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 Dotarem® by Radiographers with current HCPC (Health and Care Professions Council) & Registered nurses with a current NMC (Nursing & Midwifery Council).

For MRI examinations to be undertaken on patients aged 17 years and older, in the Imaging department, BSUHT.

Version number: 3

Change history

Version number	Change details	Date
3	Existing PGD reviewed and transferred onto NICE/BSUH template	Dec 2019
	Reviewed and approved by PGD group	Dec 2019

PGD development

Name	Job title and organisation	Signature	Date
Lead author	Helen Lewis	Via email	Dec 2019
Lead doctor	Kyriakos Iliadis	Via email	Dec 2019
Lead pharmacist*	David Annandale	Via email	Dec 2019
Representative of other professional group using PGD	Jemma Deane, Lead Superintendent Radiographer	Via email	Dec 2019
*Review of Version 3			

Organisational authorisations

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

Name	Signature & Name	Date
PGD GROUP	Joanne Pendlebury	December 2019
Chief Pharmacist	Michael Cross	May 2020
Medicines Governance Group chair	Michael Okorie	May 2020

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	Radiographers with current HCPC registration and a minimum of 12 months post qualification clinical experience Registered nurse with a current NMC (Nursing & Midwifery Council) registration and a minimum of 12 months post qualification acute clinical experience
Additional requirements	**THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.** **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.**
Initial training	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. Has undertaken appropriate training for working under patient group directions for administration of Dotarem and has been assessed as competent in the role by a consultant radiologist or the author of this PGD. Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions. Has undertaken appropriate Trust resuscitation training.
Competency assessment	PGD users will be responsible for collecting data and contributing to the audit of their practice.
Continued training requirements	Annual Trust resuscitation and anaphylaxis training update. PGD audit and training session at each renewal period. Complete NICE Competency PGD Framework PGD e-learning 3 yearly Up to date with mandatory training Maintain knowledge and skills within specialist area

Clinical condition

Clinical condition or situation to which this PGD applies	Dotarem is a contrast agent used in the following applications; MRA for suspected narrowing/occlusion of major arteries or veins. Cranial and spinal MRI to delineate tumour, trauma, infection, inflammation or vascular abnormality Whole body MRI including the facial skull, neck, thoracic and abdominal cavities, breast, pelvis and musculoskeletal system to delineate tumour, infection, trauma, inflammation or vascular abnormality.
Inclusion criteria	Consenting adult patients aged 17 years and over (see separate PGD for paediatrics).
Exclusion criteria	Patients 16 years of age and under. MRI scan contraindicated if patient has MRI unsafe pacemaker or unsafe metalwork. Pregnancy. Hypersensitivity to any constituents of Dotarem, including gadoteric acid, meglumine, or any medicinal products containing gadolinium. Impaired renal function. If eGFR known to be less than 30ml/min/1.73m^2. Patients in peri-operative liver transplantation period.
Cautions (including any relevant action to be taken)	Patients treated with beta blockers. These medicinal products decrease the efficacy of the mechanisms of cardiovascular compensation for blood pressure disorders; the covering radiologist must be informed before injection of gadolinium and resuscitation equipment must be at hand. Breast-feeding mothers - a very small percentage of the injected dose enters the breast milk with poor absorption by the gut. The decision as to whether to continue or suspend breastfeeding for 24 hours after administration of Dotarem should be at the clinician's discretion, in consultation with the mother.
Arrangements for referral for medical advice	Refer to Radiologist overseeing examination
Action to be taken if patient excluded	Refer to Radiologist overseeing examination
Action to be taken if patient declines treatment	Refer to Radiologist overseeing examination

Details of the medicine

Name, form and strength of medicine *Include ▼for black triangle medicines*	Dotarem 279.32mg (0.5mmol) gadoteric acid per 1ml Available in glass vials of 5, 10, 15 and 20ml and also pre-filled syringes of 15 and 20ml.
Legal category	*POM*
Indicate any off-label use (if relevant)	N/A
Route/method of administration	I.V. -manual injection or automatic injector
Dose and frequency	0.2ml Dotarem / kg body weight See **Appendix 1** for further details
Quantity to be administered and/or supplied	0.2ml/kg body weight
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. 0.2ml/kg body weight see **Appendix 1**.
Adverse effects	Common adverse effects listed below: Transient sensations of warmth at injection site, or of pain. Nausea and vomiting and also dermal and mucosal reactions of allergic type have been observed. Inadvertent paravenous injection may cause pain lasting up to 20 minutes. In the case of extravasation 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	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 BNF/C also has drug interaction information
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	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 For Black triangle any suspected adverse reactions should be reported via the Yellow Card Scheme.
Special considerations / additional information	N/A
Records to be kept	Patient's name, address, date of birth and hospital number. Patient's cannulation checklist to include: Positive patient ID and consent given, radiologist cover, emergency equipment available, allergies, beta-blockers. Allergy and sensitivity status. Site and size of cannula and whether eventful or uneventful contrast bolus. Contrast media used, dose, batch number and expiry date. Sodium chloride 0.9% flush. Signature of person administering contrast. Signature of person checking the contrast medium. **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.**
Written/verbal information to be given to patient or carer	Ensure written patient information has been given at time of appointment. Verbal explanation of common side effects, as part of consent prior to procedure. Patient information leaflet (PIL) available: https://www.nhs.uk/medicines/
Follow-up advice to be given to patient or carer	Examinations will be reported by a Consultant Radiologist and a copy of the report sent to the referring clinician. Patient instructed at time of examination to follow up with referring

	clinician. Patient kept in department for 30 minutes post injection. Patient advised to monitor injection site to check for bleeding/signs of infection over next couple of days and to see GP if problems occur. Patient is told to contact the Imaging Department if there are any on-going medical concerns relating to the contrast injection for the following 24 hours. Any reactions at the time of the examination will be reported to, and given the appropriate treatment by, the radiologist overseeing the examination.

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	Dotarem 279.32 mg/ml solution for injection, Summary of Product Characteristics document, www.products.mhra.gov.uk 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 accessed April 2020

Appendix 1 Dotarem dosage

Dotarem doses for MRI scans are variable dependent on the scan protocol and the body part being imaged.

For manual injections the dose is 0.2mls per kilogram body weight up to 15mls, with the exception of cardiac MRI.

Cardiac MRI the minimum dose is 0.2mls per kilogram body weight, no maximum amount.

For automatic injector pump injections please see the table below**:**

Protocol	**Contrast dose**	**Flow rate (mls/s)**	**Saline (ml)**	**Timing/test/care bolus**
Renal MRA	Dose per body weight, max 20mls	3mls/s	25mls	Care bolus Test bolus
TWIST angio	8mls	2mls/s	25mls	Inject simultaneously as scan starts
Peripheral MRA	Total of 30mls 15mls @ 15mls @	 1ml/s 0.5ml/s	25mls	Care bolus
Thoracic MRA	Dose per body weight max of 20mls	3mls/s	25mls	Care bolus Test bolus
Carotid MRA	Dose per body weight max of 20mls	3mls/s	25mls	Care bolus Test bolus
Liver	Dose per body weight max of 20mls	3mls/s	25mls	Delay of 30s
Venogram	Dose per body weight max of 20mls	3mls/s	25mls	Care bolus Test bolus
Gynae pelvis	Dose per body weight max of 20mls	3mls/s	25mls	Delay of 60s
Small bowel	Dose per body weight max of 20mls	3mls/s	25mls	Delay of 30s
AML	Dose per body weight max of 20mls	3mls/s	25mls	Delay of 30s
Pancreas	Dose per body weight max of 20mls	3mls/s	25mls	Delay of 30s

Prostate	Dose per body weight max of 20mls	3mls/s	25mls	Inject after 1st measurement
Cardiac stress perfusion	Dose per body weight	3mls/s	25mls	Care bolus
Brain perfusion	10mls	2mls/s	20mls	Inject after 10th measurement
Thoracic inlet syndrome-subclavian angio	Dose per body weight	3mls/s	25mls	Care bolus Arms up and repeated with arms down

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