East London
NHS Foundation Trust

Patient Group Direction (PGD) for the Oral Administration of Vitamin K (Phytomenadione) Injection for the Reversal of Over-Anticoagulation with Warfarin

[Bedfordshire CHS]

Version number :	2.0
Consultation Groups	Anti-Coagulation Nurses
Approved by (Sponsor Group)	July 2018
Ratified by:	Medicines Committee
Date ratified:	Medicines Committee
Name & Job Title of Author / Review Author:	1. Dupe Fagbenro, Lead Pharmacist, BCHS 2. Helen Willis, Senior Anticoagulation Nurse 3. Michelle Warke, Senior Anticoagulation Nurse
Executive Director lead :	Dr Paul Gilluley
Implementation Date :	July 2018
Last Review Date	September 2020
Next Review date:	September 2023

Services	Applicable
Trustwide	
Mental Health and LD	
Community Health Services	

Version Control Summary

Version	Date	Author	Status	Comment

Vitamin K (Phytomenadione) Injection

Patient Group Direction (PGD) for the oral administration of Vitamin K (Phytomenadione) injection for the reversal of over anticoagulation with warfarin

By a registered nurse with current Nursing and Midwifery Council (NMC) registration, working at East London NHS Foundation Trust who is assessed and deemed competent and thus authorised to work under this PGD. Access to the current edition of the British National Formulary and the Summary of Product characteristics and any relevant updates required.

>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION <<

>> OF THIS PGD BEFORE WORKING UNDER IT <<

to **Adults aged 18 years and over**

1. Clinical Condition

Define situation/condition	Reversal of excessive anticoagulation in patients on warfarin with INR ≥ 8
Criteria for inclusion	• INR ≥8 obtained from capillary or venous sampling with no signs of bleeding. (See under cautions for capillary sampling) • INR result confirmed on two samples on separate limbs. Valid consent obtained
Criteria for exclusion	• Children under 18 years of age • INR < 8 • Pregnancy • Mechanical Heart Valves • Patients not taking warfarin • Known allergy or intolerance to vitamin K and excipients • Major or life-threatening haemorrhage • Patients who have already received 2 doses of oral vitamin K in successive days • Unexpected bleeding at therapeutic levels when patient's INR is in range (this should alert the possibility of an underlying pathology which should be investigated. • Any signs of bleeding irrespective of INR e.g. epistaxis, haematuria, haematemesis, haemoptysis; rectal bleeding or bleeding from a wound. • No valid consent. • MCA - should the healthcare professional feel that the patient is unable to deliberate sufficiently with regard to the information they have been given, then the Mental Capacity Act should be followed
Action to take if patient is excluded	• Explain and discuss reasons for exclusion • Ensure all actions / decisions are documented in patient records • Inform patient's GP and refer for alternative management
Action to take if patient declines	• Contact patient's GP for medical advice. • Give advice about alternative treatment pathways. • Document refusal in patients notes. • Ensure patient/carer fully understands reasons for administration and consequences of not administering treatment and has capacity.
Refer to doctor	• Refer patients with INR > 8 showing signs of a major bleed to A&E via 999 • For patients with INR >8 showing signs of a minor bleed refer to patient's GP for advice on management • For variable readings from capillary sampling contact the Lead Clinician or Patient's registered GP for advice. • Should there be any concerns relating to vulnerable adults, adhere to Safeguarding Adults Policy and Procedure (CLPG 39) • Should there be any concerns regarding safeguarding, consult a member of the

	safeguarding team to discuss.

2. Description of treatment

Name, form and strength of medicine	Phytomenadione Injection 2mg/0.2ml (Konakion MM Paediatric ®), clear to slightly opalescent, pale yellow in colour
POM/P/GSL	POM
Use outside of the Terms of the Marketing Authorisation	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
Dose(s)	2mg (0.2mls)
Route / Method of administration	• For Oral Use • Shake the ampoule until the liquid is in the bottom of the ampoule. • Open the ampoule and draw up 0.2mls via the dispenser provided. • Administer to the patient directly from the dispenser.
Frequency	• Once in 24hours • Repeat dose after 24hours if INR remains greater than 8
Maximum or minimum treatment period	• Maximum dose in 24 hours is 2mg • Maximum duration of treatment is 2 days • Seek specialist advice after second dose is administered
Supply (Quantity to supply and administer)	One 0.2mL (2mg) ampoule
Storage requirements	• Store below 25°C • Protect from light • Do not freeze or use if turbid (cloudy or opaque)

Warnings and cautions	• Elderly/frail patients tend to be more sensitive to reversal of anticoagulation with vitamin K and so may require more frequent monitoring of INR
	• Seek further advice from GP/hospital specialist before administering vitamin K for patients with:
	  ○ Thrombophilia
	  ○ Previous PE/DVT/VTE
	  ○ High risk of clotting
	• If INR > 5 from a capillary blood test, the result should be validated by repeating testing to exclude poor sample quality, results within 0.5 each other are considered accurate. For variable readings contact the Lead Clinician or Patient's registered GP for advice.

Side Effects	• There are no reported side effects from oral administration. • Anaphylactoid reactions have been reported very rarely following intravenous administration. • Report serious suspected reactions to the Medicines and Healthcare Products Regulatory Agency using the yellow card system (www.yellowcard.gov.uk). Yellow cards and guidance on their use are available at the back of the BNF. • Any adverse reaction must also be documented in individuals' medical record, reported on Datix and communicated to the patient's GP.
Advice to patients / carer	• Reason for administering vitamin K and course of treatment should be conveyed. • Provide patient information leaflet and advise that use is outside of licence • Advise regarding discontinuation of warfarin or other anticoagulant drugs until restarted by anticoagulant clinic or patient's GP • Inform of INR repeat test required within 24 hours (communicate arrangements for repeat INR to patient and/carer) • Ask patient to report any new or worsening bleeding symptoms to warfarin clinic, patient's GP surgery or out of hours doctor immediately

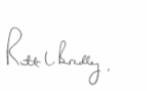
	• Provide service details and out of hours contact details
Follow up	Repeat INR after 24 hours of administration of vitamin K • If repeat INR is due outside of contracted hours advise patient to attend A&E for repeat INR and inform patient's GP • If INR >8 after 24 hours repeat treatment with vitamin K. • Withhold Warfarin till INR<5 • Reassess anticoagulation following administration of vitamin K • The cause of an elevated INR should be investigated.
Records / Audit Trail	• Complete proforma (Appendix 1), keep a copy in clinic records, scan a copy to the patient electronic records and send a copy to GP within one working day. • Document the following in patient's health record: ○ Patient consent ○ If over 16 and lacking capacity, document MCA assessment ○ Name/Brand name of medicine ○ Dose and form administered ○ Batch and expiry details ○ Advice given to patient (including side effects) ○ A statement that supply or administration is by using a PGD ○ Signature and name of staff who administered the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment ○ Follow-up and/or signposting arrangements ○ Any other relevant information that was provided to the individual ○ Details of any adverse drug reaction and actions taken including documentation in the patient's medical record ○ Referral arrangements (including self-care)
References	• Summary of Product Characteristics Konakion MM Paediatric 2mg/0.2ml Updated 22.02.2019. Accessed 29.07.2020 from https://www.medicines.org.uk/emc/product/9754 • Joint Formulary Committee. British National Formulary. February 2017. Accessed 01.03.17 from https://www.evidence.nhs.uk/formulary/bnf/current/2- cardiovascular-system28-anticoagulants-and-protamine/282- oral-anticoagulants/coumarins-and-phenindione • Haemostasis and Thrombosis Task Force of the British Committee for Standards in Haematology. Guidelines on oral anticoagulation with warfarin-fourth edition. British Journal of Haematology, 2011; 154:311-324. Accessed 29.07.2020 from https://b-s-h.org.uk/guidelines/guidelines/oral-anticoagulation-with-warfarin-4th-edition/

Organisation and individual authorisation signatures can be found on the managerial content sheet along with other non-clinical details relating to this patient group direction.

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR VITAMIN K (PHYTOMENADIONE) 2MG IN 0.2MLS INJECTION FOR ORAL ADMINISTRATION

Patient Group Direction Owner	
Details	Name: Dupe Fagbenro Position: Lead Pharmacist, Bedfordshire Community Health Services Contact Address: Twinwoods Health Resource Centre, Milton Road, Clapham, Bedfordshire MK41 6AT Contact Telephone: 07765220249 Contact Email: Dupe.fagbenro@nhs.net

Patient Group Direction Details	
Date comes into effect	September 2020
Date of expiry + review	September 2022 or sooner with significant changes in information
Staff characteristics	• Registered Nurse with current Nursing and Midwifery Council registration employed by East London NHS Foundation Trust who is assessed and deemed competent and thus authorised to work under this PGD to provide a service in the warfarin clinic. • Access to the current edition of the British National Formulary and the Summary of Product characteristics and any relevant updates is required **>> YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING UNDER IT <<**
Specialist competencies or qualifications	• Has undertaken appropriate training for working with PGDs in general including legal and accountability issues. • Has undertaken appropriate training for working with the medicine listed in this PGD, including an assessment of their understanding of the medicine. • Has demonstrated competence in understanding the diagnosis and management of the condition and performs competent and safe clinical assessment interviews with patients. • Has undergone training in the recognition and treatment of anaphylaxis, including practical training in Basic Life Support (including annual updates) • Has undergone regular training and updating in safeguarding vulnerable adults. • Has knowledge and understanding of the Mental Capacity Act
Continuing Training and Education	• The practitioner should be aware of any change to the recommendations for the medicine listed. • It is the responsibility of the practitioner to ensure they receive updates in training in the recognition and treatment of anaphylaxis, including practical training in Basic Life Support. • It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

Patient Group Direction Authorisation	
Chief Medical Officer, ELFT	Name: Dr Paul Gilluley Position: Chief Medical Officer Signature:  Date: 17/09/2020
Medical Director	Name: Dr Kate Corlett Position: Medical Director, Community Health Services Signature:  Date: 15/02/2021
Chief Pharmacist	Name: Jenny Melville Position: Chief Pharmacist Signature:  Date: 15/02/2021
Director of Nursing	Name: Ruth Bradley Position: Director of Nursing Signature:  Date: 08/07/2021

Authors		
Authors	Position	Signature and Date
Lead Doctor: Dr Jaison Mathew	Lead Clinician Warfarin Clinic	Signature:  Date: 16.09.2020
Lead Pharmacist: Dupe Fagbenro	Lead Pharmacist, Bedfordshire CHS	Signature: DFagbenro Date: 10/09/2020
Senior Anticoagulation Nurses (Managers authorising named practitioners who are competent in all areas listed in the competency checklist to use this PGD) Michelle Warke Helen Willis	Michelle Warke Senior Anticoagulation Nurses	Signature: MWarke Date: 14/09/2020
	Helen Willis Senior Anticoagulation Nurses	Signature: HJWillis Date: 16/09/2020

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR VITAMIN K (PHYTOMENADIONE) 2MG IN 0.2MLS INJECTION FOR ORAL ADMINISTRATION

Individual Authorisation

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE. YOU CANNOT DELEGATE TASKS UNDER THIS PGD TO ANYONE ELSE

IF THIS IS AN UPDATED OR REPLACEMENT PGD ENSURE THAT ALL OLDER VERSIONS ARE WITHDRAWN FROM USE WITH IMMEDIATE EFFECT

IT IS YOUR REPONSIBILITY TO MAKE SURE YOU ARE USING THE CURRENT VERSION

NOTE TO AUTHORISING MANAGERS: AUTHORISED STAFF SHOULD BE PROVIDED WITH AN INDIVIDUAL COPY OF THE CLINICAL CONTENT (NON-MANAGERIAL CONTENT PART) OF THE PGD AND A PHOTOCOPY OF THE AUTHORISATION SHEET SHOWING THEIR AUTHORISATION

THE PRACTITIONER MUST BE REGISTERED WITH THE NMC AND BE AN EMPLOYEE OF EAST LONDON NHS FOUNDATION TRUST AND WILL ENSURE THAT HE/ SHE HAS THE RELEVANT TRAINING AND IS COMPETENT IN ALL ASPECTS OF THE ADMINISTRATION OF MEDICINES PERTAINING TO THIS PATIENT GROUP DIRECTION, INCLUDING THE CONTRA-INDICATIONS AND THE RECOGNITION AND TREATMENT OF ANAPHYLAXIS. HE/SHE WILL ATTEND UPDATES AS APPROPRIATE.

THIS PRACTITIONER WILL HAVE DUE REGARD FOR THEIR REGULATORY BODY'S STANDARDS OF CONDUCT, PERFORMANCE AND ETHICS.

THIS AUTHORISATION IS VALID FOR THE LIFE OF THE CURRENT DOCUMENT OR UNTIL ANY CHANGES ARE MADE TO IT IN LIGHT OF NATIONAL GUIDANCE.

THE PGD WILL BE REVIEWED IN THE LIGHT OF NEW NATIONAL GUIDANCE

Enquiries relating to this PGD should be addressed to:
Lead Pharmacist, Bedfordshire Community Health Services

DECLARATION by Nurse Practitioner:

I have been appropriately trained to understand the criteria listed above and the administration of Vitamin K (Phytomenadione) 2mg (in 0.2mls) injection for oral administration in accordance with this Patient Group Direction.

Name of Professional	Signature	Registration Number	Date	Authorising Manager

Competency Checklist

Name of Practitioner:		Assessor's signature
Clinical and Pharmaceutical knowledge	Understands and has an up-to-date knowledge of: • the condition and its assessment • non-drug treatment alternatives • the medicine, including its mode of action and dosing details • potential side-effects, and adverse-drug-reaction reporting • any misuse potential of the medicine	
Establishing options	• Can establish why the medicine is needed, and can choose a suitable treatment, referring for medical advice where necessary and following up appropriately	
Communicating with the patient	• Does not encourage the expectation that a medicine will be given • Helps the patient make an informed choice • Negotiates an outcome that both patient and staff are satisfied with • Gives clear instructions to the patient about their medication • Checks the patient's understanding of the treatment	
Safe PGD use	• Knows the limits of own knowledge and skills, and works within them • Knows when to refer to another member of the multidisciplinary team • Will advise line manager if unable to maintain confidence and competence in using PGDs • Understands the need for, and makes complete and timely records • Recognises and deals with pressures that result in inappropriate use of PGDs	
Professional standards	• Accepts personal responsibility for working within PGDs and understands the legal implications • Understands and works within the scope of the PGD • Makes clinical decisions based on patient's needs, not personal considerations • Reflects on own practice and performance	
Practice development	• Actively participates in the review and development of practice to improve patient care	
Information in context	• Knows how to access relevant information • Can critically appraise and apply information in practice	
The NHS in context	• Understands, and works with, local and national policies and services that impact on PGD use	
The team and individual context	• Works in partnership with colleagues for the benefit of patients. Is self-aware and confident in own ability to use PGDs	

Appendix 1

Patient and Consultation Details			
Date of consultation:	NHS Number:	Date of Birth:	
Patient's address:			
Name and Address of GP:			
Indication for Anticoagulation:			
Criteria for Inclusion			
INR greater than 8	Yes	No	
Test repeated to confirm INR value	Yes	No	
Signs of Bleeding	No bleeding	Minor bleeding	
	Major bleeding	Other (details):	
Criteria for Exclusion			
Less than 8 years old	Yes	No	
Known tolerance to phytomenadione and excipients	Yes	No	
Pregnancy	Yes	No	
Has received 2 doses of phytomenadione on successive days	Yes	No	
Details of Previous Phytomenadione Administration (within the last 7 days)	Date: Dose:	Date: Dose:	
Not taking warfarin	Yes	No	
Mechanical Heart Valve	Yes	No	
Caution or Need for Further Advice			
Thrombophillia	Yes	No	
Previous PE/DVT	Yes	No	
High risk of Clotting	Yes	No	
Elderly	Yes	No	
GP Contacted	Yes	No	
Name and Address of GP / Specialist giving advice:			
Advice given:			
Information Provided to Patient			
Stop warfarin until advised by clinic staff	Yes	No	
Attend arranged next day appointment for repeat INR	Yes	No	
Patient Information Leaflet	Yes	No	
Reasons for exclusion given and signposted to appropriate service	Yes	No	n/a
Reason for refusal explored and documented	Yes	No	n/a
Other advice:			
Medication			
Dose administered:			
Batch number:			
Expiry Date:			
Consent			
I have received and understand the information on administration of oral vitamin K provided. I consent to its administration. Patient Signature: Date:			
Patient is unable to give written consent and has given verbal consent	Yes	No	n/a
Practitioner			
Name:	Signature:	Date:	

Appendix 2

Agreement by Registered Practitioner

Statement by practitioner agreeing to act under the Vitamin K within East London NHS Foundation Trust

I have received, read and fully understand the following documents:

1. The Vitamin K within East London NHS Foundation Trust
2. The Drug Monograph(s) included in the PGD
3. Operational policy/policies Name
4. The East London NHS Foundation Trust Medicines Policy
5. The East London NHS Foundation Trust Policy for PGD Approval

I have received the training set out in the PGD which practitioners must undertake before being authorised to administer or supply any medicinal product under the PGD

I agree to act as a practitioner within the terms of the PGD and to administer and/or supply medicinal products in accordance with the PGD

In return, the Trust accepts vicarious liability for the practitioner acting under the terms of the PGD

I understand that by agreeing to act as a practitioner under the PGD, I am extending my role and job description. I understand that my acceptance of this extension of my role and job description has not been a compulsory requirement of East London NHS Foundation Trust

NAME OF PRACTITIONER: (*block capitals*).....

SIGNATURE OF PRACTITIONER:.....

DATE:.....

NAME OF DESIGNATED MANAGER; (*block capitals*).....

SIGNATURE OF DESIGNATED MANAGER:.....
(TO CONFIRM THAT TRAINING HAS BEEN COMPLETED AND ATTAINED TO A SATISFACTORY STANDARD)

DATE:.....

Appendix 3

Audit Tool

Frequency of Audit:

- All PGDs to be audited once yearly.
- New PGDs to be audited after six months, then yearly subsequently.

Standards:

- 100% of administrations must be recorded as per policy
- 100% of administrations must be appropriate indications
- 100% of administrations must be STAT doses
- 100% of administrations must be by appropriately trained staff

Method:

- Review all charts, progress note entries and any records for all patients receiving medications during a specified time period for evidence of PGD use.

Suggested Audit Tool:

	Phytomenadione 0.2mg / 2ml injection for oral administration		
Date			
Recorded on Chart			
Recorded in notes			
Appropriate indication			
Dose or quantity supplied and administered			
Appropriate / competent staff member			