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 Doterem by Radiographers with current HCPC (Health and Care Professions Council) registration, Registered nurse with a current NMC (Nursing & Midwifery Council) registration.

For MRI examinations to be undertaken on patients between the ages of 2 – 16 years old, 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
3	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
Limitations to authorisation
Radiographers with HCPC registration and registered nurses with current NMC only

Name	Signature & Name	Date
PGD GROUP Chair	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 1 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 Doterem and has been assessed as competent in the role by a paediatric 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.

Clinical condition

Clinical condition or situation to which this PGD applies	Dotarem is a contrast agent used in the following applications: Magnetic Resonance Angiography (MRA) for suspected narrowing/occlusion of major arteries or veins. Cranial and spinal MRI to delineate tumour, trauma, infection 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 or vascular abnormality.
Inclusion criteria	In-patient and outpatient paediatric cases, age between 2 and 16 years, with full consent from parent or legal guardian, unless patient is deemed Gillick competent for consenting to medical procedures.
Exclusion criteria	Patients under the age of 2. MRI scan contraindicated if patient has MRI unsafe pacemaker or unsafe metalwork. Pregnancy. Hypersensitivity to any constituents of Dotarem. Patients treated with beta blockers with a pulse rate of below 50 per minute. If eGFR known to be less than 30ml/min/1.73m²
Cautions (including any relevant action to be taken)	Nil
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 for MRA)
Dose and frequency	0.2ml Dotarem / kg body weight, to a maximum dosage of 20ml. Dotarem doses for MRI scans are variable dependent on the scan protocol and the body part being imaged. One stat dose to be given during examination.
Quantity to be administered	0.2ml/kg body weight

and/or supplied	
Maximum or minimum treatment period	One stat dose during examination
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 X-ray Department if there are any on-going medical concerns relating to the contrast injection for the following 24 hours.

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

Appendix 1 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