagulation must receive the documented baseline risk assessment prior to the transfer of clinical responsibility.

Patients with cancer receiving warfarin for atrial fibrillation require particularly detailed individual assessment in view of the heterogeneous nature of cancer type, stage and co-morbidities. Regular review of risks and benefits should be undertaken with appropriate specialist input and care would usually be managed by a haematologist/oncologist.

MONITORING

An oral warfarin anti-coagulation monitoring service is designed to be one in which:

- i. Initiation of oral warfarin anticoagulant therapy is in accordance with current NICE and All Wales Medicines Strategy Group Guidance
- ii. Therapy is initiated for recognised indications for specified lengths of time (including indefinitely with review).
- iii. Systems ensure appropriate maintenance of therapeutic range (where appropriate) and management of risk
- iv. The service to the patient is convenient
- v. The need for continuation of therapy is reviewed regularly
- vi. The therapy is discontinued when appropriate.
- vii. If initiated and stabilised in secondary care (for example following pulmonary embolus, DVT or heart valve replacement), planned handover to the primary care team is carefully managed to minimise risks and to provide a clear management plan

⁸ <http://www.awmsg.org/docs/awmsg/medman/Risk-Benefit%20Assessment%20Tool%20for%20Oral%20Anticoagulant%20Treatment%20in%20People%20with%20Atrial%20Fibrillation.pdf>

- viii. If a patient is attending a warfarin-dosing clinic outside the practice, there should be a clear plan to ensure safe and appropriate prescribing across all settings. The plan should specify the lead prescriber, roles and responsibilities and arrangements for communication between clinical teams
- ix. Where patients are initiated on warfarin in primary care a slow loading regime is followed

SERVICE OUTLINE

This Directed Enhanced Service will fund:

- i. **Training.** Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills⁹.
- ii. **The development and maintenance of a register.** Participating practices must maintain an up-to-date register of all patients in receipt of anti-coagulation therapy, indicating patient name, date of birth, the indication for, and length of, treatment, including the target INR where appropriate. The Register should include an **indication of the location of monitoring using prescribed READ codes**
 - anticoagulation monitoring – secondary care 66QC
 - anticoagulation monitoring – primary care 66QD
 - self-monitoring of INR - 66QE
- iii. **A call and recall system.** To ensure that for patients managed in primary care a systematic call and recall of patients on this register is taking place including clear arrangements for home based assessment for house bound patients and care home residents.
- iv. **Initial assessment documenting; -**
 - Stroke and bleeding risk assessments (such as HASBLED) including pre-treatment blood tests:
 - Full Blood Count,

⁹ A 'doser' means any person who is suitably trained and qualified who, upon receipt of relevant information from laboratories, near-patient testing equipment or otherwise, using computer-assisted decision-making equipment, determines the anti-coagulant dosage for patients of practitioners in a practice.

Computer dosing should be interpreted and actioned by staff who are trained, accredited and competent to manage warfarin therapy. Over-reliance on computer-generated dosing should be avoided. Use clinical expertise to interpret dosing advice (AWMSG Guidance)

- Urea and electrolytes,
 - Liver function tests,
 - Coagulation screen and
 - INR
- v. Discussion with the patient about the risks and benefits of treatment, using accredited decision aids such as: -
- www.anticoagulation-dst.co.uk or
 - **NICE Patient Decision Aid**
<https://www.nice.org.uk/guidance/cg180/resources/cg180-atrial-fibrillation-update-patient-decision-aid2>
- vi. **Education for patients- both newly diagnosed and those on maintenance therapy.** To ensure that all patients (and/or their carers and support staff when appropriate) receive appropriate information in relation to the prevention and management of, the potential complications of anticoagulation, including the provision of written materials and /or audio visual aids¹⁰.
- vii. Ensure that people prescribed anticoagulants receive appropriate verbal and written information including an individual management plan, containing: -
- diagnosis,
 - planned duration
 - therapeutic range to be maintained (if appropriate)
- viii. Patients should be issued the information (yellow) booklet <http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61777>.
- ix. Patients initiated on a NOAC should be provided with written information and monitoring booklet, e.g. the European Heart Rhythm Association (EHRA) Atrial Fibrillation Oral Anticoagulation Card.
- x. Patients should be advised to carry an alert card with them at all times. The needs of carers should be considered, including appropriate information, advice and support.
- xi. Initiation of warfarin therapy in line with a recommended slow loading schedule such as an approved computer guided dosing software package or local health board guidelines.

¹⁰ <http://www.awmsg.org/docs/awmsg/medman/Warfarin%20Monitoring.pdf>

Resources available include the DVD 'Living with Warfarin' published by St George's Hospital
<http://www.sgul.ac.uk/media/productions-available/productions-available-pdfs/Living%20with%20Warfarin%20Order%20Form.pdf/view>

xii. Monitoring: INR testing should be frequent for the first few weeks or months then normally every 1–2 months in people with Atrial Fibrillation. This provides an opportunity to monitor adherence, effectiveness and safety. Self-monitoring of warfarin is an option.

xiii. **Warfarin dosing:**

- Providers should normally use computer dosing software systems (AWMSG Warfarin Monitoring)¹¹. Choice of computer dosing software (such as DAWN, RAT or INR STAR) should be agreed with the Health Board.
- Computer dosing should be interpreted and actioned by non-administrative professionals, who are trained, and competent to manage warfarin therapy.
- Avoid over-reliance on computer-generated dosing and use clinical expertise to interpret dosing advice ¹²

xiv. **Review.** To ensure that at initial diagnosis and at least annually an appropriate review of the patient's health and medication is undertaken and recorded¹³. Prescribers are reminded to consider repeating INR five days after any changes to medication.

For people who are taking an anticoagulant, review the need for anticoagulation and the quality of anticoagulation at least annually, or more frequently if clinically relevant events occur affecting anticoagulation or bleeding risk (NICE 2014)^{1 14}.

- Address modifiable risk factors
- Where warfarin is prescribed, there should be a documented process to systematically assess the percentage time in therapeutic range (TTR) for each patient. This should take place at least quarterly after initial stabilising of dosing ¹⁵

¹¹Dosing practices should use computer dosing software systems. The National Patient Safety Agency (NPSA) states that "There is evidence that anticoagulant dosing software helps to maintain the INR levels within the therapeutic range, extend the time between INR tests and effectively manage anticoagulant records facilitating service audit" Computer dosing has been shown to significantly reduce the risk of bleeding and thromboembolic events and, overall, is a more cost-effective option to manual dosing

¹² <http://www.awmsg.org/docs/awmsg/medman/Warfarin%20Monitoring.pdf>

¹³ <http://www.awmsg.org/docs/awmsg/medman/All%20Wales%20Advice%20on%20the%20Role%20of%20Oral%20Anticoagulants.pdf>

¹⁴ [34TUAWMSG Risk/Benefit Assessment Tool \[2-page version\]U34T](#)

¹⁵ See [NICE QS 93 Statement 4](#) for suggested measures

- Where NOACs are prescribed, there should be a documented process to systematically assess treatment (see UKMi Suggestions for Drug Monitoring in Adults in Primary Care¹⁶)
- Maintain an up to date medication review
- Review full blood count, renal and liver function tests annually for people taking any anticoagulant (more frequent monitoring advised if baseline tests are abnormal or there is inter-current illness that may impact renal or hepatic function)
- Self-monitoring of coagulation status in people on long-term VKA therapy should be in accordance with NICE Guidance *'Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers'*¹⁷,
- Re-assess anticoagulation where poor control is shown by any of the following¹⁸: -
 - Two INR values higher than 5 or one INR value higher than 8 within the past 6 months
 - Two INR values less than 1.5 within the past 6 months
 - TTR less than 65%
- a. The prescriber should make efforts to understand and address the reasons for non-adherence before switching to an alternative medicine (AWMSG 2014).
- b. Poor adherence to any oral anticoagulant regimen is likely to be associated with increased risk of thrombosis or bleeding (AWMSG 2014).
- When reassessing anticoagulation, take into account and if possible address the following factors that may contribute to poor anticoagulation control:
 - cognitive function
 - adherence to prescribed therapy
 - illness
 - interacting drug therapy including 'over the counter' treatments and frequent antibiotics
 - lifestyle factors including diet and alcohol consumption
- When a person is identified as having poor anticoagulation control, the re-assessment of anticoagulation should be undertaken through discussion

¹⁶<http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Drug%20monitoring%20document%20Feb%202014.pdf>

¹⁷: <http://www.nice.org.uk/guidance/dg14>

¹⁸ <http://www.nice.org.uk/guidance/cg180>

with the patient, by the healthcare professional providing dosing. Where this is not provided by the patient's own GP practice, the lead practice/ Anticoagulant clinic should liaise with the registered practice when re-assessing poor anticoagulant control to identify further possible causes.

- Patients with cancer receiving warfarin for atrial fibrillation require particularly detailed individual assessment. Where control remains poor the treatment plan should be reviewed.
 - a. Review potential complications and, as necessary, a review of the patient's own monitoring records
 - b. Ensure that all clinical information related to the Enhanced service is recorded in the patient's own lifelong record, hosted in the GP practice,

Ensure that the 'Significant medical history' summary, the medication summary and the practice records flag/notification system highlight that the patient is prescribed warfarin

Review - Peri-surgery

Perioperative anticoagulant advice should be provided by the hospital. If Low Molecular Weight Heparin is recommended, responsibility for advising the patient, informing the GP and prescribing should normally be undertaken by the hospital.

This aims to ensure that professionals familiar with peri-operative anticoagulation provide patients with consistent timely advice and treatment. Patients will be attending a preoperative assessment clinic and those prescribed warfarin are usually advised to switch to LMWH or aspirin during the peri-operative period. The duration of alternative therapy is usually less than a week but advice will be dependent on the complexity of the surgery and underlying thromboembolic risk.¹⁹

- xv. **Record-keeping.** To maintain adequate records of the performance and result of the service provided, this must include significant event analysis for every bleeding episode requiring hospital admission and deaths caused or related to anti-coagulant therapy.
- xvi. **Audit.** To complete an annual audit of the care of patients using an agreed proforma. This should be an ongoing assessment of percentage Time in Therapeutic Range (TTR) at individual patient and practice cohort level.

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<http://www.awmsg.org/docs/awmsg/medman/Prescribing%20of%20Low%20Molecular%20Weight%20Heparin%20%5BSummary%20document%5D.pdf>

xvii. **Risk management**

- To have in place a risk management strategy
- It is appropriate to administer oral phytomenadione (vitamin K1) in general practice as well as in the hospital setting for people with INR > 8, with no bleeding where the perceived risk of bleeding is high, who are being treated for AF, recurrent deep vein thrombosis (DVT) or pulmonary embolism (PE). Exceptions: People at high risk of thromboembolism, such as those with mechanical heart valves, should be managed according to specialist advice
- Give phytomenadione (vitamin K1) by mouth using the intravenous preparation orally (unlicensed use); repeat dose of phytomenadione if INR still too high after 24 hours; restart warfarin when INR < 5¹². For current advice on dose see www.awmsg.org
- To refer patients promptly to other necessary services, when appropriate, and to the relevant support agencies using locally agreed guidelines where these exist.
- To agree effective communication strategies for sharing relevant information, such as medication changes, where anticoagulation is managed in another setting

xviii. **Regular service review.** All practices involved in the Enhanced Service must perform an annual review which should include:

- a) Information on the number of patients being monitored, the indication of anticoagulation, i.e. DVT etc., and the duration of treatment
- b) Location of monitoring using the following Read codes: -
 - Anticoagulation monitoring secondary care {66QC}
 - Anticoagulation monitoring- primary care {66QD}
 - Self-monitoring of INR {66QE}
- c) Analysis of significant events, such as process errors, near misses and hospital admissions (for thrombotic or haemorrhagic stroke or other admission that may be related to anticoagulation) identifying themes and resulting actions. All INR results greater than 8 should be reviewed to ensure that risks are managed systematically and opportunities to improve the governance of the service are identified and delivered.
- d) Audit of the TTR for the practice cohort receiving warfarin treatment

xix. All suspected adverse drug reactions must be reported directly to the MHRA through the Yellow Card Scheme using the electronic form at www.yellowcard.gov.uk or using the cards available at the back of the BNF.

xx. Edoxaban and rivaroxaban are currently under 'Additional Monitoring' by the European Medicines Agency (EMA) and all suspected adverse drug reactions

(ADRs) should be reported, as well as all serious ADRs (see www.yellowcard.gov.uk for definition of serious) to apixaban, dabigatran etexilate and warfarin. ADRs should be reported directly to the Medicines and Healthcare Products Regulatory Agency (MHRA) through the Yellow Card Scheme using the electronic form at www.yellowcard.gov.uk or cards available at the back of the British National Formulary (BNF) (AWMSG 2014).

It is a condition of participation in this Enhanced Service that practitioners will give notification to the Local Health Board clinical governance Lead of all emergency admissions or deaths of any patient covered under this service, where such admission or death is or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition.

This must be reported within 72 hours of the information becoming known to the practitioner. This is in addition to a practitioner's statutory obligations.

ACCREDITATION

Those clinicians who have previously provided services similar to the enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

The Health Board will provide training to support the accreditation of clinicians with no previous experience of dosing. Accreditation of training outside the Health Board programme will be at the discretion of the Health Board. Advice on relevant training available to support accreditation will be provided by the Health board on request.

FEES

There are 3 relevant re-imburement levels under the terms of this Directed Enhanced Service:

Slow Loading Warfarin

Each practice contracted to provide this service (Level A) will receive £120 **for the first treatment quarter** to cover the initial counselling of the patient and the slow loading period. This will be a one off payment unless there is a gap in warfarin treatment of more than one month.

Only practices providing full dosing services will be commissioned to provide slow loading services. All practices providing dosing and monitoring will also be expected to provide slow loading.

Warfarin monitoring

Each practice contracted to provide this service (Level A) will receive £150 per annum per patient (£37.50 per quarter) for the provision of the INR monitoring and dosing service which will comprise of the following elements (previous level 4):

- Practice funded staff to obtain blood for sample testing
- Practice to undertake testing of blood sample
- Practice to determine and issue appropriate dose

In addition to the above fee payment the Local Health Board will fund:

- External Quality Assurance
- Point of Care co-ordinator support
- Lancets and strips
- POCT machines POCT machine training
- Dosing software and associated training

Non-Monitoring/Dosing Practices

Those practices that do not test or dose their patients (Level B) will be required to ensure appropriate information is provided to the service which undertakes this. E.g. change of medication, prescription of antibiotics in order that that appropriate adjustment can be made in terms of testing interval/dosing.

This will be supported by a standard pro-forma and attract a remuneration of £10 per patient per annum.

Housebound Patients

The arrangements for the testing and communication of dosing for housebound patients will be covered by a separate locally agreed policy.

SUMMARY OF SERVICE

- A payment of £120 per patient to cover patient initiation / slow loading.
- £150 per patient, excluding consumables (to include test strips; quality assurance; software and machines), to deliver an INR testing and warfarin dosing and monitoring service.
- £10 per patient for practices not providing a testing and dosing service - to cover the cost of the work involved in communicating with the warfarin service provider.
- The delivery of the testing and dosing service will be through a DES from April 2017. The DES will specify five health boards which will offer the service from April 2017. It has been agreed that the two health boards unable to offer a DES from 1 April 2017 will be required to offer the DES by 1 October 2017. These two health boards will be required to set out their plans to offer a DES from 1 October.

Note:

- The delivery of Novel / oral anti-coagulant treatments (NOACs) will be supported through a Local Enhanced Service , in accordance with Health Board prescribing policy.
- No extra payment to be made for prescribing warfarin / new oral anti coagulants.
- Local arrangements to apply for home visits.
- Health Boards to procure testing machines, consumables and dosing software and work towards all Wales procurement basis in 2017/18.

Description	Level	Fee
Slow Loading of Warfarin including patient information and counselling on choice of treatment	A only	£120 per patient for patient initiation / slow loading
Warfarin monitoring	A only	£150 per annum excluding consumables (to include test strips; quality assurance; software and machines)
Provision of information from non-dosing practice to dosing service	B only	£10 per annum
Prescription of Warfarin	A and B	No fee
Prescription of LMWH	A	No fee

Annex 1

Warfarin – Indications and recommended INR values

See BNF for the most recent guidance

<https://www.evidence.nhs.uk/formulary/bnf/current/2-cardiovascular-system/28-anticoagulants-and-protamine/282-oral-anticoagulants/coumarins-and-phenindione>

SUMMARY: ASSESSMENT FOR ALL PATIENTS ESTABLISHED ON WARFARIN THERAPY

For patients who are taking an anticoagulant, review the need for anticoagulation and the quality of anticoagulation at least annually, or more frequently if clinically relevant events occur affecting anticoagulation or bleeding risk (NICE 2014)¹ (see AWMSG Risk/Benefit Assessment Tool [2-page version]¹²).

structured medication review	Consideration	Notes
	Indication and duration of therapy	Confirm documented indication and duration is correct. Consider new co morbidities that adjust the risks of therapy e.g. malignant neoplasm at high risk of bleeding ⁵ .
Need and open questions	International normalised ratio (INR) target range	Confirm documented target range.
	Assess adherence ^{2,3} to medication and monitoring	Time in therapeutic range (TTR) can be indicative of adherence.
	Anticoagulation monitoring	
Tests	Blood monitoring ² : full blood count (FBC), renal and liver function at least annually. More frequent monitoring advised if baseline tests are abnormal or there is intercurrent illness that may impact renal or hepatic	FBC to assess for anaemia and thrombocytopenia, which will exacerbate the risks of bleeding.

	function.	
	Patient-held record	Ensure the person has a monitoring booklet ⁶ or card ⁷ .
Evidence	Guidance	Thromboprophylaxis is a rapidly developing field of medicine. Consider whether the latest evidence or independent guidance impacts on this person's care.
	Hospital admissions	Particularly for thrombosis or bleeding.
Adverse effects	Adverse effects	Common adverse effects of oral anticoagulants include haemorrhage, nausea and diarrhoea ⁸⁻¹¹ . All serious adverse drug reactions should be reported through the Yellow Card Scheme (www.yellowcard.gov.uk).
Risks	Review risk of stroke and risk of bleeding.	Whilst CHADS2, CHA2DS2-VASc and HAS-BLED have been validated in people with non-valvular AF, it is important to ensure that people with other indications for oral anticoagulation are also carefully assessed for modifiable risk factors. Consider using HAS-BLED tool together with other bleeding risk factors: <ul style="list-style-type: none"> • cognitive function • adherence to prescribed therapy • new diagnoses e.g. cancer • interacting drug therapy e.g. over the counter therapies, frequent antibiotics • lifestyle factors including diet and alcohol consumption. Changes to thromboprophylaxis

	Address modifiable bleeding risk factors	for people at high risk are likely to require the advice of a specialist. <hr/>
	Interactions	Use up-to-date resources to assess for interacting medicines; all oral anticoagulants have potential important interactions ^{13, 14} .
Switches, simplifications		Consider whether the medication regime should be simplified? Are there cost-effectiveness considerations? MONITOR INR following changes to the medication regime

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