Dear Colleague

This letter authorises the extended use of the following PGD until 1st February 2021:

**Patient Group Direction For The Administration Of Gadoteric Acid Dotarem® By Radiographers Working Within NHS Grampian, Version 1.1**

The review of this PGD is currently underway in collaboration with NHS Highland and NHS Western Isles using the Specialist Pharmacy Service and Royal College of Radiographers national PGD templates. This letter provides permission to continue using the PGD to a new expiry date of 1st February 2021, and should be kept with the PGD records and brought to the attention of the individual radiographers who operate under the PGD currently.

If you have any queries regarding this please do not hesitate to contact the Pharmacy and Medicines Directorate.

Yours sincerely

Lesley Coyle  
Chair Medicines Guidelines and Policies Group
Patient Group Direction For The Administration Of Gadoteric Acid Dotarem® By Radiographers Working Within NHS Grampian

<table>
<thead>
<tr>
<th>Lead Author:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant Radiologist</td>
<td>See relevant page in the PGD</td>
<td>Medicine Guidelines and Policies Group</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature:</th>
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<table>
<thead>
<tr>
<th>Identifier:</th>
<th>Review Date:</th>
<th>Date Approved:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHSG/PGD/Radio Dotarem/MGPG882</td>
<td>June 2019</td>
<td>June 2017</td>
</tr>
</tbody>
</table>

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 1.1 (Amended March 2020)
### Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2017</td>
<td>N/A</td>
<td>Gadoteric acid added in title.</td>
<td>Title/Throughout</td>
</tr>
<tr>
<td>June 2017</td>
<td>N/A</td>
<td>MRI written out in full.</td>
<td>Definition of situation/condition</td>
</tr>
<tr>
<td>June 2017</td>
<td>N/A</td>
<td>Patients who have had a blood test to confirm eGFR value within 3 weeks prior to the date of scan added</td>
<td>Inclusion criteria</td>
</tr>
<tr>
<td>June 2017</td>
<td>N/A</td>
<td>Anaphylactic removed from first bullet point and Dotarem® added.</td>
<td>Exclusion criteria</td>
</tr>
<tr>
<td>June 2017</td>
<td>N/A</td>
<td>Additional precautions added.</td>
<td>Precautions and special warnings</td>
</tr>
<tr>
<td>June 2017</td>
<td>N/A</td>
<td>Concomitant medications to be taken into account added.</td>
<td>Concurrent Medications/Drug Interactions</td>
</tr>
<tr>
<td>June 2017</td>
<td>N/A</td>
<td>Skin reactions such as erythematous rash added.</td>
<td>Identifying and managing possible adverse reactions</td>
</tr>
<tr>
<td>August 2017</td>
<td>N/A</td>
<td>Inclusion age changed to 18 years.</td>
<td>Inclusion Criteria</td>
</tr>
<tr>
<td>March 2020</td>
<td>N/A</td>
<td>Age for inclusion removed as product is licensed for use in all ages.</td>
<td>Inclusion criteria/Exclusion criteria</td>
</tr>
<tr>
<td>March 2020</td>
<td>N/A</td>
<td>Statement changed to remove specific cancers. Replaced with a generic statement regarding soft tissue structures.</td>
<td>Definition of situation/condition</td>
</tr>
<tr>
<td>March 2020</td>
<td>N/A</td>
<td>Breastfeeding removed from exclusions.</td>
<td>Exclusion criteria</td>
</tr>
<tr>
<td>March 2020</td>
<td>N/A</td>
<td>Corporate communications box removed as PGD does not require to be impact assessed.</td>
<td>Page i</td>
</tr>
<tr>
<td>March 2020</td>
<td>N/A</td>
<td>Single dose changed to ‘dependant on clinical requirement’.</td>
<td>Quantity to be administered</td>
</tr>
<tr>
<td>March 2020</td>
<td>N/A</td>
<td>Section updated in-line with updated NHSG records standards.</td>
<td>Record of administration</td>
</tr>
<tr>
<td>March 2020</td>
<td>N/A</td>
<td>Maximum total dose changed to 30mLs.</td>
<td>Dosage/Total dosage</td>
</tr>
</tbody>
</table>

**Subject:** Patient Group Direction  
**Identifier:** NHSG/PGD/Radio_Dotarem/MGPG882 Version 1.1  
**Replaces:** NHSG/PGD/Radio_Dotarem/MGPG882 Version 1  
**Keyword(s):** PGD Patient Group Direction dotarem radiographers
**Policy Statement:** It is the responsibility of individual radiographer and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

**Review date:** The review date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.

**Document:**
- **Drafted:** May 2017
- **Completed:** June 2017
- **Approved:** June 2017 (September 2017)
- **Amended:** March 2020
Patient Group Direction for the Administration of Gadoteric Acid Dotarem® by Radiographers Working Within NHS Grampian

Clinical indication to which this PGD applies

| Definition of situation/condition | This Patient Group Direction (PGD) will authorise Radiographers to administer Gadoteric Acid Dotarem® for imaging procedures within the Radiology/Radiotherapy Department(s) to allow the visualisation of soft tissue structures in individuals undergoing an MRI scan.  

**N.B.** The Radiographer acting under this PGD must have evidence of a valid referral which has been authorised by an entitled Radiologist/Clinical Oncologist/Cardiologist or appropriately qualified Radiographer and which details contrast agent to be administered.  

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and individual Summary of Product Characteristics (SPC). |
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Inclusion criteria</td>
<td>• Patients who have had a blood test to confirm eGFR value within 3 months prior to the date of scan.</td>
</tr>
</tbody>
</table>
| Exclusion criteria | Patients may be administered Dotarem® MR contrast agents under this PGD unless:  
• They have known hypersensitivity to Dotarem® or any of the excipients.  
• They have not had a blood test to confirm eGFR within 3 months prior to scan date.  
• eGFR <30mLs/min, within 3 months prior to scan.  
• They are pregnant.  
• They are in the perioperative liver transplant period.  
• They have severe/unstable asthma.  
• The usual safety requirements for magnetic resonance imaging, especially the exclusion of ferromagnetic materials, also apply when using Dotarem®. |
### Precautions and special warnings
The risk of hypersensitivity reactions may be higher in case of:
- previous reaction to contrast media
- history of bronchial asthma
- history of allergic disorders

Dotarem® must not be administered by subarachnoid (or epidural) injections.

### Referral criteria
Patients who fall into the categories detailed in the exclusion criteria.

### Action if excluded from treatment
Medical advice should be sought - Consultant Radiologist to decide if examination should include administration of Dotarem®. If appropriate Dotarem® will be prescribed by the Consultant Radiologist.

The reason why the patient was excluded under the PGD will be documented on the Radiology Information System (RIS).

### Action if patient declines treatment
Patient should be advised of the risks and consequences of not receiving Dotarem® and the examination should proceed if practicable.

Record outcome in RIS and assign non-contrast examination to in house consultant radiologist.

### Consent
Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.


### Description of treatment available under the PGD

<table>
<thead>
<tr>
<th>Name of medicine</th>
<th>Dotarem® (Gadoteric acid)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal status</td>
<td>Dotarem® is a Prescription-only Medicine (PoM).</td>
</tr>
<tr>
<td>Form/Strength</td>
<td>Dotarem® (Gadoteric acid) 0.5mmol/mL solution for injection.</td>
</tr>
<tr>
<td><strong>Route/Method of administration</strong></td>
<td>Intravenous injection by hand or by pump according to local protocol.</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>---------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Dosage/Total Dose</strong></td>
<td>0.2mL/kg.</td>
</tr>
<tr>
<td><strong>Maximum total dose allowed under this PGD is 30mL.</strong></td>
<td><strong>Dependent on clinical requirement.</strong></td>
</tr>
<tr>
<td><strong>Duration of treatment</strong></td>
<td><strong>Stored in a locked cupboard.</strong></td>
</tr>
<tr>
<td><strong>Storage requirements</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Follow-up (if applicable)</strong></td>
<td>The patient should remain in the hospital environment (but not necessarily the radiology department) for 15 minutes from the last injection and should return to the radiology department if any symptoms develop.</td>
</tr>
<tr>
<td><strong>Advice to patient (Verbal)</strong></td>
<td>Advice should be given on what to expect and what to do for major and minor reactions.</td>
</tr>
<tr>
<td></td>
<td>Advise to seek medical help if any persistent or serious adverse effects are experienced.</td>
</tr>
<tr>
<td><strong>Advice to patient (Written)</strong></td>
<td>The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</td>
</tr>
<tr>
<td></td>
<td>Copies of PIL and SPCs for all medicines can be found at <a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a> or <a href="http://www.mhra.gov.uk/spc-pil/index.htm">http://www.mhra.gov.uk/spc-pil/index.htm</a></td>
</tr>
<tr>
<td><strong>Concurrent Medications/Drug Interactions</strong></td>
<td>Concomitant medications to be taken into accountBeta-blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists: these medicinal products decrease the efficacy of the mechanisms of cardiovascular compensation for blood pressure disorders: the radiologist must be informed before injection of gadolinium complexes, and resuscitation equipment must be at hand.</td>
</tr>
</tbody>
</table>
Identifying and managing possible adverse reactions

Common side effects from Dotarem® are nausea, vomiting, paraesthesia, headache and skin reactions such as erythematous rash.

Occasional non allergic manifestations: dizziness, seizure.

Anaphylactoid/hypersensitivity reactions manifesting as pruritus, urticarial, bronchospasm, laryngeal oedema, pulmonary oedema.

This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SPC for details of all potential adverse reactions.

BNF:
https://www.medicinescomplete.com/mc/bnf/current/

SPCs/PILs:
https://www.medicines.org.uk/emc/
http://www.mhra.gov.uk/spc-pil/index.htm

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System.
https://yellowcard.mhra.gov.uk/

Medical advice in cases of anaphylaxis

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals)

Facilities and supplies required

The following should be available at sites where the medication is to be administered:

- Appropriate storage facilities.
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- Access to medical support (this may be via the telephone).
- Approved equipment for the disposal of used materials.
- Clean and tidy work areas, including access to hand washing facilities.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals working within NHS Grampian.

**Characteristics of staff authorised to administer medicine under PGD**

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Radiographers as recognised by the Health and Care Professions Council (HCPC).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist competencies</td>
<td>MR Radiographers who have been trained in intravenous drug administration, cannulation and assessed as competent to evaluate the suitability of the patient for administration of Dotarem®.</td>
</tr>
<tr>
<td></td>
<td>Be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.</td>
</tr>
<tr>
<td></td>
<td>Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.</td>
</tr>
<tr>
<td></td>
<td>Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.</td>
</tr>
<tr>
<td></td>
<td>Is competent in the administration of the drug.</td>
</tr>
<tr>
<td>Ongoing training and competency</td>
<td>Have attended basic life support training which is required to be updated annually.</td>
</tr>
<tr>
<td></td>
<td>Have undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning® tool.</td>
</tr>
</tbody>
</table>
Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.

The practitioner must be familiar with the summary of product characteristics (SPC) for all medicines supplied in accordance with this PGD.

<table>
<thead>
<tr>
<th>Professional managers/Lead Radiographers will be responsible for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensuring that the current PGD is available to staff providing care under this direction.</td>
</tr>
<tr>
<td>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</td>
</tr>
<tr>
<td>Maintain up to date record of all staff authorised to administer drug specified in PGD.</td>
</tr>
</tbody>
</table>

**Documentation**

**Authorisation of administration**

Radiographers working within NHS Grampian MRI departments can be authorised to administer the drug specified in this PGD by their MR Consultant.

All authorised staff are required to read the PGD and sign the Agreement to administer Medicines under PGD (**Appendix 1**).

A certificate of authorisation (**Appendix 2**) signed by the authorising doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally.

**Record of administration/supply**

The Radiology Information system (RIS) must be used for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

- Date and time of administration
- Individuals name and CHI
- Exclusion criteria, record why the medicine was not administered (if applicable)
- Record that valid consent to treatment under this PGD was obtained
- The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered/supplied
Advice given, including advice given if excluded or declined treatment under this PGD

Signature and name in capital letters of the healthcare professional who administered the medicine

Record of any adverse effects (advise individuals GP/relevant medical practitioner).

Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:

- Consent forms
- Secondary Care Medical Notes
- Individual service specific systems.

Audit

All records of the drug specified in this PGD will be filed with the normal records of medicines in radiology. A designated person within each H&SCP/practice/service will be responsible for auditing completion of drug records and collation of data.

References


Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction

Name:               Title:

Mrs Frances Adamson  Medicines Management Specialist Nurse
Dr Senthil Ragupathy  Medical Practitioner: Consultant Radiologist
Dr Shona Olson        Lead Author: Consultant Radiologist
Mr Sandy Thomson      Pharmacist: Principal Pharmacist and Lead H&SCP pharmacist Moray
Miss Rachel Watt      Superintendent Radiographer
Authorising Managers

Dr Nick Fluck  
Medical Director, NHS Grampian

Mr David Pfleger  
Director of Pharmacy and Medicines Management, NHS Grampian

Professor Amanda Croft  
Director of Nursing, Midwifery and AHPs, NHS Grampian
Appendix 1

Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I: ________________________________ (Insert name)

Working within: ________________________________ e.g. H&SCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

**Patient Group Direction For The Administration Of Gadoteric Acid Dotarem® By Radiographers Working Within NHS Grampian**

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: ________________________________

Print Name: ________________________________

Date: ________________________________

Professional Registration No: ________________________________
Appendix 2

Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: ____________________________

Working within: ____________________________ e.g. H&SCP, Practice

To administer medicines under the following Patient Group Direction

Patient Group Direction For The Administration Of Gadoteric Acid Dotarem® By Radiographers Working Within NHS Grampian

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction

Signed: _________________________________ Authorising Manager/Doctor

Print Name: ______________________________

Date: _________________________________