

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

For the administration of Omnipaque 300 by Radiographers with current HCPC (Health and Care Professions Council) registration, Registered nurse with a current NMC (Nursing & Midwifery Council) registration.

For patients undergoing CT examinations, in the Imaging department, BSUH.

Version number: 3

Change history

Version number	Change details	Date
3	Transfer of old PGD onto NICE/BSUH template and review with PGD committee	Dec 2019
4		

PGD development

Name	Job title and organisation	Signature	Date
Lead author	Edward Hussey	Via email	31/3/21
Lead doctor	Joon Lee	Via email	31/3/21
Lead pharmacist	Joanne Pendlebury	Via email	31/3/21
Representative of other professional group using PGD	Jemma Deane, Lead Superintendent Radiographer	Via email	31/3/21

Organisational authorisations

Brighton & Sussex University Hospitals NHS Trust authorises this PGD for use by the services or providers listed below:
Imaging department, BSUH Sussex Cancer Centre Radiotherapy department, BSUH
Limitations to authorisation
Radiographers with current HCPC registration, Registered nurse with a current NMC only

Name	Signature & Name		Date
PGD GROUP	Joanne Pendlebury	Via email	31/3/21
Chief Pharmacist	Michael Cross	via email	May 2021
Medicines governance group chair	Michael Okorie	via email	May 2021

Local enquiries regarding the use of this PGD may be directed to Bsuh.pgdgroup@nhs.net or PGD group chair.

Appendix 2 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	<p>Radiographers with current HCPC registration and a minimum of 12 months post qualification clinical experience</p> <p>Registered nurse with a current NMC registration and a minimum of 12 months post qualification acute clinical experience</p>
Additional requirements	<p>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</p> <p>The individual practitioner is required to have a working knowledge of adverse reactions to the medication used with the PGD and how to identify drug interactions.</p>
Initial training	<p>Has undertaken appropriate IV administration training with relevant updates as required by the Brighton and Sussex University Hospitals NHS Trust IV policy and has been assessed as competent in the role.</p> <p>Has undertaken appropriate training for working under patient group directions for administration of contrast media and has been assessed as competent in the role by a consultant radiologist or the author of this PGD.</p> <p>For Radiotherapy, a band 7 pre-treatment radiographer can assess staff as competent under this PGD.</p> <p>Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions.</p> <p>Has undertaken appropriate training for working under patient group directions for administration of contrast media and has been assessed as competent in the role.</p> <p>Has undertaken appropriate Trust resuscitation training and anaphylaxis training</p>
Competency assessment	<p>PGD users will be responsible for collecting data and contributing to the audit of their practice.</p>
Continued training requirements	<p>Annual Trust resuscitation and anaphylaxis training update.</p> <p>PGD audit and training session at each renewal period.</p> <p>Complete NICE Competency PGD Framework</p> <p>PGD e-learning 3 yearly</p> <p>Up to date with mandatory training</p>

	Maintain knowledge and skills within specialist area
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Clinical condition

Clinical condition or situation to which this PGD applies	<p>Omnipaque 300 is a contrast agent used in CT examinations to investigate vascular anatomy and demonstrate pathology.</p> <p>Indications for a diagnostic CT examination include:</p> <ul style="list-style-type: none">- Renal obstruction- Trauma- Infection- Diagnosis or suspicion of primary or secondary cancer- Possible vascular abnormality- Brain perfusion- Exclusion of a bleed <p>Indications for a radiotherapy CT planning scan include:</p> <ul style="list-style-type: none">- Delineation of nodal groups requiring radiation therapy- Volumes of interest (VOIs) and Organs at risk (OAR) that need radiation therapy or avoidance of radiation therapy respectively.
Inclusion criteria	In-patient and out-patient adults, 17 years and over.
Exclusion criteria	<p>Patients 16 years of age and under.</p> <p>Patients with known sensitivity to iodine preparations and the excipients.</p> <p>Patients who have an eGFR of <30ml/min within the last month.</p> <p>Patients with any risk factors associated with renal disease and/or taking Metformin with an eGFR of 30-59ml/min within the last month must be managed in accordance with the departmental Policy for Managing Patients at risk of Contrast Induced Nephrotoxicity.</p> <p>Patients with asthma that is currently not well controlled (Royal College of Radiologists guidelines) i.e. patient states currently experiencing increased use of medication and is wheezy.</p> <p>Patients with infections around the injection site for IV cannulation and a VIP score of 1.</p> <p>Patients who are pregnant.</p> <p>Manifest thyrotoxicosis.</p>

Approved date: May 2021

Expiry date: May 2023

Cautions (including any relevant action to be taken)	<i>Please refer to the Imaging Department SOP for Management of Patients at Risk of Contrast Induced Nephrotoxicity – intravenous use.</i>
Arrangements for referral for medical advice	Refer to Radiologist overseeing examination. Refer to CCO in the radiotherapy setting.
Action to be taken if patient excluded	Refer to Radiologist overseeing examination. Refer to CCO in the radiotherapy setting.
Action to be taken if patient declines treatment	Refer to Radiologist overseeing examination. Refer to CCO in the radiotherapy setting.

Details of the medicine

Name, form and strength of medicine <i>Include ▼ for black triangle medicines</i>	Omnipaque 300 Injection solution containing 647mg Iohexol per ml (equivalent to 300mg iodine per ml). For more detailed information, please refer to SPC.
Legal category	<i>POM</i>
Indicate any off-label use (if relevant)	N/A
Route/method of administration	I.V. -manual injection or automatic injector
Dose and frequency	Details are listed under each protocol for each individual CT scanner in the appropriate protocol folder (also see Appendix 1). Usually once but can be up to 2 administrations during the examination, for timing scan and actual scan or for different phases of renal function on the same scan. One administration at the start of the examination for hand injections.
Quantity to be administered and/or supplied	Details are listed under each protocol for each individual CT scanner in the appropriate protocol folder (see Appendix 1).
Maximum or minimum treatment period	Up to 2 administrations during the examination, for a timing scan and for the main acquisition scan as per protocol. See Appendix 1 .
Adverse effects	<i>Please refer to the Imaging Department SOP for Management of Patients at Risk of Contrast Induced Nephrotoxicity – intravenous use.</i> <i>Special precautions for use of non-ionic monomeric contrast media in general:</i> <ul style="list-style-type: none"> • A positive history of allergy, asthma, or untoward reactions to

iodinated contrast media.

- Patients using β -blockers may present with atypical symptoms of anaphylaxis which may be interpreted as vagal reaction.
- Adequate hydration should be assured before and after contrast media administration.
- Patients with acute cerebral pathology, tumours or a history of epilepsy are predisposed for seizures and merit particular care. Also alcoholics and drug addicts have an increased risk for seizures and neurological reactions.
- Use of iodinated contrast media may cause contrast induced nephropathy, impairment of renal function or acute renal failure.
- The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis.
- Special care should be exercised in patients with hyperthyroidism. Patients with multinodular goitre may be at risk of developing hyperthyroidism following injection of iodinated contrast media.

In the case of extravasation, please refer to the departmental procedure.

A detailed list of adverse reactions is available in the SPC, which are available from the electronic Medicines Compendium website: www.medicines.org.uk.

BNF/C also has information on adverse effects.

Drug interactions	<p>A detailed list of drug interactions is available in the SPC (summary of product which are available from the electronic Medicines Compendium website: www.medicines.org.uk)</p> <p>BNF/C also has drug interaction information</p>
Supplies	Protocols for the ordering, storage and handling of medicines should be followed to prevent wastage
Storage	Protocols for the ordering, storage and handling of medicines should be followed
Reporting procedure of adverse reactions	<p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk</p> <p>For Black triangle any suspected adverse reactions should be reported via the Yellow Card Scheme.</p>
Special considerations / additional information	N/A
Records to be kept	<ul style="list-style-type: none"> - Patient's name, address, date of birth and hospital number. - Patient's checklist to include positive ID of patient and consent given, radiologist cover, emergency equipment available, precautions taken due to allergies, asthma, and if on metformin. - The site and size of cannula and whether eventful, or uneventful IV contrast bolus. - Contrast media used, dose, batch number and expiry date. - Saline flush. <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy OR the patients should be identifiable in a timely manner for audit purposes.</p>
Written/verbal information to be given to patient or carer	<p>Ensure written patient information has been given at time of appointment.</p> <p>Verbal explanation of common side effects as part of consent prior to procedure.</p> <p>Aftercare letters for the patient and information letters for the GP will also be given to those patients who have temporarily stopped taking metformin and/or had an eGFR of <30ml/min.</p> <p>Patient information leaflet (PIL) available:</p> <p>https://www.nhs.uk/medicines/</p>
Follow-up advice to be given to patient or carer	<p>Routine or emergency CT examinations will be reported by a radiologist and a copy of the report sent to the referring clinician.</p> <p>Patient instructed to arrange follow up with referring clinician at the time</p>

	<p>of examination.</p> <p>Patients are asked to remain in the department for 15 minutes post contrast injection and in the hospital environment for a further 15 minutes post injection. Patient must return to radiology if any symptoms develop.</p> <p>Any unwanted side effects following the appointment patient advised to report to GP.</p>
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Audit

Plan for audit , It is essential for PGD renewal that audits have occurred.	Retrospective audit of compliance with PGD to be completed.
Frequency	At each renewal period
Nominated lead to manage audit	Jemma Deane, Lead Superintendent Radiographer

Key references

Key references	<p>Omnipaque injection 300mg I/ml solution for injection, Summary of Product Characteristics, www.products.mhra.gov.uk</p> <p>Standards for intravascular contrast administration to adult patients, 3rd edition, Royal College of Radiologists, https://www.rcr.ac.uk/sites/default/files/Intravasc_contrast_web.pdf</p> <p>Management of Patients at Risk of Contrast Induced Nephrotoxicity – intravenous use, Imaging department BSUH, T: drive</p>
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Appendix 1

Omnipaque 300 doses for CT scans are variable dependent on the scan protocol and scanner manufacturer. Please refer to the following guidance on the dose differentials between protocols;

BSUH SCANNERS

Scan protocol	Dose
Bladder TCC follow up	Up to 100mls single bolus
Traumagram	140mls single bolus
Urogram	Up to 120mls (two administrations)
Chest and Neck Staging	Up to 90mls single bolus
Cardiac Coronary artery	Up to a total of 100mls
TAVI	Up to a total of 120mls
Grafts	Up to a total of 100mls
All other routine body and head scans	Up to 90mls single or double bolus

Appendix 2 Health professionals' agreement to practise

PGD Title

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 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 of health professional	Role	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Brighton & Sussex University Hospitals NHS Trust for the above named health care professionals who have signed the PGD to work under it.

Name	Role	Signature	Date