University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration (intravenous) of non-ionic low osmolar iodinated contrast agent
By registered therapeutic radiographer in radiotherapy at Royal Derby Hospital

Documentation details

Reference no:	UHDB012
Version no:	2.0
Valid from:	15/08/2023
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Change history

Version number	Change details	Date
1.0	New PGD	19/01/2021
2.0	Review – Update to typographical error on iodine content only	31/07/2023

Glossary

Abbreviation	Definition

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
Sue Marriott	Radiotherapy Services Manager
James Hooley	Pharmacist, Clinical Governance & Medicines Safety
Prantik Das	Consultant Oncologist (ACD)
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
Not required	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
RDH is listed in the title, as the radiotherapy service is not being delivered on any other sites at the point of publication. If the service is extended to any other sites, the PGD Governance group is to be contacted to authorise via uhdb.pgdgovernance@nhs.net Minor amendments may be required at alternative sites in relation to medical contact or escalation.
Limitations to authorisation
None in addition to the framework described in the remainder of this document.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Chief Pharmacist or assigned deputies)*	**James Hooley**	**Signed copy held by Pharmacy**	**15/08/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from PGD working group*	Maja Moldawa	**Signed copy held by Pharmacy**	**31/07/2023**
ACD for Cancer Business Unit *Doctor*	Dr Vijayan	**Signed copy held by Pharmacy**	**03/08/2023**
Principal Pre-Treat Superintendent *Registered Professional representing users of the PGD*	Michelle Bradley	**Signed copy held by Pharmacy**	**03/08/2023**
n/a *CD Accountable Officer (CDs only)*	**n/a**	**n/a**	**n/a**

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	Radiotherapy staff Therapeutic radiographer with current HCPC registration
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) - Has undertaken appropriate training in the administration of intravenous iodinated contrast agents (e.g. Royal College affiliated training + UHDB IV Training & Workbook). - Has undertaken appropriate training to operate pump injectors, where applicable. - Current ANTT training. - Basic Life Support
Competency assessment	Completion of Electronic Training Record. State registered therapeutic radiographer with a current registration. 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 the 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 UHDB essential-to-role training for medicines management/safety. ANTT & BLS as per UHDB essential to role schedule
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	To be administered, intravenously, to patients as an inherent part of a justified Radiotherapy Planning CT scan. Administration must be according to the protocol / agreed scheme of work for the planning CT scan.
Criteria for inclusion Use BNF/BNFC/SPC. Take into account any clinical guidelines or policies that are available locally or nationally, e.g. BASHH/NICE/JCVI	• Patients over 16 years of age requiring a Radiotherapy planning CT scan to support the Radiotherapy planning process. • Patient has a Justified Radiotherapy request for planning CT scans requiring contrast enhancement
Criteria for exclusion	• Patients under 16 years of age • Patients who have experienced a previous significant reaction to iodinated contrast agent or to iodine • Manifest thyrotoxicosis
Cautions including any relevant action to be taken	Patients with cautions (identified via verbal pre-scan checks) may still be administered contrast depending on the severity. Any concerns should be clarified and documented with the referring Consultant Clinical Oncologist prior to contrast administration. • Severe asthma • Multiple allergies • Heart problems • Acute and chronic alcoholism or drug addiction • Patients with acute cerebral pathology, tumours or a history of epilepsy • Phaeochromocytoma • Myasthenia Gravis • Diabetes • Pregnancy or lactation: Discuss with a Consultant Clinical Oncologist prior to administration. • Kidney problems Renal Function: Clinicians must indicate if a patient is in a renal failure, and the degree of renal failure, on the Radiotherapy referral. (See Trust Prevention of Contrast Induced Acute Kidney Injury (AKI) CG-T/2011/104). The Radiotherapy Department pre-administration check includes kidney problems as a 'safety net' in case referrers have omitted this information. Seek advice from the Consultant Clinical Oncologist as appropriate
Action to be taken if the patient is excluded	• Record reasons for exclusion on CRIS (or medical notes) • Advise patient on alternative treatment • Document and inform patient on any advice from Consultant Clinical Oncologist if discussed
Action to be taken if the patient or carer declines treatment	• Document refusal and advice given on CRIS (or medical notes) • Advise patient on alternative treatment
Arrangements for referral	Contact a Consultant Clinical Oncologist / registrar if present in the

for medical advice	Radiotherapy department. If no Consultant Clinical Oncologist in the Radiotherapy Department: • Bleep 1296 / Ext. 83289 / 86104 for medical assistance • Contact Resus team using 2222 for a deteriorating patient

5. Description of treatment

Name, strength & formulation of drug	Non-ionic Low osmolar Contrast agent e.g. Omnipaque (Iohexol): *Omnipaque 300 (300mg iodine/ml)* *Omnipaque 350 (350mg iodine/ml)*
Legal category	POM
Route / method of administration	Intravenous
Indicate any off-label use (if relevant)	*n/a*
Dose and frequency of administration	Omnipaque 300: 50 – 100 ml of 300 mg/ml concentration (of Iodine), or equivalent; as set out in the Radiotherapy protocols Omnipaque 350: 50ml of 350 mg/ml concentration (of Iodine), or equivalent (as per radiotherapy protocols: CT 5.15.01 – Contrast Agents Used and Related Anatomical Sites)
Duration of treatment	Length of Radiotherapy planning CT scan.
Quantity to be supplied (leave blank if PGD is administration ONLY)	*n/a Administration only*
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Omnipaque should be stored at or below 30°C protected from light. Furthermore, the product in glass vials and bottles can be stored at 37°C for up to 3 months prior to use. The product in polypropylene bottles 40, 50, 75, 100, 150, 175, 200 and 500 ml volumes may be stored at 37°C for up to 1 month prior to use.
Drug interactions	Diabetics taking metformin – stop taking metformin for 48 hours after the IV administration of Iodinated contrast media. • Hypersensitivity reactions can be aggravated in patients on beta-blockers. • certain neuroleptics or tricyclic antidepressants can reduce • the seizure threshold • Previous treatment (up to several weeks) with Interleukin-2 is associated with an increased risk of delayed reactions to Gastrografin. • All iodinated contrast media may interfere with tests on thyroid function, thus the • Iodine binding capacity of the thyroid may be reduced for up to several weeks. • High concentrations of contrast media in serum and urine can

	interfere with laboratory tests for bilirubin, proteins or inorganic substances (e.g. iron, copper, calcium and phosphate). These substances should therefore not be assayed on the day of CT contrast. A detailed list of drug interactions is available in the SPC, which is available via the MHRA https://products.mhra.gov.uk/product/
Identification & management of adverse reactions	Common: • Feeling hot Uncommon: • Nausea & vomiting Rare: • Allergy like reactions including anaphylaxis • Bradycardia or Tachycardia • Headache / Dizziness • Decreased renal function • Oedema / Rash / Pruritis • Fluid or electrolyte imbalance Very rare: • Hypertension • Hypotension • Diarrhoea and abdominal pain • Bronchospasm / Dysponoea • Hyperthyroidism A detailed list of adverse reactions is available in the SPC, which is available via the MHRA https://products.mhra.gov.uk/product/
Management of and reporting procedure for adverse reactions	• The clinical area requires access to Oxygen, suction, emergency drugs (minimum, anaphylaxis box), telephone • 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 (or CRIS). • 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. • Seek immediate medical assistance in the event of serious adverse reactions, anaphylaxis or suspected anaphylactic symptoms.
Written information to be given to patient or carer	Written advice is provided in the patient Information leaflet given to the patient prior to the planning CT scan. Monitor for sensitivity reactions. IV access to be maintained for 15 minutes, and the Patient to be observed for 20 minutes (or 30minutes if high risk as per CT2.15.01), after contrast agent has been administered.
Patient advice / follow up treatment	Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of sensitivity reactions or adverse reaction of concern

Records	Details of the drug and staff involved in its administration should be recorded as set out in Radiotherapy protocols: - Documented contraindications check in Aria checklist. - A record of who supplied, prepared, checked and administered the drug. All required information will be documented in Aria, will include initials or signatures; and will also subsequently be recorded in CRIS Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/dpcument 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 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	• Summary of Product Characteristics https://mhraproducts4853.blob.core.windows.net/docs/e3102621a157d2bb8755813b10871888e4d33748 • Trust Prevention of Contrast Induced Acute Kidney Injury (AKI) CG-T/2011/104 https://derby.koha-ptfs.co.uk/cgi-bin/koha/opac-detail.pl?biblionumber=1057 • CT 2.15.01 - Working Arrangements for Contrast Media

7. Registered health professional authorisation sheet

PGD Name [version]: Administration (intravenous) of non-ionic low osmolar iodinated contrast agent by registered therapeutic radiographer in radiotherapy [v2.0]
PGD ref: UHDB012

Valid from: 15/08/2023 Expiry date: 14/08/2026

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.