Patient Group Direction (PGD)

Vitamin K

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.

Reference: Phytomenadione 10mg/ml 0.2ml amp

Valid from: October 2020
Review date: August 2023
Expiry date: October 2023

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.
1. Clinical condition or situation to which the direction applies

| **Indication** | Patients on vitamin K antagonists, being managed by primary care level 4 anticoagulation management service accredited practitioners, with a high INR, who are at risk of bleeding and haemorrhagic stroke. |
| **Objective** | Reversal of anticoagulation where INR is above the normal range. |
| **Criteria for inclusion** | Patients taking Vitamin K antagonists (warfarin, phenindione, or acenocoumarol) who have **INR > 8.0* with no signs of bleeding**  
  * INR result should be confirmed on two samples using a coagulometer - a further venous sample should also be sent but vitamin K should not be delayed.  
  In all cases of bleeding GP or specialist advice should be sought and secondary care referral arranged where appropriate. |

### Criteria for Exclusion

- Children 17 years and under
- INR ≤8
- Pregnancy
- Patients not taking warfarin, phenindione or acenocoumarol
- Known allergy or intolerance to vitamin K
- Patients who have already received 3 doses of oral vitamin K in successive days
- Major or life threatening haemorrhage
- 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. Patient should be referred to GP or specialist).

**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)

### Action to be taken if excluded

- Explain and discuss reason for exclusion.
- Document action taken in patient’s clinical record.
- Refer patient to their normal GP for admission to hospital, or if urgent arrange emergency admission to A&E through 999. Seek specialist advice where required.

### Action if patient or carer declines treatment

- Document refusal and reason if possible in clinical records.
- Refer patient to their normal GP for admission to hospital, or if urgent arrange emergency admission to A&E through 999. Seek specialist advice where required.

### Reference to National / Local policies or Guidelines

- British National Formulary [www.bnf.org.uk](http://www.bnf.org.uk)
- Summary of Product Characteristics (SPC) [www.medicines.org.uk](http://www.medicines.org.uk)
- Local Clinical Guidelines

### Precautions

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 refer patient to GP/ Out of hours GP
2. Description of Treatment

<table>
<thead>
<tr>
<th>Name, strength &amp; formulation of drug</th>
<th>Phytomenadione 10mg/ml 0.2ml amp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presentation</td>
<td>Amber glass ampoules containing 2 mg phytomenadione in 0.2 ml.</td>
</tr>
<tr>
<td>Storage</td>
<td>Phytomenadione ampoule solution should be stored below 25°C and be protected from light. The solution should not be frozen. Do not use if the solution is turbid.</td>
</tr>
<tr>
<td>Legal Status</td>
<td>Prescription Only Medicine (POM).</td>
</tr>
<tr>
<td>Black Triangle ▼</td>
<td>No</td>
</tr>
<tr>
<td>Unlicensed / Off label use</td>
<td>Yes</td>
</tr>
<tr>
<td>Route / method of administration</td>
<td>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.</td>
</tr>
</tbody>
</table>
| Dose                              | **INR >8.0** Give 2 mg (0.2mls) phytomenadione 10mg/ml  
**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. |
| Frequency of administration        | Only one dose may be given in 24 hours. |
| Total doses                       | Up to 3 doses over 3 consecutive days (see dose above) |
| Disposal                          | 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, 2013).  
| Drug Interactions                 | No significant interactions are known other than antagonism of coumarin anticoagulants. |
| Potential Adverse Reactions       | Bleeding complications in spite of corrective action. No adverse side effects reported from oral vitamin K administration |
| Reporting procedure of 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), see  
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 |
### Advice to patient / carer including written information and follow up treatment

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 doctor on call immediately

### Special considerations and additional information

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.

### 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
- Patient’s name, address, date of birth and GP with whom the patient is registered.
- Dose and form of medicine administered
- Route of administration
- Brand, batch number and expiry date of medicine
- Date given
- Name of the practitioner administering the medicine
- Consent – following local guidelines
- Advice given to the patient/carer
- Advice given if excluded or declines treatment
- For any contraindications/exclusions the 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

Medications given under a PGD must be appropriately READ coded in the patients clinical record.

Entries made in any record should ensure the practitioner delivering the care is clearly identifiable. Record keeping should be in line with Records Management: NHS Code of Practice Parts 1 & 2  

Clinical records must be kept for at least 8 years following completion of treatment. For children and young people – retain until the patient’s 25th birthday or 26th if the young person was 17 at conclusion of treatment All others retain for 10 years after conclusion of treatment or for 8 years following a child’s death.

A record of the intervention must, where given by a provider other than the patients registered GP or Practice Nurse, be provided to the patients registered GP/practice within one working day.
### 3. Characteristics of Staff

#### Qualifications required

- 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.
- Registered nurses with a current NMC registration.
- Registered Pharmacists with a current GPC registration.
- Successful accreditation of Derbyshire County Level 4 anticoagulation management service.
- 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.
- The practitioner has undertaken training in the recognition and treatment of anaphylaxis, including practical training in Basic Life Support.
- Practitioners using a PGD MUST be named and have signed an authorisation form.

#### Additional requirements

- 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 vaccination 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:
  - NMC (2009) Record Keeping Guidance (Nurses and Midwives)
  - NMC (2010) Standards for Medicines Management (Nurses and Midwives)
  - Relevant professional code of practice
  - CCG or individual organisations’ Consent Policy

#### Continued training requirements

- 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.
1. PGD Development Team

This PGD has been developed by the Derbyshire Medicines Management Guideline and Shared Care Group and ratified by Derbyshire Joint Area Prescribing Committee (JAPC).

2. Organisational Authorisations

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

<table>
<thead>
<tr>
<th>DESIGNATION</th>
<th>NAME</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Medical Director, NHS Derby and Derbyshire Clinical Commissioning Group</td>
<td>Dr. Steven Lloyd</td>
<td>14/10/2020</td>
<td></td>
</tr>
</tbody>
</table>
PATIENT GROUP DIRECTION (PGD)

Vitamin K – Phytomenadione 10mg/ml 0.2ml amp

Individual Practitioner Authorisation

Provider organisations must complete an Individual Practitioner Authorisation sheet for each person planning to practice under this PGD. You should retain copies as part of your organisation’s internal governance arrangements. You may wish to retain a copy in the individual’s personal file.

Practitioner

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.

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

Signed........................................................................................................ Date..........................................................

Name (Print).................................................................................................................................

Designation.................................................................................................................................

Authorising Manager

Designated Manager to give authorisation * for the Health Care Professional named above and who has signed the PGD

Signed........................................................................................................ Date..........................................................

Name (Print) .................................................................................................................................

Designation.................................................................................................................................

On behalf of: Name of organisation ...........................................................................................

*Note to Authorising Manager

By signing this you are confirming that you have assessed the staff member as competent to work under this PGD and that they have the organisational approval to do so.

You must give this signed PGD to each Authorised Practitioner as it shows their authorisation to use the PGD.