

PATIENT GROUP DIRECTION (PGD)

**Supply/Administration of Iodinated Contrast Media for Oral
Administration**
**By State Registered Non-medical staff in Imaging Facilities at all sites
where UHDB Imaging deliver services**

Documentation details

Reference no:	UHDB258
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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</p>

	<p>at their Appraisal at least once every 3 years. Managers and staff 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 examination. Administration must be according to the protocol / agreed scheme of work for the examination.
Criteria for inclusion	<ul style="list-style-type: none"> • Justified Imaging requests for examinations requiring opacification of the Gastrointestinal Tract or Faecal Tagging for Patients over 16 years of age presenting for the above type of examination. • Adult patients attending for Imaging examinations with contrast agent are provided with information about the risks and benefits of the examination including those relating to Iodinated contrast agents. Patients are given the opportunity to discuss the risks and benefits of the examination and must give verbal consent to proceed.
Criteria for exclusion	<ul style="list-style-type: none"> • Consent not gained. • Patients aged 16 years or under. • Patients who have experienced a previous significant reaction to iodinated contrast agent of any type. • Previous anaphylaxis from any cause. • Family history of anaphylactic reaction to Iodinated contrast agent. • Diabetes • Multiple allergies • Heart problems or high blood pressure • Pregnancy or Lactation • Severe Asthma • Kidney disease or impaired renal function (in addition to the clinical indications for the examination) <p>Undiluted gastrografin must not be administered in dehydrated patients or in patients with suspected possibility of aspiration or broncho-oesophageal fistula.</p> <p>Referrers should indicate a patient's impaired renal function as part</p>

	<p>of the referral, in accordance with the Trust Clinical Guideline on the Prevention of Contrast Induced Kidney Injury. Imaging staff conduct checks for contraindications (exclusion criteria) via verbal pre-examination checks with the patient. These are also undertaken as part of the telephone appointments process and /or as part of patient preparation prior to the scan.</p>
Cautions including any relevant action to be taken	<p>If the patient is receiving any concomitant medication or treatment, it is the responsibility of the person identified on the 'Professional Authorisation Sheet' to ensure that treatment with the drug detailed in this direction is appropriate.</p> <p>Pregnancy or lactation: Discuss with a Consultant Radiologist prior to administration. If breast-feeding, there needs to be consideration of the benefits of contrast agent use against the risks. Small amounts of contrast agent are excreted via milk and whilst safe for infants, some patients may choose to suspend breast feeding for 24 hours and use formula. In some cases, it may be appropriate for examinations to be delayed to allow patients to express sufficient breast milk to feed the child for 24 hours after contrast administration</p> <p>If in any doubt, advice should be sought and recorded before the drug is administered.</p>
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>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	<p>Iodinated contrast media:</p> <p>Typically: Gastrografin: 100mg/ml sodium amidotrizoate & 660 mg/ml meglumine amidotrizoate.</p> <p>Omnipaque: Iohexol.</p> <p>Other examples: Visipaque: Iodixanol. Xenetix: Iobitridol. Niopam: Iopamidol. Iomeron: Iomeprol.</p> <p>Please note: the brand name is followed by a number indicating the concentration of Iodine, e.g., Omnipaque 300 contains 300mg iodine/ml.</p>
Legal category	POM
Route / method of administration	Oral administration.
Indicate any off-label use (if relevant)	N/A
Dose and frequency of administration	<p>As per imaging protocol. Typically:</p> <ul style="list-style-type: none"> • Gastrografin (opacification of GIT): As Required. Usual Dose – 20ml in 880ml of water. • Gastrografin (faecal tagging): Usual Dose – 2 x 50ml • Omnipaque (or equivalent) : As Required Usual Dose – up to 100ml of Omnipaque 300 without reference to a Radiologist
Duration of treatment	Length of examination.
Quantity to be supplied (leave blank if PGD is administration ONLY)	<p>Please see departmental procedure for Supply of Oral Contrast Agents to Patients for Self Administration</p> <p>A maximum of 100ml of Gastrografin or Omnipaque (or alternatives) per patient.</p> <p>Must only be supplied for use in a Justified Imaging examination. Gastrografin must not be supplied to wards for use as a laxative.</p>
Storage	Stock must be securely stored according to UHDB medicines policy and manufacturer's instructions.
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines:

	<ul style="list-style-type: none"> In patients with cardiovascular disease, kidney disease or diabetes the following groups of drugs increase the risk of depressed renal function: <ul style="list-style-type: none"> Renin-angiotensin system blockers. (e.g., furosemide). Non-steroidal anti-inflammatory drugs (e.g., Ibuprofen). Diuretics Metformin. <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>Gastrografin has a significant laxative effect.</p> <p>Adverse reactions to Iodinated contrast agent via oral administration are rare. They may include: Nausea, vomiting, Diarrhoea and Abdominal pain, Allergy like reactions including anaphylaxis, Bradycardia or Tachycardia, Headache / Dizziness, Decreased Renal Function of, Oedema / Rash / Pruriti, Fluid or electrolyte imbalance, Hypertension, Hypotension, Bronchospasm, Dyspnoea, Hyperthyroidism</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.</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> <p>State 'administered under PGD' with name and signature of authorised registered Radiographer or Nurse.</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/• <i>NICE Medicines practice guideline "Patient Group Directions"</i> 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.
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7. Registered health professional authorisation sheet

PGD Name [version]: Imaging - Iodinated contrast (oral) [v5.0]
PGD ref: UHDB258

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.