Derby and Derbyshire
Integrated Care Board

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply/ Administration of Phytomenadione (vitamin K)

Version Number 1.0

For the oral administration of Vitamin K in over anticoagulated patients by nurses currently registered with the Nursing and Midwifery Council (NMC) and/or other registered healthcare professionals e.g. pharmacists working under anticoagulant management service in primary care within Derbyshire.

Change History	
Version / Date	**Change details**
1.0	New document

Practitioners intending to work under the PGD must be individually authorised by their/the designated manager, under the current version of this PGD before working according to it. Each practitioner is professionally accountable for ensuring they have undergone appropriate training and are competent and understand the contents of this PGD and the requirements of the anticoagulation management service.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	December 2023
Review date	May 2026
Expiry date:	November 2026

This PGD template has been peer reviewed by the DDICB Guideline Group in accordance with their Terms of Reference. It has been approved by the Derbyshire Joint Area Prescribing Committee.

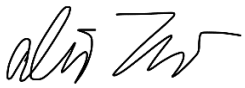
This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Alice Thai	Pharmacist, Head of MM, CP & High-Cost Interventions, DDICB
Alison Muir	Medicines Optimisation Pharmacist, DDICB
Dr. Ruth Gooch	GP, JAPC chair
Dr. Andrew Mott	GP, Medical Director, Derbyshire GP Provider Board
David Giles	Nurse Jessop Medical Practice

ORGANISATIONAL AUTHORISATIONS (legal requirement)

Job title and organisation	Name	Signature	Date
Director of Medicines Management & Clinical Policies NHS Derby and Derbyshire Integrated Care Board	Steve Hulme		18/12/2023

Additional signatories

Job title and organisation	Name	Signature	Date
Pharmacist from PGD working group	Alice Thai		30/11/2023
Doctor	Dr. Ruth Gooch		12/12/2023

Glossary

INR	International Normalised Ratio

1. Characteristics of staff

Qualifications and professional registration	• Registered professional who is deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD.
	  ○ NMC registered nurses.
	  ○ GPhc registered Pharmacists
	• Successful accreditation of Derbyshire anticoagulation management service.

Initial training	All health professionals must have appropriate training for resuscitation of a patient with anaphylaxis to prevent disability and loss of life. They must be familiar with their employing organisation's policy on the management of anaphylaxis for adults and children. If the employing organisation does not have such a policy/protocol then administration under this PGD is not permitted. The practitioner is expected to practice only within the bounds of their own competency, use their own clinical judgement and refer the patient to appropriate services as they see fit. Practitioners using a PGD MUST be named and have signed an authorisation form. Knowledge of and access to: • Resuscitation Council (UK) (2021): Emergency treatment of anaphylactic reactions https://www.resus.org.uk/library/additional-guidance/guidance-anaphylaxis/emergency-treatment • NICE (2011, updated 2020): Clinical Guideline 134. Anaphylaxis • NMC (2018) The Code (Nurses and Midwives) https://www.nmc.org.uk/standards/code/ • Relevant professional code of practice • Individual organisations' Consent Policy • NICE (2013, updated 2017): MPG2. Patient Group Directions – Section 1.5 Using patient group directions • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions https://www.nice.org.uk/guidance/mpg2/resources
Ongoing training and competency	• Annual updates on resuscitation skills for adults and children (including defibrillation training where defibrillator is available) and the management of anaphylaxis within the community. • The practitioner should be aware of any change to the recommendations for the medicines listed. • It is the responsibility of the practitioner to keep up to date with continual professional development and to work within the limitations of individual scope of practice. • Maintain competency by participating in peer review process.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Reversal of anticoagulation where INR is above the normal range. Patients treated with vitamin K antagonists, being managed by primary care anticoagulation management service accredited practitioners, with an INR equal or greater than 8.0 .
Criteria for inclusion	• Patients taking Vitamin K antagonists (warfarin, phenindione, or acenocoumarol) who have **INR ≥ 8.0* with <u>no</u> signs of bleeding** ** INR result should be confirmed on two samples using a coagulometer – if practical a further venous sample should also be sent but vitamin K should not be delayed.* • Patients aged 18 and over who consent to the treatment and are able to understand the administration direction. • Patients for whom INR reversal is in their best interest, following assessment by accredited anticoagulation management service practitioner.
Criteria for exclusion	• Patients who do not consent to the treatment or are unable to understand the administration direction. • Children 17 years and under • INR <8 • Pregnancy • Patients not taking warfarin, phenindione or acenocoumarol • Patients with previous local or systemic reactions or known hypersensitivity to the active ingredient or to any component of the product Patients who have already received oral vitamin K in successive days • **Any signs of bleeding (irrespective of INR)** eg epistaxis, haematuria, haematemesis, haemoptysis, PR bleeding or bleeding from a wound ***(seek advice from GP and/or arrange hospital admission as soon as possible)***
Cautions including any relevant action to be taken	• If INR is >5 on capillary blood it is advisable to validate the result with a re-test to exclude poor sample quality, results within 0.5 of one another are deemed accurate. For INR management >5 refer to the JAPC guideline on oral anticoagulation • For variable readings >0.5 the practitioner is expected to use their own clinical judgement and discuss patient with supervising GP to consider best course of action.- refer patient to GP/ Out of hours GP services/A&E/Emergency Services/Minor Injuries Unit/Walk in Centre as appropriate and • Discuss with GP for any concerns over reversing INR, eg patients with recent VTE, patients with a high range due to mechanical heart valve
Action to be taken if the individual is excluded	• Explain and discuss reason for exclusion. • Document reasons for exclusion and action taken in patient's clinical record. • Refer patient to their usual/ registered GP
Action to be taken if the individual or carer declines treatment	• Document refusal and reason in clinical records. • Advise patient to have INR the following day and attend ED with • any bleeding • Refer patient to their usual/ registered GP on the same day/as soon as practicable

3. Description of treatment

Name, strength & formulation of drug	Phytomenadione (vitamin K) 2mg in 0.2ml solution for injection For ORAL USE
Legal category	Prescription Only Medicine (POM).
Route / method of administration	For oral administration, oral dispensers are provided in the pack. After breaking the ampoule open, 0.2 ml of solution should be withdrawn into the oral dispenser until it reaches the mark on the dispenser (0.2 ml = 2 mg vitamin K). Drop the contents of the dispenser directly into the patient's mouth by pressing the plunger. Equipment should be disposed of according to local sharps and/or waste management policy and HTM 07-01 the Safe Management of Healthcare Waste (Department of Health, 2023). https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/
Indicate any off-label use (if relevant)	Best practice advice in accordance with British Committee for Standards in Haematology Guidelines on Oral Anticoagulation with Warfarin and BNF is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes the following unlicensed use(s): • Oral use in adults *Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the medicine is being offered in accordance with national guidance but that this is outside the product licence.*
Dose and frequency of administration	**INR ≥8.0 Give 2 mg (0.2mls) phytomenadione** Omit warfarin until INR <5.0. Repeat INR next day. **Only one dose may be given in 24 hours.** The dose may be repeated if INR is still too high after 24 hours - seek specialist advice if INR not falling.
Duration of treatment	Only one dose may be given in 24 hours.
Quantity to be supplied	One 2mg dose of injection given orally
Storage	Phytomenadione ampoule solution should be stored below 25°C and be protected from light. The solution should not be frozen. At the time of use, the ampoule contents should be clear (SPC states solution is clear to slightly opalescent, pale yellow in colour). Following incorrect storage, the contents may become turbid or present a phase-separation. In this case the ampoule must no longer be used.
Drug interactions	No significant interactions are known other than antagonism of coumarin anticoagulants.
Identification & management of adverse reactions	Bleeding complications in spite of corrective action. No adverse side effects reported from oral vitamin K administration
Management of and reporting procedure for adverse reactions	Suspected adverse events following administration must be reported in line with guidance as issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) https://yellowcard.mhra.gov.uk/ Defective medicines e.g. errors in packaging, labelling, contamination etc. must be reported to the Defective Medicines Report Centre (DMRC) at the MHRA – Information available from https://www.gov.uk/government/publications/a-guide-to-defective-medicinal-products

Written information to be given to individual or carer	Give marketing authorisation holder's product information leaflet (PIL) provided with the product.
Advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • Not to take any further warfarin or other anticoagulant drug until recommended by accredited practitioner or GP • To return for repeat INR within 24 hours and further advice • To report any new or worsening bleeding symptoms to the surgery or out of hours Services e.g. 111 or ED
Records	Clinicians must ensure that records are kept in line with NMC Record Keeping Guidance (2009) and other professional codes of practice as applicable. The record should include: • Assessment of the patient's need in relation to the intervention • Valid informed consent was given • Patient's name, address, date of birth and GP with whom the patient is registered. • Name of registered health professional • Name, dose, form, route and quantity of medicine administered • Brand, batch number and expiry date of medicine • Date of administration • Name of the practitioner administering the medicine • • Advice given to the patient/carer • • For any contraindications/exclusions the advice given and course of action taken and the outcome. • Record how the patient's central record or GP surgery record will be updated, where applicable • Details of any adverse drug reactions and actions taken • Record that the supply was made via PGD Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • JAPC anticoagulation (oral) guideline with warfarin • British Society for Haematology Oral Anticoagulation with Warfarin - 4th Edition (b-s-h.org.uk) • SPS PGD page https://www.sps.nhs.uk/home/guidance/patient-group-directions/ • Patient Group Direction- Supply/Administration of Phytomenadione (vitamin K) By Specialist Nurses in Anticoagulation at University Hospitals of Derby and Burton NHS Foundation Trust v2 UHDB215 https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-retrieve-file.pl?id=7aa83e7fd89ec80e1fda56b7bfe232ea

Appendix A – Registered health professional authorisation sheet

Vitamin K – Phytomenadione 2mg in 0.2ml solution for injection ampoules [v1]
Valid from: December 2023 Expiry: November 2026

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this Patient Group Direction you are indicating that you agree to its contents and that you will work within it.

Patient Group Directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of [INSERT NAME OF ORGANISATION] for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.