

PATIENT GROUP DIRECTION (PGD)

Administration of Glyceryl Trinitrate 500 microgram tablets / 400 microgram spray.

By State Registered non-medical staff in Imaging Facilities at all sites where UHDB Imaging deliver services

Documentation details

Reference no:	UHDB254
Version no:	5.0
Valid from:	28/04/2023
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Expiry date:	27/04/2026

Change history

Version number	Change details	Date
5.0	Reformatting, now applies to all UHDB sites	31/03/2023

Glossary

Abbreviation	Definition
RDH	Royal Derby Hospital
QHB	Queen's Hospital, Burton on Trent
FNCH	Florence Nightingale Community Hospital, Derby
SJCH	Samuel Johnson Community Hospital, Lichfield
SRPCH	Sir Robert Peel Community Hospital, Tamworth
ICH	Ilkeston Community Hospital
RCH	Ripley Community Hospital
LEHC	Long Eaton Health Centre
St. O	St. Oswald's Hospital, Ashbourne
Mob CT	UHDB owned and operated Mobile CT scanner
Mob MRI	UHDB owned and operated Mobile MRI scanner
Mob BS	UHDB owned and operated Mobile Mammography
UHDB	University Hospitals of Derby and Burton NHS Foundation Trust
POM	Prescription only medication

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
Mike Barnard	Clinical Manager: Compliance, Imaging Business Unit (HCPC Registered Diagnostic Radiographer)
Dr Rathy Kirke	Consultant Radiologist & Imaging Clinical Director
Dr Rajeev Singh	Consultant Radiologist & Imaging Clinical Director
James Hooley	Medication Safety Officer, Clinical governance pharmacist

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
University Hospitals of Derby and Burton NHS Foundation Trust staff at the following sites: RDH, QHB, SRPCH, SJCH, FNCH, ICH, RCH, LEHC, St. O and Mob CT / Mob MRI / Mob BS units at locations in Staffordshire and Derbyshire.
Limitations to authorisation
This organisation does not authorise the use of this PGD by staff not employed by UHDB, either directly or via an agency.

Organisational Authorisation (legal requirement).			
Role	Name	Sign	Date
Medicines Safety Officer (Pharmacist)	James Hooley	Signed copy held by Pharmacy	28/04/2023

Additional signatories (required as per legislation and locally agreed policy)			
Role	Name	Sign	Date
Medicines Safety Officer (Pharmacist)	James Hooley	Signed copy held by Pharmacy	28/04/2023
Consultant Radiologist & Imaging Clinical Director	Dr Rathy Kirke	Signed copy held by Pharmacy	02/03/2023
Consultant Radiologist & Imaging Clinical Director	Dr Rajeev Singh	Signed copy held by Pharmacy	02/03/2023
Professional Lead for Radiography	David Tipper	Signed copy held by Pharmacy	02/03/2023

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	HCPC registered Radiographers and NMC registered Nurses
Initial training	<ul style="list-style-type: none"> - Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Completion of training to ensure competent in all aspects of IV injection (Trust IV training, SCoR accredited training for IV contrast agent administration, or equivalent) - Individual has read and understood full content of this PGD and signed authorisation (section 7) <p>The completion of NICE's self-competency check lists available at: https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-msword-13672765</p>
Competency assessment	<p>Competency evidence through core qualifications, recognised IV training or masters level training which will have included assessment for the following:</p> <ul style="list-style-type: none"> - Surface anatomy and palpation skills - Injection and aseptic techniques - Knowledge of medically screening patients - Knowledge of relevant pharmacology - Contraindications and precautions - Emergency procedures - Safety - A period of supervised clinical practice by a medical practitioner, or an authorised non-medical injector <p>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/competency-framework-for-health-professionals-using-patient-group-directions-msword-13672765</p> <p>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 the either authorising manager (section 7) or the clinical manager for their Imaging modality so that further training can be provided as required.</p>
Ongoing training and competency	<p>Staff working under this PGD must take part in continuing professional development. Staff are encouraged to complete the self-assessment competency tool NICE Competency Framework for health professionals using patient group directions. https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-msword-13672765 and present this as part of their evidence of CPD at their Appraisal at least once every 3 years. Managers and staff</p>

	<p>must consider the need for any additional local training if staff do not regularly undertake work covered by the PGD, for example career breaks or parental leave, or when gaps in knowledge arise.</p> <p>Annual mandatory training updates for Immediate Life Support/ Resus Automatic External Defibrillation AED training *, managing anaphylaxis and aseptic 'non-touch' technique provided by UHDB.</p> <p>*Unless exempt from doing life support training due to personal risk assessment</p>
<p><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></p>	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To be administered to patients as an inherent part of a Justified Imaging procedure). Administration must be according to the examination protocol / agreed scheme of work for the examination.
Criteria for inclusion	Justified Imaging requests for examinations involving the sub-lingual administration of Glyceryl Trinitrate.
Criteria for exclusion	<ul style="list-style-type: none"> • Under 16 years • Previous adverse reaction to Glyceryl Trinitrate • Hypersensitivity to nitrites. • Acute circulatory failure (shock, collapse). • Hypotension with systolic <90mmHg. • Hypovolaemia. • Aortic &/or mitral stenosis. • Cardiac tamponade. • Constrictive pericarditis. • Hypertrophic cardiomyopathy. • Toxic pulmonary oedema or primary pulmonary hypertension. • Known severe anaemia. • Recent (last 24 hours) use of Sildenafil, Tadalafil and Vardenafil. • Known closed-angle glaucoma. • Known severe renal or hepatic impairment. • Raised intracranial pressure due to cerebral haemorrhage or cerebral / head trauma. <p>Contraindications (exclusion criteria) are identified via verbal pre-examination checks with the patient.</p>
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • Pregnancy – Not known to be harmful but consider risk v benefit prior to administration. • Breast-feeding – Limited information – manufacturer advises avoid unless potential benefit outweighs risk. However, discuss with patient as it may be appropriate to suspend breast-feeding or expressing milk for a period after administration use e.g., if formula or previously expressed milk is available for the infant.

	<ul style="list-style-type: none"> • Tolerance to this drug and cross-tolerance to other nitrates may occur (see BNF for more information). • Should be used with caution in patients with cerebrovascular disease since symptoms may be precipitated by hypotension. • Hypoxaemia - may worsen hypoxaemia in patients with lung disease or cor pulmonale. • Special caution and close medical control is required in patients predisposed to postural hypotension. • This medicine should be administered carefully to patients with narrow angle glaucoma, or migraine. • Manufacturer advises caution in; hypothyroidism; malnutrition; hypothermia; recent myocardial infarction. • Alcohol should be avoided because of the hypotensive effect. <p>PLEASE NOTE:</p> <ul style="list-style-type: none"> • This medicine contains ethanol (alcohol). Its use may affect patient with liver disease, alcoholism, epilepsy, cerebral trauma and other CNS diseases, pregnancy and childhood. • This medicine contains propylene glycol and may cause skin irritation.
Action to be taken if the patient is excluded	<ul style="list-style-type: none"> • Discuss alternative imaging options with a Radiologist. Administration may still be indicated or alternative Imaging possible. • Record reasons for exclusion and Radiologist advice in the patient record (CRIS) • If the examination is no longer Justified, advise the referrer via a report and the patient of the need for alternative Imaging. Where alternative imaging is not appropriate, the referrer should tell the patient this, and what their management plan now is. <p>If identified when the patient has attended for their scan, advise the patient of the need for alternative Imaging and of any additional risks; or that Imaging cannot be performed.</p>
Action to be taken if the patient or carer declines treatment	<ul style="list-style-type: none"> • Discuss with a Radiologist or the referring clinical team. • Document advice given / arrangements made. <p>If the examination cannot proceed, mark the procedure as not done on CRIS and produce a report to inform the referring clinician that the procedure has not been performed, why and the advice given to the patient.</p>
Arrangements for referral for medical advice	<p>Medical advice should be sought from a Radiologist in the first instance.</p> <p>In the event of anaphylaxis/cardiac arrest, follow local medical emergency procedures (e.g., 2222 / 3333 / 999 procedures)</p> <p>Advice provided, including the need for the patient to discuss their ongoing care with the referrer is documented as a report; available as hardcopy, or on CRIS, PACS, Lorenzo, Meditech and other IT systems.</p>

5. Description of treatment

Name, strength & formulation of drug	Glyceryl Trinitrate 400 micrograms/metered dose, sublingual spray or Glyceryl Trinitrate 500 microgram sublingual tablet.
Legal category	P
Route / method of administration	Spray / place tablet under tongue and close mouth.
Indicate any off-label use (if relevant)	N/A
Dose and frequency of administration	<p>As per examination protocol,</p> <p>1 to 2 sprays (400-800 micrograms) to be administered under tongue and then close mouth.</p> <ul style="list-style-type: none"> • The canister should be held vertically with the spray head uppermost. • There is no need to shake the canister before dosing, but the pump may need to be primed when first used or if the product has not been used for a period of time. The priming actuation should be released into the air. <p>1 to 2 tablets (500 - 000 micrograms) to be place under the tongue.</p> <p>Dose may not be repeated without reference to a Radiologist.</p> <p>**Ensure patient is sitting / lying down before treatment is administered**</p>
Duration of treatment	Duration of the Imaging examination.
Quantity to be supplied (leave blank if PGD is administration ONLY)	N/A
Storage	<p>Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:</p> <ul style="list-style-type: none"> • Do not store above 25°C. Do not refrigerate or freeze. • Glyceryl Trinitrate Spray is an aerosol spray and contains a pressurised liquid. Do not expose to temperatures higher than 50°C. • Do not pierce the aluminium container (canister), even when empty. • It should not be sprayed at a naked flame or any incandescent material. <p>Further details are available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: Phosphodiesterase type 5 inhibitors (e.g., sildenafil, vardenafil and tadalafil) have been shown to potentiate the hypotensive effects

	<p>of nitrates - See Exclusions: Never co-administer within 24 hours.</p> <ul style="list-style-type: none"> • Treatment with other agents with hypotensive effects (Vasodilators, antihypertensives, β-blockers, calcium antagonists, neuroleptics, tricyclic antidepressants, and diuretics) can increase nitrate induced hypotension. • Alcohol can increase side effects. • N-acetylcysteine may potentiate the vasodilator effects of glyceryl trinitrate. • There is evidence that systemic nitrates may interfere with the anticoagulant effects of heparin. <p>A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk.</p>
Adverse reactions	<p>Common or very common: Arrhythmias; asthenia; cerebral ischaemia; dizziness; drowsiness; flushing; headache; hypotension; nausea; vomiting.</p> <p>Uncommon Circulatory collapse; diarrhoea; skin reactions; syncope; cyanosis; tongue blistering</p> <p>Rare or very Rarely: methaemoglobinaemia; respiratory disorder; restlessness</p> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk</p>
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • 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. • 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. • Patients who are exhibiting signs of anaphylaxis will be referred for medical assistance (call Resuscitation Team if at an acute hospital: QHB or RDH) and call 999 and request urgent medical assistance if in a community setting.
Written information to be given to patient or carer	<p>Patients and/or carers advised to:</p> <ul style="list-style-type: none"> • Monitor for adverse reactions. • Read the patient information leaflet covering risks / side-effects provided before giving consent (sensitively ensure patient is able to read and understand, if not then cover verbally) <p>Patients are provided with contact details during working hours and are advised what to do outside working hours in case of any adverse reaction.</p>

	<p>Any specific advice for a particular patient will be written down and given to the individual patient. This will also be documented in the healthcare record.</p>
Patient advice / follow up treatment	<p>The patient/carer will be provided with verbal advice on aftercare requirements following their procedure.</p> <p>Patients will be monitored for sensitivity reactions before leaving the department. IV access will be maintained for 10 minutes, and the Patient to be observed for 20 minutes, after contrast agent has been administered.</p> <p>Follow up appointments will usually be with the referrer. Imaging staff should ensure that the patient has details of their follow up appointment or has details of how to contact the referrer to make this appointment.</p>
Records	<p>Patient records may be written in the hospital notes, written and scanned or electronic (Lorenzo, Meditech, CRIS, etc.)</p> <p>Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following:</p> <ul style="list-style-type: none"> • 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 • That the medications used were administered via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password-controlled e-records).</p> <p>All records should be clear, legible, and contemporaneous.</p> <p>If you are not recording using an 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.</p>

6. Key references

Key references	<ul style="list-style-type: none"> • <i>Electronic Medicines Compendium</i> http://www.medicines.org.uk/ • <i>Electronic BNF</i> https://bnf.nice.org.uk/
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- *NICE Medicines practice guideline "Patient Group Directions"*
<https://www.nice.org.uk/guidance/mpg2>
<https://medusa.wales.nhs.uk>
- Imaging department workflow for examinations involving medications.
- Imaging scheme of work the supply of laxative or contrast agent to patients for preparation and self-administration at home.
- Imaging scheme of work the supply of contrast agent to inpatients for self-administration in the Imaging Department.
- Imaging scheme of work the supply of contrast agent to inpatients for self-administration on the ward.
- Imaging IV injections policy.
- Trust Clinical Guideline for the Prevention of Contrast Induced Kidney Injury.

7. Registered health professional authorisation sheet

PGD Name [version]: Imaging - GTN Tablets and Spray [v5.0] **PGD ref:** UHDB254

Valid from: 28/04/2023 **Expiry date:** 27/04/2026

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.