University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Phytomenadione (vitamin K) By Specialist Nurses in Anticoagulation at University Hospitals of Derby and Burton NHS Foundation Trust

Documentation details

Reference no:	UHDB215
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Change history

Version number	Change details	Date
1.0	New document	19/07/2019
2	PGD reviewed	30/09/22

Glossary

Abbreviation	Definition
INR	International Normalised Ratio

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Heather Hygate	Lead Anticoagulation Specialist Nurse
Dr Charalampos Kartsios	Consultant Haematologist
Maja Moldawa	Divisional lead pharmacist, CDCS

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Anticoagulation Service
Limitations to authorisation
Only for use by Anticoagulation Specialist Nurses

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer	James Hooley	Signed copy held by Pharmacy	12/12/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Pharmacist *Clinical Pharmacist from PGD working group*	**Maja Moldawa**	Signed copy held by Pharmacy	**05/12/2022**
Consultant Haematologist *Doctor*	**Dr Charalampos Kartsios**	Signed copy held by Pharmacy	**09/12/2022**
Lead Anticoagulation Specialist Nurse *Registered Professional representing users of the PGD*	**Heather Hygate**	Signed copy held by Pharmacy	**23/11/2022**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	NMC Registered Nurse
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
Competency assessment	Staff operating under this PGD must read, understand and sign the document. Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Annual Medicines Safety Training (essential to role) Review/repeat initial training above when this PGD is revised
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	INR 8.0 or higher *Or* Authorisation from a doctor that reversing an INR below 8.0 is in the patient's best interest
Criteria for inclusion	• Patients aged 18 and over who consent to the treatment • Patients for whom INR reversal is in their best interest, following assessment by a specialist nurse (with haematologist advice where necessary) • Patients who are able to understand the directions to administer and manipulate the injection for oral use themselves
Criteria for exclusion	• Patients who do not consent to the treatment • Patients aged 17 years and younger • Patients with previous local or systemic reactions to the medication • Patients with a known hypersensitivity to the active ingredient or to any component of the product • Patients who cannot understand the directions to administer or cannot manipulate the injection for oral use
Cautions including any relevant action to be taken	• Discuss with haematologist 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 patient is excluded	• Refer patient to appropriate department (eg GP/DHU if cannot self-administer; KITE team for <18 years of age; consultant haematologist if hypersensitive to constituents • Document reason for exclusion in patient's DAWN notes
Action to be taken if the patient or carer declines treatment	• Document advice given in patient's DAWN and CITO notes • Advise patient to have INR the following day and attend ED with any bleeding • Report refusal to patient's GP
Arrangements for referral for medical advice	• Consult with GP or haematology consultant as appropriate, via telephone or email • Document advice given alongside name of adviser in the patient's DAWN record

5. Description of treatment

Name, strength & formulation of drug	Phytomenadione (Vitamin K) 2mg in 0.2ml injection FOR ORAL USE
Legal category	Prescription-only medication
Route / method of administration	Oral

Indicate any off-label use (if relevant)	Not applicable
Dose and frequency of administration	• One dose only, to be administered as soon as possible. INR 8.0 – 12.0 = 2mg dose. INR >12.0 = 4mg dose.
Duration of treatment	Once only
Quantity to be supplied (leave blank if PGD is administration ONLY)	One x 2mg vial if INR 8.0 – 12.0, or two x 2mg vials if INR >12.0
Storage	Stock must be securely stored according to UHDB medicines policy, at room temperature in a locked cupboard inside a locked room
Drug interactions	Antagonism of coumarin anticoagulants
Adverse reactions	None within normal dosing limits. Adverse events have only been associated with overdose and relate to liver or GI changes for which the majority of reactions were reversible (see BNF / manufacturer information in the event of overdose)
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record and DAWN record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Information sheet to be given to patient with the medication, informing them how to open the glass ampoule and administer the medication safely at the correct dose
Patient advice / follow up treatment	• Advise patient to omit warfarin immediately and have an INR the next day, after which they should wait for advice from the nurses prior to re-starting warfarin treatment • Advise patient to attend ED with any bleeding • Explain the treatment being offered and the possible consequences of refusal. Direct patients with active significant bleeding to ED. Inform patient of proposed treatment and gain consent. Advise patient to omit warfarin on the day and have a repeat INR the following day • **Administration instructions: For oral administration; oral dispensers are provided in the pack. Advice is provided on breaking open the ampoule using gauze to protect the patient from laceration. After breaking the ampoule open, 0.2ml of solution should be withdrawn into the oral dispenser until it reaches the mark on the dispenser (0.2ml = 2mg vitamin K). A second pack and dose is provided for any patient who requires 4mg**

Records	Record administration of vitamin K in the patient's electronic DAWN record, and also in the paper file in the Anticoagulation office. Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. 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* • *https://medusa.wales.nhs.uk* • CG-T/2014/072

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7. Registered health professional authorisation sheet

PGD Name [version]: Anticoagulation – Phytomenadione [v2] PGD ref: UHDB215

Valid from: 12/12/2022 Expiry date: 11/12/2025

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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 / Assessor

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 University Hospitals of Derby & Burton NHS Foundation Trust 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 must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.