Warfarin for anticoagulation

Information sheet for Primary Care Prescribers

Therapeutic Summary

Warfarin is an anticoagulant that has a narrow therapeutic index and regular titration of the dose against the anticoagulant effect in the blood, as assessed by the INR, is essential.

Overall responsibility for the care of the patient will reside with the registered GP practice who will be prescribing warfarin for anticoagulation therapy. This includes:

• Being aware of appropriate advice and guidelines for anticoagulant care

• Giving advice on duration and intensity of anticoagulation

• Being aware of the potential effects of additional therapy given to a patient on

anticoagulants, and arranging earlier INR testing as required

- Arranging referral / admission to hospital if required
- Issuing anticoagulation therapy prescriptions

• Completing the annual review of patients on long term anticoagulation therapy

• Ensuring that all patients receive appropriate monitoring, either with a primary care

anticoagulation service provider or in secondary care

In addition, some practices may offer enhanced warfarin monitoring services at 1 of 3 levels:

Level 2- The GP Practice takes the blood samples; laboratory undertakes the INR tests and doses.

Level 3- The GP Practice takes the blood, undertakes the INR tests, indicates the dose and communicates the dose to the patient.

Level 4- The GP Practice **initiates** and continues treatment, takes the blood samples, undertakes the tests, indicates the dose and communicates the results to the patient.

For further details see the Locally Enhanced Service specification (Teamnet login required)

Indications

The decision relating to diagnosis, indication for anticoagulation and INR target and range will be made in secondary care except for stroke risk reduction in atrial fibrillation patients, where warfarin may be considered when DOACs are contraindicated, unlicensed or not recommended. See AF guideline for further details.

ļ	Indication	Target INR & Range		Duration	
	Pulmonary embolus	2.5	2.0-3.0	3 months to long term (if unprovoked)	
	Proximal DVT	2.5	2.0-3.0	3 months to long term (if unprovoked)	
	 Distal DVT Isolated calf vein DVT Provoked by surgery or other transient risk factors (e.g. COC use, pregnancy, plaster cast) 	2.5 2.5	2.0-3.0 2.0-3.0	6 weeks 3 months	
	 Recurrent events PE &/or DVT Whilst off warfarin or sub- therapeutic INR Whilst on warfarin within therapeutic range 	2.5 3.5	2.0-3.0 3.0-4.0	6 months to long term Long term	
	Non-valvular AF with CHA₂DS₂-VASc score ≥2 (see <u>AF guideline</u>)	2.5	2.0-3.0	Long term	
	AF secondary to valvular (mitral stenosis related) heart disease	2.5	2.0-3.0	Long term	
	Cardioversion for AF	2.5	2.0-3.0	Minimum 3 weeks before to 4 weeks after	
	Rheumatic mitral valve disease	2.5	2.0-3.0	Long term	
	Dilated cardiomyopathy	2.5	2.0-3.0	Long term	
	LV mural thrombus post MI +/- LV aneurysm	2.5	2.0-3.0	3 months	
	 Mechanical Prosthetic Heart Valves Low thrombogenicity* No patient risk factors Patient related risk factors⁺ Medium thrombogenicity* No patient risk factors Patient related risk factors+ High thrombogenicity* No patient risk factors Patient related risk 	2.5 3.0 3.0 3.5 3.5 3.5 3.5	2.0-3.0 2.5-3.5 2.5-3.5 3.0-4.0 3.0-4.0 3.0-4.0	Long term	
ĺ	factors+				

Table 1. Indications for warfarin; target INR, therapeutic range and duration of treatment ¹

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 Bioprosthetic Heart Valves Mitral position Previous systemic embolism Left atrial thrombus at surgery Other risk factors, e.g. AF, low LVEF 	2.5 2.5 2.5 2.5	2.0-3.0 2.0-3.0 2.0-3.0 2.0-3.0	3 months >3 months Until clot resolution Long term
Inherited thrombophilia with DVT &/or PE	2.5	2.0-3.0	Variable
Antiphospholipid syndrome	2.5	2.0-3.0	Long term

*Prosthesis thrombogenicity: Low: Carbomedics (aortic position), Medtronic Hall, St Jude Medical (without Silzone); Medium: Bjork-Shiley, other bileaflet valves; High: Starr-Edwards, Omniscience, Lillehei-Kaster

+Patient-related risk factors: mitral, tricuspid or pulmonary position; previous arterial thromboembolism; AF; left atrium diameter >50mm; mitral stenosis; left ventricular ejection fraction <35%; left atrial dense spontaneous echo contrast.

Medicine Initiation:

Anticoagulation service providers offering a level 4 service may choose, or be asked, to initiate anticoagulation therapy for suitable patients who require non-urgent anticoagulation e.g. in atrial fibrillation.

Prior to warfarin initiation, baseline FBC, Coagulation screen, Liver function tests (LFT) and Urea and Electrolytes should be measured (see monitoring requirements).

There are various schedules for initiating anticoagulation. An example is given below: This is a guide only; approved clinical decision support software (CDSS) should be used to guide doses, with clinical judgment applied in all cases to determine decisions.

Day	INR (9 - 10 am)	Standard dose schedule (Dose at 5-7pm)	Reduced dose schedule if age >70 years or weight < 50kg or CCF or liver disease.
1		9mg	6mg
2		9mg	6mg
3	Less than 1.3 1.3 - 1.6 1.7 - 2.1 2.2 - 2.5 2.6 - 3.1 3.2 - 3.5 Greater than 3.5	12mg 9mg 6mg 4.5mg 3mg 1.5mg Nil	9mg 6mg 4.5mg 3mg 1.5mg Nil Nil
4	Less than 1.4 1.4 - 1.7 1.8 - 2.1 2.2 - 2.6 2.7 - 3.7 3.8 - 4.5 Greater than 4.5	Guide to predicted da 9mg (or more) 7.5mg 6mg 4.5mg 3mg Nil x 1 day, then 1.5m Nil x 2 days, then 1.5 r INR.	g ng or less according to
CHECK INR ON DAY 6. (or earliest possible routine working day following a weekend or bank holiday) SUBSEQUENT DOSE and RETEST INTERVAL ACCORDING TO INP			

In primary care initiation should only be done by accredited practitioners who have had the necessary training and competence to do so- see sources of support.

When starting warfarin, antiplatelet therapy (aspirin/ clopidogrel/ dipyridamole/ ticagrelor/ prasugrel) should be stopped, once INR is within therapeutic range; unless continuation is explicitly advised by Secondary care.

At the first appointment to initiate anticoagulation therapy, the anticoagulation service provider must ensure that the patient is given all the relevant information and education verbally and in writing – see information given to patients. The anticoagulation service provider should also complete the relevant sections of the hand-held Anticoagulation Therapy book, and issue this to the patient.

Supplies of information booklets can be ordered from Primary Care Support England (PCSE) via the PCSE online portal at <u>PCSS: Login (england.nhs.uk)</u>

Maintenance Dosage:

The dose required to achieve the therapeutic target is very variable between patients, but usually lies between 3 and 9mg daily. The anticoagulant dose should be adjusted by the practitioner, with reference to the patient's INR and any other changes that may be identified during the appointment. Dosage decisions MUST be supported using approved clinical decision support software (CDSS) but clinical judgment must be applied in all cases to determine decisions.

All organisations within the Nottinghamshire ICS* have agreed the exclusive use of **only** warfarin 3mg tablets.

*In Bassetlaw, the processes align to those of South Yorkshire acute trusts and local policy regarding available tablet strengths should be followed.

Patients will, where possible, be encouraged to take their anticoagulation therapy daily and at a regular time. This is usually at 18:00hrs. Patients are mostly seen during the day therefore a late afternoon or evening dose enables the managing practitioner to ask the patient to miss a dose when required. Management can be more difficult if the patient has already taken their anticoagulant.

All dosing instructions must be written in the patient's Anticoagulation Therapy Booklet or single sheet therapy record (SSTR). For those patients where a dose adjustment is necessary before they are in receipt of the SSTR or Anticoagulation booklet the patient must be contacted for verbal instruction to be given.

Dosage instructions should include details of dose, frequency and number of tablets, e.g. 3mg once a day (1 x 3mg – blue tablet). In practise, fine tuning of dosage by using alternate day regimens of e.g. 4.5mg/3mg may need to be used if INR fluctuates too much.

If a patient misses a dose of warfarin they should be told NOT to take a double dose the next day, but to continue with their normal dose. If the patient is very sensitive to changes or at high risk if under dosed, they should contact the service provider as soon as possible. Other patients may be asked to arrange earlier monitoring if their appointment is not due for some time, depending on the stability of patient and clinical judgment of the managing practitioner.

Contraindications:

- Recent haemorrhagic stroke or other intracerebral bleeding
- Significant active bleeding
- Uncontrolled severe hypertension (systolic ≥200mmHg; diastolic >110 mmHg)
- Bleeding peptic ulcer disease
- Excessive alcohol intake with binge drinking

• Pregnancy: exposure of the embryo to warfarin during the 6th to 12th weeks of gestation may be associated with the development of an embryopathy and throughout gestation there is a continuing risk of foetal haemorrhage. Women of childbearing age should be warned of the risks and counselled in the use of effective contraception.

Relative contraindications to warfarin include;

- History of GI bleeding
- Uncontrolled severe hypertension
- Liver disease with abnormal baseline coagulation screen
- Oesophageal varices
- End stage renal failure discuss with renal team before prescribing if GFR < 15ml/min
- Cancer discuss with oncology team before prescribing
- Infective endocarditis
- Hereditary haemorrhagic telengectasia (HHT) suggest discuss with haematology before prescribing
- Bleeding disorders discuss with haemophilia team before prescribing
- Significant thrombocytopenia If the platelet count is <100 x109 /L discuss with Haematology before prescribing
- Inability to monitor warfarin due to patient factors
- Concomitant use of drugs which increase bleeding risk

• A history of falls is not a contraindication to treatment with warfarin but if the patient has had a fall causing intra-cranial bleeding, the risks versus benefits of anticoagulant therapy should be carefully considered and discussed with the patient before initiation.

Precautions:

There are certain conditions/problems where caution should be taken when monitoring patients and, where required, advice from the Anticoagulation Clinic should be sought. These include severe heart failure, liver failure, DVT /PE in the previous month, thyroid disorders and chronic alcohol intake.

Risk factors for bleeding should be considered. The following patient characteristics are indicative of a high risk for bleeding: Age >65, uncontrolled hypertension, diabetes, renal failure, previous MI, previous CVA, previous gastrointestinal or cerebral bleed, patients with liver disease. For patients anticoagulated due to AF, see AF guideline for further details (including assessing bleeding risk using HAS-BLED tool).

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 <u>MHRA, July 2016</u> for further details.

Monitoring requirements:

Baseline blood tests				
Patient group	U + Es (Creatinine clearance)	Full blood count	Coagulation screen	Liver function tests
All			 Image: A start of the start of	 ✓
Follow up tests				
Patient group	International Normalis	sed Ratio (INR)		Time in therapeutic range (TTR)
All	As required or as per protocol for self monitoring patients (length of time between tests will depend on the patient's stability and untoward occurrences likely to cause instability, the maximum length of time being 12 weeks*)			
N.B. In addition to adequate clinical surveillance, laboratory testing of haemoglobin/haematocrit could be of value to detect occult bleeding, as judged to be appropriate. It is not unreasonable to monitor FBC, UE and LFT annually in these patients, but this isn't strictly required. FBC monitoring could provide early detection of anaemia (which may indicate underlying bleeding issue) and thrombocytopenia (which will				

increase the risk of bleeding).

*Recall dates will be suggested by the CDSS; however, if the patient's clinical condition is changing, or there have been alterations in medication, then the INR should be checked more frequently and clinical judgment should override the CDSS.

Each time that a patient attends to have their INR tested, the practitioner should obtain the following information:

- Has the patient experienced any signs of bleeding or bruising?
- Is the patient planning any dental or other surgery?
- Has the patient followed their advised dosage instructions?
- Has there been a change in the patient's other medications or dietary habits since their last test?

If the practitioner undertaking the blood test is not giving the dosing instructions, then any relevant information obtained from the patient should be passed on to the relevant clinician to inform their dosing decision.

For patients who self- monitor their INR, a periodic review should be performed based on the stability of the patients INR and condition (s).

A robust system should be in place to ensure all DNAs (did not attends) are followed up and monitored effectively. It must be stressed to the patient that careful monitoring of warfarin is essential to avoid complications. Where patients repeatedly fail to attend then the risks of continuing therapy should be considered against the benefits.

For practices offering a level 3 or 4 service, time in therapeutic range (TTR) should be reviewed at each visit once the patient is stabilised:



Clinically relevant medicine interactions and their management:

The drugs in this list are more usually associated with loss of INR control in patients already established on warfarin. This list is not exhaustive - refer to the British National Formulary (BNF) for further information. If any of the drugs below are to be started in these patients then the use of alternatives in the same therapeutic class may be considered. If this is not possible then the patient's INR should be monitored as detailed below. Those drugs highlighted in bold are significant interactions and should be avoided or used with caution.

• Drugs marked * are liver enzyme inhibitors and increase the INR. They act very quickly (can be within 24 hours) and if the drug is withdrawn the effect disappears quickly depending on the drug half-life. The INR should if possible be monitored within 72 hours of starting the interacting drug and on withdrawal.

Drugs marked \$ are liver enzyme inducers and decrease the INR. They act more slowly (up to a week) with peak effect at 2-3 weeks and can persist for up to 4 weeks after stopping depending on drug half-life. The INR will need checking after 1 week of concurrent therapy.
Drugs with neither have other mechanisms, which affect the INR.

	Drugs that increase the INR and risk of bleed
Gastrointestinal	cimetidine*, omeprazole* esomeprazole
Cardiovascular	amiodarone * (liver enzyme inhibition is slow and may persist long after withdrawal requiring weekly monitoring over 4 weeks), fibrates , ezetimibe, propafenone *, propranolol, statins – no clinically relevant interaction will normally be seen however it is prudent to check INR in the weeks after initiation and at any dose change
CNS	Entacapone, fluvoxamine*, SNRIs, SSRIs*, tramadol
Anti-infectives (anti- infectives in general may cause raised INR's)	azole antifungals* (esp. miconazole including oral gel and vaginal), co- trimoxazole*, macrolides* (can be serious but unpredictable), metronidazole*, quinolones* (can be serious but unpredictable), tetracyclines, influenza vaccine
Endocrine	anabolic steroids (and danazol), high dose corticosteroids, glucagon (high dose 50mg+ over 2 days), flutamide, levothyroxine
NSAIDs	Ibuprofen at lowest effective dose (+/-PPI) is probably safest if NSAID is required N.B. All NSAIDs can increase the risk of bleeds and should be avoided if possible
Antiplatelets – increased bleed risk	Aspirin, clopidogrel, dipyridamole, ticagrelor and prasugrel
Anti-coagulants	Fondaparinux, heparin; low molecular weight heparin eg enoxaparin, tinzaparin; NOACs eg apixaban, dabigatran, rivaroxaban
Cytotoxics	Erlotinib, etoposide, fluorouracil, gefitinib, gemcitabine, imetinib, sorafenib, vemurafenib
Miscellaneous	Alcohol (acute), actiretin, allopurinol*, benzbromarone*, colchicine, disulfiram, interferon, paracetamol (prolonged use at high dose), sulfinpyrazone, tamoxifen, topical salicylates , zafirlucast*
Herbal preparations/Food supplements	Carnitine, chamomile, cranberry juice *, curbicin, dong quai, fenugreek, fish oils, garlic, gingko biloba, glucosamine , grapefruit juice*, lycium*, mango, quilinggao

N.B. If a patient on warfarin were started on ANY other new medication a repeat INR after 1 week would be sensible.

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Drugs that decrease the INR		
Miscellaneous	Alcohol ^{\$} (chronic), azathioprine, barbiturates ^{\$} , bosentan ^{\$} , carbamazepine ^{\$} , carbimazole, griseofulvin ^{\$} , mercaptopurine, nevirapine ^{\$} , OCP/HRT, phenobarbital, phenytoin, propylthiouracil, raloxifene, rifampicin ^{\$} (most potent inducer), trazodone	
Herbal preparations etc	Avocado, co-enzyme Q10, green tea, natto, soya beans, St Johns wort^{\$} (avoid)	
Binding agents	Colestyramine, sucralfate	
Warfarin antagonist	Vitamin K	
Drugs that increase or decrease the INR		
Anti-virals	Atazanavir, efavirenz, ritonavir, telapravir	
Miscellaneous	Ginseng, phenytoin, quinidine, tricyclic antidepressants	

Criteria for review and discontinuation of the medicine:

The patient should be maintained within their therapeutic range, (see Table 1). Deviation from the therapeutic range is associated with an increased risk of haemorrhage (if too high), or thrombosis and increased risk of stroke (if too low). Many clinical factors and drugs may affect the sensitivity of the patient to the effects of warfarin. Particular attention should be placed on checking changes in medication, food and lifestyle and the impact of these on the INR.

Side Effect	Action
INR below target value	Check compliance, investigate interacting medication (prescribed, OTC, herbal) and/or dietary/ lifestyle changes. Decide on individual case basis whether to increase dose/ address cause. Retest INR in 7-14 days. If INR falls outside therapeutic range within first 4 weeks of acute VTE, seek advice from haematology regarding LMWH. If >2 INRs below therapeutic range without improvement following intervention, seek advice from relevant Specialist (eg Cardiologist for artificial valve).
Bleeding and over- anticoagulation	ANY SIGNS OF BLEEDING REQUIRE MEDICAL ADVICE AND/OR DIRECT REFERRAL TO SECONDARY CARE. Coagulometers using capillary blood may not be accurate when the INR is elevated. For CoaguChek XS plus, when the INR is >8.0 the capillary blood INR result should be confirmed with a second test and in addition a sample obtained by venepuncture and sent to the laboratory to determine the exact INR reading. The therapeutic decision around dosing and clinical management of the patient should not be delayed until the laboratory result is obtained.

NHS

Exclude possibility of intra about headache, nausea an memory loss/ personality ch arrange urgent admission.	cranial bleeding by aski nd vomiting, blurred visio nange/ If cause for conce
INR Major bleeding irrespective	Recommended action
of INR	care.
Minor bleeding e.g minor trauma, minor nose bleeds etc, INR <5.0	Seek advice from GP or specialist. Reduce warfarin dose appropriately. If minor bleeding despite INR being within target INR range, then plan for anticoagulation needs to be reviewed (e.g. brief
Minor blooding IND - 5	Stop worforin rofor
Minor bleeding, INK >5	secondary care.
3.0-6.0 (target 2.5), no signs of bleeding	Reduce weekly warfar dose by 10-20%. Repeat IN in 1-2 weeks.
4.0-6.0 (target 3.5), no signs of bleeding	Reduce weekly warfar dose by 10-20%. Repeat IN in 1-2 weeks.
6.0-8.0, no signs of bleeding	Stop warfarin for 1-2 day reduce weekly dose by 50% Consider or phytomenadione (vitamin H 2mg if bleeding risks*, Check INR within 7 days of next day after phytomenadione.
INR >8.0, no signs of bleeding	Stop warfarin, Give oral phytomenadior (vitamin K) 2mg, Check INR following day ar repeat dose if still hig Restart warfarin appropriate dose when IN in range. Check INR within Z days

Suspected warfarin related skin necrosis/ calciphylaxis	Stop warfarin and seek specialist advice.
Planned surgery/ dental procedures	Warfarin may need to be stopped- see <u>CKS</u> for further guidance.

Duration of treatment:

The duration of anticoagulant therapy varies by indication- see table 1. The maximum duration of overall treatment will be documented on the initial referral form and in the patient's Anticoagulation Therapy booklet or single sheet record.

Consideration may need to be given to the early discontinuation of therapy in situations where the risks outweigh the benefits of continued treatment for example patients not attending regular monitoring, or those unable to follow the dosing regimen.

Information given to patients:

At the first appointment following transfer from secondary care or when the primary care provider initiates the anticoagulant, education should be re-enforced (according to a counselling checklist). The counselling should be comprehensive to ensure that patients (and/or their carers and support staff when appropriate) are fully aware of their treatment and should include:

- The name of the drug and current dose
- The reason they are taking the drug
- Therapeutic goal / target INR
- The anticipated length of treatment
- What to do in the event of a missed dose; If a patient misses a dose of warfarin they should be told not to take double the dose the next day but to continue with their normal dose. If the patient is very sensitive to changes, or at high risk if under dosed, they should contact the service provider as soon as possible. Other patients may be asked to arrange earlier monitoring if their appointment is not due for some time, depending on stability of patient and clinical judgment of managing practitioner.
- Symptoms of under dose/overdose and action to take if these occur
- Drug/drug and drug/food interactions
- Monitoring arrangements and how to obtain further medicine supplies
- What to do if dental treatment/surgery is required
- What to do if a surgical procedure is required/indicated
- Who to contact regarding any worries or concerns relating to their anticoagulation management.
- Information for women of childbearing age

An information booklet should be given to the patient to reinforce the verbal counselling; Oral Anticoagulant Therapy: Important information for patients.

Patients should be encouraged to carry their Anticoagulation Therapy booklet or alert card with them at all times and to show it to their GP/health practitioner whenever they seek medical or dental treatment or purchase medicines from a pharmacy.

Oral Anticoagulation Therapy booklets, alert cards, information booklets and record sheets can be ordered from Primary Care Support England (PCSE) via the PCSE online portal at <u>PCSS: Login (england.nhs.uk)</u>

Availability:

Warfarin tablets are colour coded; 0.5mg (white), 1.0mg (brown), 3.0mg (blue) and 5.0mg (pink). In order to maintain a consistent approach across primary and secondary care, and to minimise risk, only **Warfarin 3mg (blue) tablets should be used across the Nottinghamshire ICS***.

In exceptional circumstances e.g. high anticoagulation therapy sensitivity, anticoagulation services may recommend the use of 1mg (brown) tablets. The use of multiple strengths of warfarin should not occur.

*In Bassetlaw, the processes align to those of South Yorkshire acute trusts and local policy regarding available tablet strengths should be followed.

References and sources of further support:

Practitioners managing anticoagulation should have had the necessary training and competence to do so. The National Patient Safety Agency (NPSA) supported the British Medical Journal (BMJ) to produce e-learning modules on initiating and maintaining patients on anticoagulant therapy (links below). These can help practitioners assess their current level of competence and provide training covering knowledge and understanding to promote safe practice.

https://learning.bmj.com/learning/module-intro/anticoagulantsprimary.html?moduleId=10052760&searchTerm=%E2%80%9Canticoagulation%E2 %80%9D&page=1&locale=en_GB

https://learning.bmj.com/learning/module-intro/anticoagulants-maintaining-.html?moduleId=5004429&searchTerm=%E2%80%9Canticoagulation%E2%80%9D &page=1&locale=en_GB

Useful Contacts:

Nottingham University Hospitals Anticoagulation team: 0115 9249924 (switchboard) ext 86005 Direct line 0115 9194413

Sherwood Forest Hospitals Anticoagulation team Kingsmill Hospital 01623 622515 ext 3601 Newark Hospital 01636 681681 ext 5807

Doncaster and Bassetlaw Teaching Hospitals Anticoagulation Monitoring Service 01302 642880

Warfarin Information Sheet for Primary Care Prescribers Version 1.0 January 2025 Accessibility checked References and further guidance:

- 1. Adapted from Derbyshire Joint Area Prescribing Committee (JAPC) Guideline on oral anticoagulation with warfarin. Feb 2023 with thanks.
- 2. NHS Nottingham & Nottinghamshire ICB Anticoagulation Monitoring Local Enhanced Service (Level 2, 3 & 4). 2024/2026
- 3. NottsAPC: Atrial Fibrillation (Non-valvular): prescriber decision support on anticoagulation. July 2024. <u>anticoagulants-in-af.pdf (nottsapc.nhs.uk)</u>
- 4. NUH guideline; Common warfarin drug interactions. June 2023
- 5. DRUGS TO TRY AND AVOID IN WARFARIN PATIENTS (koha-ptfs.co.uk)
- 6. SFH guideline; DOSE SCHEDULE FOR STARTING WARFARIN GUIDELINE, December 2017
- 7. <u>NUH guideline; Management of adult patients receiving a vitamin K</u> <u>antagonist (e.g. Warfarin) who are over-anticoagulated, bleeding, or in need</u> <u>of an urgent invasive procedure, Nov 2021</u>
- 8. BCSH guideline on anticoagulation with Warfarin from 2011 (4th edition)
- 9. CKS: <u>Scenario: Warfarin | Management | Anticoagulation oral | CKS | NICE</u>, Last updated April 2024.