

**Patient Group Direction for the Administration of Medicines Included  
 in the Radiographers Contrast Agent PGD Formulary by  
 Radiographers Working Within NHS Grampian, Highland, Orkney,  
 Shetland and Western Isles**

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| <b>Lead Author:</b><br>Medicines Management<br>Specialist Nurse NHSG | <b>Consultation Group:</b><br>See relevant page in the<br>PGD | <b>Approver:</b><br>NoS PGD Group<br><br><b>Authorisation:</b><br>NHS Grampian |
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| <b>Signature:</b><br> |  | <b>Signature:</b><br> |
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| <b>NoS Identifier:</b><br>NoS/PGD/<br>Rad_Contrast/MGPG1173 | <b>Review Date:</b><br>June 2023<br><br><b>Expiry Date:</b><br>June 2024 | <b>Date Approved:</b><br>June 2021 |
|---|--|------------------------------------|

NHS Grampian, Highland, Orkney, Shetland and Western Isles have authorised  
 this Patient Group Direction to help individuals by providing them with more  
 convenient access to an efficient and clearly defined service within the NHS  
 Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are  
 completed.

**Uncontrolled when printed**  
  
**Version 1.1 (Amended July 2023)**

## Revision History:

|   |   |                        |
|---|---|------------------------|
| <b>Reference and approval date of PGD that has been adapted and/or superseded</b> | New PGD Adapted from the following NHSG PGDs:<br>NHSG/PGD/Radio_Dotarem/MGPG882,<br>NHSG/PGD/Radio_Gadovist/MGPG883,<br>NHSG/PGD/GIExam/MGPG964 (Iohexol (Omnipaque®) only)<br>NHSG/PGD/ContrastMedia/MGPG889<br><br>Adapted from the following NHH PGDs:<br>MultiHance® - 16_03_v5<br>Gadovist® 16_05_v5 |                        |
| <b>Date of change</b>   | <b>Summary of Changes</b>   | <b>Section heading</b> |
| September 2019  | New NoS PGD formulary created for use by radiographers in NHSG, NHH, NHSS and NHSWI.  |                        |
| July 2023   | NHS Orkney added.   | Throughout PGD         |
| July 2023   | Expiry date added to front cover.   | Front cover            |

**NoS Identifier:**

NoS/PGD/Radio\_Contrast/MGPG1173

**Keyword(s):**

PGD Patient Group Direction contrast agent radiographer

**Policy Statement:** It is the responsibility of the individual healthcare professionals 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 individual, 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 safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

|           |            |                                     |
|-----------|------------|-------------------------------------|
| Document: | Drafted:   | September 2019                      |
|           | Completed: | May 2021                            |
|           | Approved:  | June 2021 (published – August 2021) |
|           | Amended:   | July 2023                           |


## Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.


PGD Developed/Reviewed by;

|   |  |
|---|--|
| <p><b>Medical practitioner</b></p>  | <p><b>Name:</b> Dr Dympna McAteer<br/> <b>Health Board:</b> NHSG<br/> <b>Title:</b> Consultant Radiologist<br/> <b>Contact email:</b> <a href="mailto:dympna.mcateer@nhs.scot">dympna.mcateer@nhs.scot</a><br/> <b>Signature:</b> .....  .....</p>                   |
| <p><b>Senior representative of the professional group who will provide care under the direction</b></p> | <p><b>Name:</b> Adam Scotson<br/> <b>Health Board:</b> NHSH<br/> <b>Title:</b> MRI Team Leader<br/> <b>Contact email:</b> <a href="mailto:adam.scotston@nhs.scot">adam.scotston@nhs.scot</a><br/> <b>Signature:</b> .....  .....</p>                                |
| <p><b>Lead author</b></p>   | <p><b>Name:</b> Frances Adamson<br/> <b>Health Board:</b> NHSG<br/> <b>Title :</b> Medicines Management Specialist Nurse<br/> <b>Contact email:</b> <a href="mailto:frances.adamson@nhs.scot">frances.adamson@nhs.scot</a><br/> <b>Signature:</b> .....  .....</p> |
| <p><b>Pharmacist</b></p>  | <p><b>Name:</b> Kim Cruttenden<br/> <b>Health Board:</b> NHSG<br/> <b>Title :</b> Principal Pharmacist Acute Sector<br/> <b>Contact email:</b> <a href="mailto:kim.crutenden3@nhs.scot">kim.crutenden3@nhs.scot</a><br/> <b>Signature:</b> .....  .....</p>        |

**Approved for use within NoS Boards by;**

| North of Scotland (NoS) PGD Group Chair | Signature   | Date Signed |
|---|---|-------------|
| Lesley Coyle                            |  | 24/08/21    |

**Authorised and executively signed for use within NoS Boards by;**

| NHS Grampian Chief Executive | Signature  | Date Signed |
|------------------------------|--|-------------|
| Professor Caroline Hiscox    |  | 25/08/21    |

**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.

| <b>Name:</b>      | <b>Title:</b>  |
|-------------------|--|
| Frances Adamson   | <b>Lead Author:</b> Medicines Management Specialist Nurse NHSG |
| Kim Cruttenden    | <b>Pharmacist:</b> Principal Pharmacist Acute Sector NHSG      |
| Dr Dympna McAteer | <b>Medical Practitioner:</b> Consultant Radiologist NHSG       |
| Adam Scotson      | <b>Senior Representative:</b> MRI Team Leader NESH             |
| Laura Farquharson | Superintendent MRI Radiographer NHSG                           |
| Lorna Main        | Superintendent CT Radiographer                                 |
| Lauren Gault      | Specialist Radiographer NHSG                                   |
| Jane MacDonald    | Radiographer NHSWI   |
| Nicola Fox        | Radiographer NESH  |

**Patient Group Direction for the Administration of Medicines Included in the Radiographers Contrast Agent PGD Formulary by Radiographers Working Within NHS Grampian, Highland, Orkney, Shetland and Western Isles**

**Clinical indication to which this PGD applies**

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| <p><b>Definition of situation/ Condition</b></p> | <p>This Patient Group Direction (PGD) will authorise radiographers to administer medications as included in the Radiographers Contrast PGD Formulary (<a href="#">Appendix 3</a>) to individuals attending radiology departments for investigation or treatment.</p> <p>This PGD should be used in conjunction with the individual Board protocols and the recommendations in the current <a href="#">British National Formulary (BNF)</a>, <a href="#">British National Formulary for Children (BNFC)</a>, and the <a href="#">individual Summary of Product Characteristics (SmPC)</a>.</p>   |
| <p><b>Inclusion criteria</b></p>                 | <ul style="list-style-type: none"> <li>• Individuals aged 16 years and over attending radiology departments for investigation or treatment (<b>NHS Highland ONLY</b>).</li> <li>• Individuals attending radiology departments for investigation or treatment.</li> </ul> <p><b>NOTE:</b> For specific age inclusion criteria see individual monographs.</p> <ul style="list-style-type: none"> <li>• The Radiographer acting under this PGD must have evidence of a valid referral which has been authorised by an entitled Radiologist/Clinical Oncologist or appropriately qualified Radiographer and which details contrast agent to be administered.</li> <li>• Individual must have completed a pre-examination checklist relevant to the imaging procedure being undertaken.</li> </ul> <p><b>NOTE:</b> To be treated under this PGD with any iodine or gadolinium based contrast media an eGFR should be obtained only in individuals with known kidney disease when renal function has not been recorded within the past 6 months, or if recorded renal function was &lt;30mL/min/1.73m<sup>2</sup>.</p> <p>Where individual Boards use approved eGFR questionnaires there is no need to obtain an eGFR. However, If an individual has been acutely unwell or known to have renal impairment, eGFR should have been obtained within past 7 days before the administration of contrast agent.</p> <p>See individual medicine monographs for specific inclusions and follow local individual Board protocols.</p> |

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|  | <p>Prior to the administration of the medicine, valid consent to receive treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.</p>   |
| <b>Exclusion criteria</b>                | <ul style="list-style-type: none"> <li>• Individuals aged less than 16 years of age (<b>NHSH ONLY</b>)</li> <li>• For specific age exclusion criteria see individual monographs</li> <li>• Where there is no valid consent.</li> </ul> <p><b>NOTE:</b> See individual medicine monographs for specific exclusions.</p>   |
| <b>Precautions and special warnings</b>  | <ul style="list-style-type: none"> <li>• If there is any concern about the appropriate use of the medicine in the specific indications given within the PGD then medical advice should be sought.</li> <li>• Precautions listed in the individual monographs should be taken into account.</li> <li>• The individual should be questioned to ensure they have no known allergies and the Radiology Information System (RIS) should be checked for any previous reaction to contrast agent.</li> </ul> <p>See individual medicine monographs for specific precautions and warnings.</p> |
| <b>Action if excluded from treatment</b> | <p>Medical advice must be sought – refer to radiologist or relevant medical practitioner.</p> <p>Document the reason for exclusion under the PGD and any action taken in the individual’s appropriate clinical records.</p>  |
| <b>Action if treatment is declined</b>   | <p>Inform/refer to the relevant medical practitioner if individual declines treatment.</p> <p>Document that the administration or supply was declined, the reason and advice given in appropriate clinical records.</p>  |

### Description of treatment available under the PGD

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| <b>Name form and strength of medicine</b> | See individual medicine monographs.  |
| <b>Legal status</b>                       | The medicines included in this PGD are either Pharmacy (P) medicines or Prescription-only Medicines (POM). |

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| <b>Dosage/Maximum total dose</b>                           | See individual medicine monographs.  |
| <b>Frequency of dose/Duration of treatment</b>             | See individual medicine monographs.  |
| <b>Maximum or minimum treatment period</b>                 | See individual medicine monographs.  |
| <b>Route/Method of administration</b>                      | See individual medicine monographs.  |
| <b>Quantity to be administered</b>                         | See individual medicine monographs.  |
| <b>Storage requirements</b>                                | See individual medicine monographs.  |
| <b>Follow-up (if applicable)</b>                           | Individuals should not leave if they are feeling unwell without speaking to the radiographer who administered the medicine first. If necessary a radiologist should be contacted if the individual continues to feel unwell following the administration of a contrast agent.  |
| <b>Advice (Verbal)</b>                                     | Advise individual what to expect and what to do for minor and major reactions.<br><br>If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24.  |
| <b>Advice (Written)</b>                                    | The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.  |
| <b>Identifying and managing possible adverse reactions</b> | There should be a system in place to call an appropriately trained clinician who can deal immediately with a severe contrast agent reaction in the MR / CT environment. If required the crash or resuscitation team should be called immediately (link to organisation protocol/s as relevant).<br><br>Extravasation may be associated with large volumes of contrast agent, high-pressure injection and fragile or damaged veins. Although most injuries caused by extravasation are minor, severe injuries may include skin ulceration, soft tissue necrosis and compartment syndrome. Should there be any |

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|  | <p>concerns about extravasation consult a medical practitioner immediately.</p> <p>See individual medicine monographs.</p> <p><b>This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.</b></p> <p><b>BNF/BNFC:</b><br/> <a href="#">BNF British National Formulary - NICE</a><br/> <a href="#">BNF for Children British National Formulary - NICE</a></p> <p><b>SmPC/PIL/Risk Minimisation Material:</b><br/> <a href="#">Home - electronic medicines compendium (emc)</a><br/> <a href="#">MHRA Products   Home</a><br/> <a href="#">RMM Directory - medicines starting with A - (emc)</a></p> <p>If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.</p> <p>Report any severe reactions using the Yellow Card System.<br/> <a href="#">Yellow Card Scheme - MHRA</a></p>              |
| <p><b>Facilities and supplies required</b></p> | <p>The following are to be available at sites where the medicine is to be administered:</p> <ul style="list-style-type: none"> <li>• Appropriate storage facilities</li> <li>• An acceptable level of privacy to respect individual’s right to confidentiality and safety</li> <li>• Basic airway resuscitation equipment (e.g. pocket mask, bag valve mask, supraglottic airway)</li> <li>• Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection</li> <li>• Access to a working telephone</li> <li>• Another competent adult, who can summon urgent emergency support if required should ideally be present</li> <li>• Access to medical support (this may be via the telephone)</li> <li>• Approved equipment for the disposal of used materials</li> <li>• Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel</li> <li>• A copy of this current PGD in print or electronically</li> </ul> |

**Characteristics of staff authorised to administer medicine(s) under PGD**

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| <p><b>Professional qualifications</b></p> | <p>Radiographers registered with the Health and Care Professions Council (HCPC).</p> |
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| <p><b>Specialist competencies</b></p>                     | <p><b>Approved by the organisation as:</b></p> <ul style="list-style-type: none"> <li>• Competent to assess the individual capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent</li> <li>• Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual</li> <li>• Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD.</li> <li>• Competent to undertake administration of the medicine</li> <li>• Competent to work under this PGD.</li> </ul>  |
| <p><b>Ongoing training and competency</b></p>             | <p><b>All professionals working under this PGD must:</b></p> <ul style="list-style-type: none"> <li>• Have undertaken PGD training as required/set out by each individual Health Board</li> <li>• Have attended basic life support training either face to face or online and updated in-line with individual Board requirements</li> <li>• Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with individual Board requirements</li> <li>• Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct</li> <li>• Have knowledge and familiarity of the following;             <ul style="list-style-type: none"> <li>○ <a href="#">SmPC</a> for the medicine(s) to be administered in accordance with this PGD.</li> </ul> </li> </ul> |
| <p><b>Responsibilities of professional manager(s)</b></p> | <p><b>Professional manager(s) will be responsible for;</b></p> <p>Ensuring that the current PGD is available to all staff providing care under this direction.</p> <p>Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.</p> <p>Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.</p>   |

**Documentation**

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| <p><b>Authorisation of administration</b></p> | <p>Radiographers working within NHS Grampian, Highland, Shetland and Western Isles can be authorised to administer the medicine(s) specified in this PGD by their Unit Clinical Director or Consultant Radiologist.</p> |
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|  | <p>All authorised staff are required to read the PGD and sign the Agreement to Supply and/or Administer Medicines Under PGD (<a href="#">Appendix 1</a>).</p> <p>A Certificate of Authorisation (<a href="#">Appendix 2</a>) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.</p>   |
| <p><b>Record of administration</b></p> | <p>An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:</p> <ul style="list-style-type: none"> <li>• Date and time of administration</li> <li>• Individuals name and CHI</li> <li>• Exclusion criteria, record why the medicine was not administered (if applicable)</li> <li>• Record that valid consent to treatment under this PGD was obtained</li> <li>• The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered/supplied</li> <li>• Advice given, including advice given if excluded or declined treatment under this PGD</li> <li>• Signature and name in capital letters of the healthcare professional who administered the medicine</li> <li>• Record of any adverse effects (advise individuals GP/relevant medical practitioner).</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• Secondary Care Medical Notes</li> <li>• Individual radiology specific systems.</li> </ul> |
| <p><b>Audit</b></p>                    | <p>All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.</p>  |

| References   | Electronic Medicines Compendium<br><a href="http://www.medicines.org.uk">http://www.medicines.org.uk</a>                                 |                         |                      |
|--|--|-------------------------|----------------------|
|  | <b>Medicine</b>  | <b>Date of Revision</b> | <b>Date Accessed</b> |
|  | Gadovist® 1.0 mmol/mL solution for injection   | 02/08/20                | 05/04/21             |
|  | Iomeron® 400, solution for injection   | 31/05/19                | 05/04/21             |
|  | MultiHance® 0.5 M solution for injection   | July 2019               | 05/04/21             |
|  | Primovist® 0.25 mmol/mL, solution for injection  | 02/10/19                | 05/04/21             |
|  | ProHance® 279.3 mg/mL solution for injection syringe   | 05/02/20                | 05/04/21             |
|  | Medicines and Healthcare Products Regulatory Agency (MHRA) <a href="http://www.mhra.gov.uk/spc-pil/">http://www.mhra.gov.uk/spc-pil/</a> |                         |                      |
| <b>Medicine</b>  | <b>Date of Revision</b>  | <b>Date Accessed</b>    |                      |
| Clariscan 0.5mmol/mL Solution for injection                  | 19/11/20   | 05/04/21                |                      |
| Cyclolox® 279.32 mg/mL Solution for injection                | 30/06/20   | 05/04/21                |                      |
| Dotarem® 279.32 mg/mL Solution for injection                 | 09/12/19   | 05/04/21                |                      |
| Dotagraf® 0.5mmol/mL (279.32 mg/mL) Solution for injection   | 02/12/19   | 05/04/21                |                      |
| E-Z-HD® Barium Sulphate 98% W/V Powder for Oral Suspension   | 22/11/20   | 05/04/21                |                      |
| E-Z-Paque Barium Sulphate 96% W/V Powder for Oral Suspension | 13/01/21   | 05/04/21                |                      |
| Omnipaque® 350mg l/mL solution for injection                 | 27/01/21   | 05/04/21                |                      |



## Appendix 1

### Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: \_\_\_\_\_ (Insert name)

Working within: \_\_\_\_\_ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

#### **Patient Group Direction for the Administration of Medicines Included in the Radiographers Contrast Agent PGD Formulary by Radiographers Working Within NHS Grampian, Highland, Orkney, Shetland and Western Isles**

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: \_\_\_\_\_

Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Profession: \_\_\_\_\_

Professional Registration number/PIN: \_\_\_\_\_



## Appendix 2

### Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

**The Lead manager/Professional** of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

**The Senior Nurse/Professional** who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

**The Healthcare Professional** that is approved to administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

#### **Patient Group Direction for the Administration of Medicines Included in the Radiographers Contrast Agent PGD Formulary by Radiographers Working Within NHS Grampian, Highland, Orkney, Shetland and Western Isles**

**Local clinical area(s) where the listed healthcare professionals will operate under this PGD:**

| <b>Name of Healthcare Professional</b> | <b>Signature</b> | <b>Date</b> | <b>Name of Manager</b> | <b>Signature</b> | <b>Date</b> |
|--|------------------|-------------|------------------------|------------------|-------------|
|  |                  |             |                        |                  |             |
|  |                  |             |                        |                  |             |
|  |                  |             |                        |                  |             |





### Appendix 3 - Medicine Monographs

| <b>Contrast Agent</b>   | <b>Page</b> |
|---|-------------|
| E-Z-HD <sup>®</sup> Barium Sulphate 98.45% W/V Powder For Oral Suspension .....   | 12          |
| E-Z-Paque <sup>®</sup> Barium Sulphate 96% W/V Powder For Oral Suspension .....   | 15          |
| Gadobutrol (Gadovist <sup>®</sup> ) 1.0mmol/mL Solution for Injection.....  | 18          |
| Gadobenate Dimeglumine (MultiHance <sup>®</sup> ) 0.5M Solution for Injection.....  | 21          |
| Gadoxedate Sodium (Primovist <sup>®</sup> ) 0.25mmol/mL, Solution for Injection .....   | 24          |
| Gadoteric Acid Meglumine (Dotarem <sup>®</sup> , Clariscan <sup>®</sup> , Dotagraf <sup>®</sup> or Cyclolux <sup>®</sup> ) 0.5<br>mmol/mL containing 279.3mg/mL Gadoteric Acid , Solution for Injection ..... | 27          |
| Gadoteridol (ProHance <sup>®</sup> ) 279.3mg/mL, Solution for Injection.....  | 30          |
| Iohexol (Omnipaque <sup>®</sup> ) 140mg I/mL, 240mg I/mL, 300mg I/mL or 350mg I/mL Solution<br>for Injection .....  | 33          |
| Iomeprol (Iomeron <sup>®</sup> ) 400 Solution for Injection.....  | 38          |

## Radiographers Contrast Agent PGD Formulary

| <b>E-Z-HD<sup>®</sup> Barium Sulphate 98.45% W/V Powder for Oral Suspension</b> |   |
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| <b>Indication</b>   | E-Z-HD <sup>®</sup> is a high-density suspension for use as a radiopaque agent during X-ray visualisation of the upper gastro-intestinal tract (oesophagus, stomach and duodenum). It is designed for optimal use in double contrast X-ray examinations.  |
| <b>Inclusion Criteria</b>   | As per main PGD inclusion criteria and additionally; <ul style="list-style-type: none"> <li>• Individuals aged 12 years and over.</li> </ul>  |
| <b>Exclusion Criteria</b>   | As per main PGD inclusion criteria and additionally: <ul style="list-style-type: none"> <li>• Individuals under 12 years of age</li> <li>• A known or suspected, perforation of the gastrointestinal tract</li> <li>• Known or suspected trachea-oesophageal fistula</li> <li>• Gastrointestinal haemorrhage</li> <li>• Gastrointestinal ischaemia</li> <li>• Megacolon or toxic megacolon</li> <li>• Necrotising enterocolitis</li> <li>• Severe ileus</li> <li>• Individuals who are dehydrated (general assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake))</li> <li>• With rare hereditary problems of fructose intolerance</li> <li>• E-Z-HD<sup>®</sup> should not be administered directly after gastrointestinal surgery</li> <li>• Individuals currently receiving radiotherapy and up to four weeks after radiotherapy to the rectum or prostate</li> <li>• Individuals with new injuries or chemical burns of the gastrointestinal tract.</li> </ul> |
| <b>Precautions and Special Warnings</b>   | <p>E-Z-HD<sup>®</sup> preparations used as radiopaque media contain a number of additives to provide diagnostic properties and individual palatability. Allergic responses following the use of E-Z-HD<sup>®</sup> suspensions have been reported.</p> <p>Skin irritation, redness, inflammation and hives have been reported for infants and small children following spillage of E-Z-HD<sup>®</sup> suspension on their skin.</p> <p>A history of bronchial asthma, atopy, as evidenced by hay fever and eczema, a family history of allergy, or a previous reaction to a contrast agent warrant special attention. These responses are thought to be caused by the flavours and/or preservatives used in the product.</p>  |



## Radiographers Contrast Agent PGD Formulary

| <b>E-Z-HD<sup>®</sup> Barium Sulphate 98.45% W/V Powder for Oral Suspension</b> |  |
|---|--|
|   | <p>E-Z-HD<sup>®</sup> contains sodium among the excipients. Care should be taken in individuals on a controlled sodium diet, especially in individuals with congestive heart failure.</p> <p>Emergency equipment and trained personnel should be immediately available for treatment of a hypersensitivity reaction.</p> <p>E-Z-HD<sup>®</sup> is not contraindicated in pregnancy; however a radiographic procedure of the abdomen is unlikely to be performed whilst the individual is pregnant due to risks from the radiation.</p> <p>Since the absorption of barium sulphate is negligible, its use is not contra-indicated during breastfeeding.</p> |
| <b>Legal Status</b>   | E-Z-HD <sup>®</sup> is a Pharmacy (P) Medicine.  |
| <b>Dose/Maximum total dose</b>  | <p>The contents of one pre-filled bottle (340g) are dispersed in 65mL of water to produce a 250 % w/v suspension. The administered dose of E-Z-HD<sup>®</sup> will depend on the individual in question and the section of the gastrointestinal tract to be viewed.</p> <p><b>Maximum dose of one 340g pre-filled bottle only allowed under this PGD.</b></p>  |
| <b>Frequency of dose/Duration of treatment</b>                                  | Once only during procedure.  |
| <b>Maximum or minimum treatment period</b>                                      | See Frequency of dose/Duration of treatment section above.   |
| <b>Route/Method of Administration</b>   | <p>Oral administration</p> <p>E-Z-HD<sup>®</sup> must be administered orally. The powder must be reconstituted prior to administration as follows;</p> <ol style="list-style-type: none"> <li>1. Add 65mL of water to bottle.</li> <li>2. Secure lid and invert bottle, tapping base to loosen powder.</li> <li>3. Shake well for 10-20 seconds. Leave until required.</li> <li>4. Immediately before giving to individual to drink shake again for 10-20 seconds.</li> </ol>  |

## Radiographers Contrast Agent PGD Formulary

| <b>E-Z-HD<sup>®</sup> Barium Sulphate 98.45% W/V Powder for Oral Suspension</b> |   |
|---|---|
|   | <p>Any unused, opened product or waste material should be disposed of in accordance with local requirements.</p> <p>If a suitable gas producing agent is required, this should be administered prior to the reconstituted suspension being swallowed by the individual.</p> <p>As per the SmPC E-Z-HD<sup>®</sup> should be administered immediately following reconstitution and must not be stored</p>  |
| <b>Quantity to be administered</b>  | One prefilled 340g bottle.  |
| <b>Potential Adverse Reactions</b>  | <p>The most frequently reported undesirable effects include; diarrhoea, nausea, abdominal pain/distention, constipation.</p> <p>Skin and subcutaneous reactions such as urticaria, erythema and rash have been commonly reported.</p>   |
| <b>Advice</b>   | <p>After administration advise individual to:</p> <ul style="list-style-type: none"> <li>• Maintain adequate hydration</li> <li>• Seek medical attention for worsening of constipation or slow gastrointestinal passage</li> <li>• Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty.</li> </ul>   |
| <b>Follow up (If applicable)</b>  | <p>Individuals who have undergone barium meal, barium swallow, or video-fluoroscopy examinations should remain under observation until they have been seen to recover from the procedure. It is not possible to specify an exact length of time, but individual should remain on the premises for at least 10-15 minutes.</p> <p>Individuals should not leave if they are feeling unwell without speaking to the GI Advanced Practice Radiographer first. If necessary, a doctor should be contacted for advice. If any complications arise during or immediately after the procedure then the opinion of a consultant or supervising radiologist should be sought.</p> |
| <b>Storage</b>  | Do not store above 25° C.   |

## Radiographers Contrast Agent PGD Formulary

| <b>E-Z-Paque® Barium Sulphate 96% W/V Powder for Oral Suspension</b> |  |
|--|--|
| <b>Indication</b>  | E-Z-Paque® is indicated for use as a positive contrast medium for radiographic visualisation of the gastrointestinal tract.  |
| <b>Inclusion Criteria</b>  | As per main PGD inclusion criteria and additionally; <ul style="list-style-type: none"> <li>• Individuals aged 12 years and over.</li> </ul>   |
| <b>Exclusion Criteria</b>  | As per main PGD inclusion criteria and additionally: <ul style="list-style-type: none"> <li>• Individuals under 12 years of age</li> <li>• A known or suspected, perforation of the gastrointestinal tract</li> <li>• Known or suspected trachea-oesophageal fistula</li> <li>• Gastrointestinal haemorrhage</li> <li>• Gastrointestinal ischaemia</li> <li>• Megacolon or toxic megacolon</li> <li>• Necrotising enterocolitis</li> <li>• Severe ileus</li> <li>• Individuals who are dehydrated (general assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake))</li> <li>• Individuals with rare hereditary problems of fructose intolerance</li> <li>• E-Z-HD® should not be administered directly after gastrointestinal surgery</li> <li>• Individuals currently receiving radiotherapy and up to four weeks after radiotherapy to the rectum or prostate</li> <li>• Individuals with new injuries or chemical burns of the gastrointestinal tract.</li> </ul> |
| <b>Precautions and Special Warnings</b>                              | <p>E-Z-Paque® preparations used as radiopaque media contain a number of additives to provide diagnostic properties and individual palatability. Allergic responses following the use of E-Z-Paque® suspensions have been reported. Skin irritation, redness, inflammation and hives have been reported for infants and small children following spillage of E-Z-Paque® suspension on their skin.</p> <p>A history of bronchial asthma, atopy, as evidenced by hay fever and eczema, a family history of allergy, or a previous reaction to a contrast agent warrant special attention. These responses are thought to be caused by the flavours and/or preservatives used in the product.</p>  |

## Radiographers Contrast Agent PGD Formulary

| <b>E-Z-Paque® Barium Sulphate 96% W/V Powder for Oral Suspension</b> |   |
|--|---|
|  | <p>E-Z-Paque® contains sodium among the excipients. Care should be taken in individuals on a controlled sodium diet, especially in individuals with congestive heart failure. Emergency equipment and trained personnel should be immediately available for treatment of a hypersensitivity reaction.</p> <p>E-Z-Paque® is not contraindicated in pregnancy, however a radiographic procedure of the abdomen is unlikely to be performed whilst the individual is pregnant due to risks from the radiation.</p> <p>Since the absorption of barium sulphate is negligible, its use is not contra-indicated during breastfeeding.</p> |
| <b>Legal Status</b>  | E-Z-Paque® is a Pharmacy (P) Medicine.  |
| <b>Dose/Maximum total dose</b>                                       | <p>Single contrast of the oesophagus, stomach and duodenum to be given orally 175mL to 300mL of suspension at 100 % w/v.</p> <p>Small bowel – To be given orally 250mL to 300mL of suspension at 60 % w/v.</p> <p>The actual administered dose should be determined from experience by the Advanced Practice Radiographer.</p> <p><b>Maximum dose of one 177g unit dose bottle only allowed under this PGD.</b></p>   |
| <b>Frequency of dose/Duration of treatment</b>                       | Once only during procedure.   |
| <b>Maximum or minimum treatment period</b>                           | See Frequency of dose/Duration of treatment section above.  |
| <b>Route/Method of Administration</b>                                | <p>Oral administration</p> <p>Add water to approximately 2.5 cm above barium level. Secure lid, invert bottle and shake vigorously. Add more water to desired % w/v line on bottle. Replace lid and shake for 30 seconds.</p> <p>Important: Always re-shake just prior to administration to the individual.</p>   |

## Radiographers Contrast Agent PGD Formulary

| <b>E-Z-Paque® Barium Sulphate 96% W/V Powder for Oral Suspension</b> |  |
|--|--|
|  | <p>Any unused, opened product or waste material should be disposed of in accordance with local requirements.</p> <p>As per the SmPC E-Z-Paque® should be administered immediately following reconstitution and must not be stored.</p>   |
| <b>Quantity to be administered</b>                                   | See Dose/Maximum total dose section above.   |
| <b>Potential Adverse Reactions</b>                                   | <p>The most frequently reported undesirable effects include; diarrhoea, nausea, abdominal pain/distention, constipation.</p> <p>Skin and subcutaneous reactions such as urticaria, erythema and rash have been commonly reported.</p> <p>Following oral administration, aspiration, with pulmonary complications, may occur and may be fatal in rare cases.</p>  |
| <b>Advice</b>  | <p>After administration advise individuals to:</p> <ul style="list-style-type: none"> <li>• Maintain adequate hydration</li> <li>• Seek medical attention for worsening of constipation or slow gastrointestinal passage</li> <li>• Seek medical attention for any delayed onset of hypersensitivity: rash, urticaria, or respiratory difficulty.</li> </ul>   |
| <b>Follow up (If applicable)</b>                                     | <p>Individual who have undergone barium meal, barium swallow, small bowel study or video-fluoroscopy examinations should remain under observation until they have been seen to recover from the procedure. It is not possible to specify an exact length of time, but individual should remain on the premises for at least 10-15 minutes.</p> <p>Individual should not leave if they are feeling unwell without speaking to the Advanced Practice Radiographer first. If necessary, a doctor should be contacted for advice. If any complications arise during or immediately after the procedure then the opinion of a consultant or supervising radiologist should be sought.</p> |
| <b>Storage</b>   | Do not store above 25° C.  |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadobutrol (Gadovist®) 1.0mmol/mL solution for injection</b> |  |
|---|--|
| <b>Indication</b>   | <p>Imaging procedures within the Radiology/Radiotherapy Department(s) to allow the visualisation of soft tissue structures in individuals undergoing an MRI scan.</p> <p><b>NOTE:</b> Follow local individual Board protocols.</p>   |
| <b>Inclusion Criteria</b>                                       | <p>As per main PGD inclusion criteria and additionally;</p> <ul style="list-style-type: none"> <li>• Individuals and infants of all ages</li> <li>• Individuals with an estimated glomerular filtration rate (eGFR) of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math>.</li> </ul>   |
| <b>Exclusion Criteria</b>                                       | <p>As per main PGD exclusion criteria and additionally:</p> <ul style="list-style-type: none"> <li>• Previous adverse drug reaction (allergic, hypersensitivity or other) after administration of gadobutrol or a contrast agent of a similar nature or to any component of gadobutrol</li> <li>• Pregnancy</li> <li>• Known renal impairment with an estimated glomerular filtration rate (eGFR) of <math>&lt; 30\text{mL}/\text{min}/1.73\text{m}^2</math></li> <li>• Liver transplantation or peri-operative liver transplantation period.</li> </ul>   |
| <b>Precautions and Special Warnings</b>                         | <ul style="list-style-type: none"> <li>• <b>Previous history of any adverse drug reaction to an intravascular contrast agent not listed in the exclusion criteria.</b> Caution should be exercised where there is a known previous moderately severe reaction to intravascular contrast such as bronchospasm or urticaria requiring treatment or severe reactions (e.g. laryngeal or angioneurotic oedema, severe bronchospasm or collapse) to intravascular contrast. Any individual known to have had a previous moderately severe or severe reaction to contrast agent should be discussed with the supervising Radiologist, Clinical Oncologist (or other medically qualified imaging expert) prior to administration of contrast agents under this PGD. If the practitioner acting under this PGD decides to continue to administer the named agent under the PGD a full record of the decision must be made in the individual's clinical record.</li> <li>• Breastfeeding.</li> <li>• History of severe/multiple allergy including food allergies, hay fever and urticaria that has required medical intervention.</li> <li>• Dehydration – General assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake).</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadobutrol (Gadovist®) 1.0mmol/mL solution for injection</b> |   |
|---|---|
|   | <ul style="list-style-type: none"> <li>As with other gadolinium containing contrast agents special precaution is necessary in individuals with a low threshold for seizures.</li> </ul>   |
| <b>Legal Status</b>   | Gadovist® is a Prescription-only Medicine (POM).  |
| <b>Dose/Maximum total dose</b>                                  | 0.1mmol/kg.<br><br><b>Maximum total dose should be as per manufacturer's guidelines and local Board protocols.</b>  |
| <b>Frequency of dose/Duration of treatment</b>                  | Single dose for procedure indicated. However, repeated doses may be given under PGD in line with the following guidance (as a separate episode of care): <ul style="list-style-type: none"> <li>In individuals with an eGFR of <math>\geq 30\text{mL/min/1.73m}^2</math> a repeat dose is permitted after 30 minutes.</li> </ul>  |
| <b>Maximum or minimum treatment period</b>                      | See Frequency of dose/Duration of treatment section above.  |
| <b>Route/Method of Administration</b>                           | Intravenous, by pump injection: 3mL/second.   |
| <b>Quantity to be administered</b>                              | Dependent on clinical requirement.  |
| <b>Potential Adverse Reactions</b>                              | Refer to the product Summary of Product Characteristics ( <a href="#">SmP 1C</a> ) for full details of known adverse effects. The below list details only commonly reported adverse effects (>1 in 100) and does not represent all the product's known adverse effects: <ul style="list-style-type: none"> <li>Nausea and/or vomiting</li> <li>Headache</li> <li>Dizziness</li> <li>Injection site reactions (e.g. pain, coldness, warmth)</li> <li>Dysgeusia and feeling hot.</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadobutrol (Gadovist®) 1.0mmol/mL solution for injection</b> |   |
|---|---|
| <b>Advice</b>   | <ul style="list-style-type: none"> <li>• If relevant advise on the management of injection site/s and any infection control or self-management required.</li> <li>• Individuals should be informed that whilst uncommon a mild allergic reaction such as a rash, itchiness, feeling hot or cold, runny nose, watery eyes can occur and that they must inform a healthcare professional if they experience these symptoms.</li> </ul>  |
| <b>Follow up (If applicable)</b>                                | <ul style="list-style-type: none"> <li>• Individuals should be assessed prior to being discharged from the department for any adverse effects from the administered agent or for any signs of extravasation.</li> <li>• Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.</li> </ul>   |
| <b>Storage</b>  | <ul style="list-style-type: none"> <li>• Stock must be securely stored in a lockable cupboard.</li> <li>• Storage conditions - protect from light and freezing. Store between 15 and 30°C.</li> <li>• After the vial/bottle has been opened or the pre-filled syringe has been prepared for use gadobutrol remains stable for 24 hours at 20-25°C after which time it must be discarded. However from a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.</li> <li>• Contrast agent should ideally be warmed to body temperature prior to administration.</li> </ul> |



## Radiographers Contrast Agent PGD Formulary

| <b>Gadobenate Dimeglumine (MultiHance®) 0.5M solution for injection</b> |  |
|---|--|
| <b>Indication</b>   | <p>Imaging procedures within the Radiology/Radiotherapy Department(s) to allow the visualisation of soft tissue structures in individuals undergoing an MRI scan.</p> <p><b>NOTE:</b> Follow local individual Board protocols.</p>   |
| <b>Inclusion Criteria</b>   | <p>As per main PGD inclusion criteria and additionally;</p> <ul style="list-style-type: none"> <li>• Individuals aged 2 years and older</li> <li>• Individuals with an estimated glomerular filtration rate (eGFR) of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math>.</li> </ul>  |
| <b>Exclusion Criteria</b>   | <p>As per main PGD exclusion criteria and additionally:</p> <ul style="list-style-type: none"> <li>• Individuals aged less than 2 years of age</li> <li>• Previous adverse drug reaction (allergic, hypersensitivity or other) after administration of a contrast agent</li> <li>• Known renal impairment with an estimated glomerular filtration rate (eGFR) of <math>&lt;30\text{mL}/\text{min}/1.73\text{m}^2</math></li> <li>• Liver transplantation or peri-operative liver transplantation period.</li> </ul>  |
| <b>Precautions and Special Warnings</b>                                 | <ul style="list-style-type: none"> <li>• <b>Previous history of any adverse drug reaction to an intravascular contrast agent not listed in the exclusion criteria.</b> Caution should be exercised where there is a known previous moderately severe reaction to intravascular contrast such as bronchospasm or urticaria requiring treatment or severe reactions (e.g. laryngeal or angioneurotic oedema, severe bronchospasm or collapse) to intravascular contrast. Any individual known to have had a previous moderately severe or severe reaction to contrast agent should be discussed with the supervising Radiologist, Clinical Oncologist (or other medically qualified imaging expert) prior to administration of contrast agents under this PGD. If the practitioner acting under this PGD decides to continue to administer the named agent under the PGD a full record of the decision must be made in the individual's clinical record.</li> <li>• Breastfeeding.</li> <li>• History of severe/multiple allergy including food allergies, hay fever and urticaria that has required medical intervention.</li> <li>• Dehydration – General assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake).</li> <li>• Caution is advised in individuals with cardiovascular disease.</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadobenate Dimeglumine (MultiHance®) 0.5M solution for injection</b> |  |
|---|--|
|   | <ul style="list-style-type: none"> <li>• Uncorrected hypokalemia.</li> </ul>   |
| <b>Legal Status</b>   | Gadobenate Dimeglumine (MultiHance®) 0.5M solution for injection is a Prescription-only Medicine (POM).  |
| <b>Dose/Maximum total dose</b>  | <p>0.05mmol/kg of 0.5M Solution.</p> <p>The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.</p> <p><b>Maximum total dose should be as per manufacturer's guidelines and local Board protocols.</b></p>  |
| <b>Frequency of dose/Duration of treatment</b>                          | <p>Single dose for procedure indicated. However, repeated doses may be given under PGD in line with the following guidance (as a separate episode of care):</p> <ul style="list-style-type: none"> <li>• In individuals with an eGFR of <math>\geq 30\text{mL/min/1.73m}^2</math> a repeat dose is permitted after 4 hours.</li> </ul>   |
| <b>Maximum or minimum treatment period</b>                              | See Frequency of dose/Duration of treatment section above.   |
| <b>Route/Method of Administration</b>                                   | Intravenous, by pump injection: 10mL/min.  |
| <b>Quantity to be administered</b>                                      | Dependent on clinical requirement.   |
| <b>Potential Adverse Reactions</b>                                      | <p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects.</p> <p>The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <ul style="list-style-type: none"> <li>• Nausea and/or vomiting</li> <li>• Headache</li> <li>• Injection site reactions (e.g. pain, coldness, warmth).</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadobenate Dimeglumine (MultiHance®) 0.5M solution for injection</b> |   |
|---|---|
| <b>Advice</b>   | <ul style="list-style-type: none"> <li>• If relevant advise on the management of injection site/s and any infection control or self-management required.</li> <li>• Individual should be informed that whilst uncommon a mild allergic reaction such as a rash, itchiness, feeling hot or cold, runny nose, watery eyes can occur and that they must inform a healthcare professional if they experience these symptoms.</li> </ul> |
| <b>Follow up (If applicable)</b>  | <ul style="list-style-type: none"> <li>• Individuals should be assessed prior to being discharged from the department for any adverse effects from the administered agent or for any signs of extravasation.</li> <li>• Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.</li> </ul>   |
| <b>Storage</b>  | <ul style="list-style-type: none"> <li>• Stock must be securely stored in a lockable cupboard.</li> <li>• Storage conditions - protect from light and freezing.</li> <li>• Use immediately after preparation and discard any unused product in accordance with local waste protocols.</li> <li>• Contrast agent should ideally be warmed to body temperature prior to administration.</li> </ul>                                    |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoxetate Disodium (Primovist®) 0.25mmol/mL, Solution for Injection</b> |  |
|---|--|
| <b>Indication</b>   | <p>Imaging procedures within the Radiology/Radiotherapy Department(s) to allow the visualisation of soft tissue structures in individuals undergoing an MRI scan.</p> <p><b>NOTE:</b> Follow local individual Board protocols.</p>   |
| <b>Inclusion Criteria</b>   | <p>As per main PGD inclusion criteria and additionally;</p> <ul style="list-style-type: none"> <li>• Individuals aged 2 years of age and over</li> <li>• Individuals with an estimated glomerular filtration rate (eGFR) of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math>.</li> </ul>  |
| <b>Exclusion Criteria</b>   | <p>As per main PGD exclusion criteria and additionally:</p> <ul style="list-style-type: none"> <li>• Individuals aged less than 2 years</li> <li>• Previous adverse drug reaction (allergic, hypersensitivity or other) after administration of an MRI contrast agent</li> <li>• Pregnancy</li> <li>• Known renal impairment with an estimated glomerular filtration rate (eGFR) of <math>&lt; 30\text{mL}/\text{min}/1.73\text{m}^2</math></li> <li>• Liver transplantation or peri-operative liver transplantation period.</li> </ul>  |
| <b>Precautions and Special Warnings</b>                                     | <ul style="list-style-type: none"> <li>• <b>Previous history of any adverse drug reaction to an intravascular contrast agent not listed in the exclusion criteria.</b> Caution should be exercised where there is a known previous moderately severe reaction to intravascular contrast such as bronchospasm or urticaria requiring treatment or severe reactions (e.g. laryngeal or angioneurotic oedema, severe bronchospasm or collapse) to intravascular contrast. Any individual known to have had a previous moderately severe or severe reaction to contrast agent should be discussed with the supervising Radiologist, Clinical Oncologist (or other medically qualified imaging expert) prior to administration of contrast agents under this PGD. If the practitioner acting under this PGD decides to continue to administer the named agent under the PGD a full record of the decision must be made in the individual's clinical record.</li> <li>• Breastfeeding.</li> <li>• History of severe/multiple allergy including food allergies, hay fever and urticaria that has required medical intervention.</li> <li>• Dehydration – General assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake).</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoxetate Disodium (Primovist®) 0.25mmol/mL, Solution for Injection</b> |   |
|---|---|
|   | <ul style="list-style-type: none"> <li>Caution should be exercised when Primovist® is administered to individuals with severe cardiovascular problems because only limited data are available so far.</li> </ul>  |
| <b>Legal Status</b>   | Gadoxetate Disodium (Primovist®) 0.25mmol/mL, solution for injection is a Prescription-only Medicine (POM).   |
| <b>Dose/Maximum total dose</b>  | <p>0.1mL/kg of the 0.25mmol/mL solution.</p> <p>The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.</p> <p><b>Maximum total dose should be as per manufacturer's guidelines and local Board protocols.</b></p>   |
| <b>Frequency of dose/Duration of treatment</b>                              | <p>Single dose for procedure indicated. However, repeated doses may be given under PGD in line with the following guidance (as a separate episode of care):</p> <ul style="list-style-type: none"> <li>In individuals with an eGFR of <math>\geq 30\text{mL/min/1.73m}^2</math> a repeat dose is permitted after 4 hours.</li> </ul>                      |
| <b>Maximum or minimum treatment period</b>                                  | See Frequency of dose/Duration of treatment section above.  |
| <b>Route/Method of Administration</b>                                       | Intravenous, by pump injection.   |
| <b>Quantity to be administered</b>  | Dependent on clinical requirement.  |
| <b>Potential Adverse Reactions</b>  | <p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects. The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <ul style="list-style-type: none"> <li>Nausea</li> <li>Headache.</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoxetate Disodium (Primovist®) 0.25mmol/mL, Solution for Injection</b> |  |
|---|--|
| <b>Advice</b>   | <ul style="list-style-type: none"><li>• If relevant advise on the management of injection site/s and any infection control or self-management required.</li><li>• Individual should be informed that whilst uncommon a mild allergic reaction such as a rash, itchiness, feeling hot or cold, runny nose, watery eyes can occur and that they must inform a healthcare professional if they experience these symptoms.</li></ul> |
| <b>Follow up (If applicable)</b>  | <ul style="list-style-type: none"><li>• Individuals should be assessed prior to being discharged from the department for any adverse effects from the administered agent or for any signs of extravasation.</li><li>• Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.</li></ul>   |
| <b>Storage</b>  | <ul style="list-style-type: none"><li>• Stock must be securely stored in a lockable cupboard.</li><li>• Contrast agent should ideally be warmed to body temperature prior to administration.</li></ul>   |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoteric Acid Meglumine (Dotarem<sup>®</sup>, Clariscan<sup>®</sup>, Dotagraf<sup>®</sup> or Cyclolux<sup>®</sup>) 0.5 mmol/mL containing 279.3mg/mL Gadoteric Acid , solution for injection</b> |   |
|--|---|
| <b>Indication</b>  | <p>Imaging procedures within the Radiology/Radiotherapy Department(s) to allow the visualisation of soft tissue structures in individuals undergoing an MRI scan.</p> <p><b>NOTE:</b> Follow local individual Board protocols.</p>  |
| <b>Inclusion Criteria</b>  | <p>As per main PGD inclusion criteria and additionally;</p> <ul style="list-style-type: none"> <li>• Individuals 2 years of age and over</li> <li>• Individuals with an estimated glomerular filtration rate (eGFR) of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math>.</li> </ul>  |
| <b>Exclusion Criteria</b>  | <p>As per main PGD exclusion criteria and additionally:</p> <ul style="list-style-type: none"> <li>• Individuals aged less than 2 years</li> <li>• Previous adverse drug reaction (allergic, hypersensitivity or other) after administration of a contrast agent</li> <li>• Pregnancy</li> <li>• Known renal impairment with an estimated glomerular filtration rate (eGFR) of <math>&lt; 30\text{mL}/\text{min}/1.73\text{m}^2</math></li> <li>• Liver transplantation or peri-operative liver transplantation period</li> <li>• Asthma which is poorly controlled at the time of the procedure.</li> </ul>  |
| <b>Precautions and Special Warnings</b>  | <ul style="list-style-type: none"> <li>• <b>Previous history of any adverse drug reaction to an intravascular contrast agent not listed in the exclusion criteria.</b> Caution should be exercised where there is a known previous moderately severe reaction to intravascular contrast such as bronchospasm or urticaria requiring treatment or severe reactions (e.g. laryngeal or angioneurotic oedema, severe bronchospasm or collapse) to intravascular contrast. Any individual known to have had a previous moderately severe or severe reaction to contrast agent should be discussed with the supervising Radiologist, Clinical Oncologist (or other medically qualified imaging expert) prior to administration of contrast agents under this PGD. If the practitioner acting under this PGD decides to continue to administer the named agent under the PGD a full record of the decision must be made in the individual's clinical record.</li> <li>• Breastfeeding.</li> <li>• History of severe/multiple allergy including food allergies, hay fever and urticaria that has required medical intervention.</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoteric Acid Meglumine (Dotarem<sup>®</sup>, Clariscan<sup>®</sup>, Dotagraf<sup>®</sup> or Cyclolux<sup>®</sup>) 0.5 mmol/mL containing 279.3mg/mL Gadoteric Acid , solution for injection</b> |  |
|--|--|
|  | <ul style="list-style-type: none"> <li>• Dehydration – General assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake).</li> <li>• Like with other gadolinium containing contrast agents special precaution is necessary in individuals with a low threshold for seizures. Precautionary measures should be taken, e.g. close monitoring.</li> <li>• Concomitant medications to be taken into account. Beta-blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists. A radiologist must be available within the department and resuscitation equipment must be at hand.</li> </ul> |
| <b>Legal Status</b>  | Gadoteric Acid Meglumine (Dotarem <sup>®</sup> ) 0.5mmol/mL, solution for injection is a Prescription-only Medicine (POM).   |
| <b>Dose/Maximum total dose</b>   | <p>0.2mmol/kg.</p> <p>The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.</p> <p><b>Maximum total dose allowed under this PGD should be as per manufacturer’s guidelines and local Board protocols.</b></p>   |
| <b>Frequency of dose/Duration of treatment</b>   | <p>Repeated doses may be given under PGD in line with the following guidance (as a separate episode of care):</p> <ul style="list-style-type: none"> <li>• In individuals with an eGFR of <math>\geq 30</math> mL/min/1.73m<sup>2</sup> a repeat dose is permitted after 4 hours.</li> </ul>   |
| <b>Maximum or minimum treatment period</b>   | See Frequency of dose/Duration of treatment section above.   |
| <b>Route/Method of Administration</b>  | Intravenous injection by hand or by pump in accordance with local protocol.  |
| <b>Quantity to be administered</b>   | Dependent on clinical requirement.   |



## Radiographers Contrast Agent PGD Formulary

| <b>Gadoteric Acid Meglumine (Dotarem<sup>®</sup>, Clariscan<sup>®</sup>, Dotagraf<sup>®</sup> or Cyclolux<sup>®</sup>) 0.5 mmol/mL containing 279.3mg/mL Gadoteric Acid , solution for injection</b> |   |
|--|---|
| <b>Potential Adverse Reactions</b>   | <p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects. The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Headache</li> <li>• Pruritus and hypersensitivity reactions.</li> </ul>                    |
| <b>Advice</b>  | <ul style="list-style-type: none"> <li>• If relevant advise on the management of injection site/s and any infection control or self-management required.</li> <li>• Individual should be informed that whilst uncommon a mild allergic reaction such as a rash, itchiness, feeling hot or cold, runny nose, watery eyes can occur and that they must inform a healthcare professional if they experience these symptoms.</li> </ul> |
| <b>Follow up (If applicable)</b>   | <ul style="list-style-type: none"> <li>• Individuals should be assessed prior to being discharged from the department for any adverse effects from the administered agent or for any signs of extravasation.</li> <li>• Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.</li> </ul>   |
| <b>Storage</b>   | <ul style="list-style-type: none"> <li>• Stock must be securely stored in a lockable cupboard.</li> <li>• Store at room temperature and do not freeze.</li> <li>• Contrast agent ideally should be warmed to body temperature prior to administration.</li> </ul>   |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoteridol (ProHance®) 279.3mg/mL, solution for injection</b> |  |
|---|--|
| <b>Indication</b>   | <p>Imaging procedures within the Radiology/Radiotherapy Department(s) to allow the visualisation of soft tissue structures in individuals undergoing an MRI scan.</p> <p><b>NOTE:</b> Follow local individual Board protocols.</p>   |
| <b>Inclusion Criteria</b>   | <p>As per main PGD inclusion criteria and additionally;</p> <ul style="list-style-type: none"> <li>• Individuals 2 years of age and over</li> <li>• Individuals with an estimated glomerular filtration rate (eGFR) of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math>.</li> </ul>   |
| <b>Exclusion Criteria</b>   | <p>As per main PGD exclusion criteria and additionally:</p> <ul style="list-style-type: none"> <li>• Previous adverse drug reaction (allergic, hypersensitivity or other) after administration of a contrast agent</li> <li>• Known renal impairment with an estimated glomerular filtration rate (eGFR) of <math>&lt; 30\text{mL}/\text{min}/1.73\text{m}^2</math></li> <li>• Liver transplantation or peri-operative liver transplantation period</li> <li>• Asthma which is poorly controlled at the time of the procedure.</li> </ul>  |
| <b>Precautions and Special Warnings</b>                           | <ul style="list-style-type: none"> <li>• <b>Previous history of any adverse drug reaction to an intravascular contrast agent not listed in the exclusion criteria.</b> Caution should be exercised where there is a known previous moderately severe reaction to intravascular contrast such as bronchospasm or urticaria requiring treatment or severe reactions (e.g. laryngeal or angioneurotic oedema, severe bronchospasm or collapse) to intravascular contrast. Any individual known to have had a previous moderately severe or severe reaction to contrast agent should be discussed with the supervising Radiologist, Clinical Oncologist (or other medically qualified imaging expert) prior to administration of contrast agents under this PGD. If the practitioner acting under this PGD decides to continue to administer the named agent under the PGD a full record of the decision must be made in the individual's clinical record.</li> <li>• Breastfeeding.</li> <li>• History of severe/multiple allergy including food allergies, hay fever and urticaria that has required medical intervention.</li> <li>• Dehydration – General assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake).</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoteridol (ProHance®) 279.3mg/mL, solution for injection</b> |  |
|---|--|
|   | <ul style="list-style-type: none"> <li>Like with other gadolinium containing contrast agents special precaution is necessary in individuals with a low threshold for seizures. Precautionary measures should be taken, e.g. close monitoring.</li> </ul>   |
| <b>Legal Status</b>   | Gadoteridol (ProHance®) 279.3 mg/mL, solution for injection is a Prescription-only Medicine (POM).   |
| <b>Dose/Maximum total dose</b>                                    | <p>0.1mmol/kg.</p> <p>The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.</p> <p><b>Maximum total dose allowed under this PGD should be as per manufacturer's guidelines and local Board protocols.</b></p>   |
| <b>Frequency of dose/Duration of treatment</b>                    | <p>Single dose for procedure indicated. However, repeated doses may be given under PGD in line with the following guidance (as a separate episode of care):</p> <ul style="list-style-type: none"> <li>In individuals with an eGFR of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math> a repeat dose is permitted after 4 hours.</li> </ul> |
| <b>Maximum or minimum treatment period</b>                        | See Frequency of dose/Duration of treatment section above.   |
| <b>Route/Method of Administration</b>                             | Intravenous injection by hand or by pump in accordance with local protocol.  |
| <b>Quantity to be administered</b>                                | Dependent on clinical requirement.   |
| <b>Potential Adverse Reactions</b>                                | <p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects. The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <ul style="list-style-type: none"> <li>Nausea</li> </ul>             |

## Radiographers Contrast Agent PGD Formulary

| <b>Gadoteridol (ProHance®) 279.3mg/mL, solution for injection</b> |   |
|---|---|
| <b>Advice</b>   | <ul style="list-style-type: none"> <li>• If relevant advise on the management of injection site/s and any infection control or self-management required.</li> <li>• Individual should be informed that whilst uncommon a mild allergic reaction such as a rash, itchiness, feeling hot or cold, runny nose, watery eyes can occur and that they must inform a healthcare professional if they experience these symptoms.</li> </ul> |
| <b>Follow up (If applicable)</b>                                  | <ul style="list-style-type: none"> <li>• Individuals should be assessed prior to being discharged from the department for any adverse effects from the administered agent or for any signs of extravasation.</li> <li>• Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.</li> </ul>   |
| <b>Storage</b>  | <ul style="list-style-type: none"> <li>• Stock must be securely stored in a lockable cupboard.</li> <li>• Store at room temperature (15-30°C).</li> <li>• Do not freeze.</li> <li>• Contrast agent should ideally be warmed to body temperature prior to administration.</li> </ul>   |

## Radiographers Contrast Agent PGD Formulary

| <b>Iohexol (Omnipaque®) 140mg I/mL, 240mg I/mL, 300mg I/mL or 350mg I/mL solution for injection</b> |   |
|---|---|
| <b>Indication</b>   | <p>Imaging procedures within the Radiology/ Radiotherapy Department to allow the visualisation of blood vessels, solid organs and other organs.</p> <p><b>NOTE:</b> Follow local individual Board protocols.</p>  |
| <b>Inclusion Criteria</b>   | <p>As per main PGD inclusion criteria and additionally;</p> <ul style="list-style-type: none"> <li>• Individuals 2 years of age and over</li> <li>• Individuals with an estimated glomerular filtration rate (eGFR) of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math>.</li> </ul>  |
| <b>Exclusion Criteria</b>   | <p>As per main PGD exclusion criteria and additionally:</p> <ul style="list-style-type: none"> <li>• Previous adverse drug reaction (allergic, hypersensitivity or other) after administration of a contrast agent</li> <li>• Known renal impairment with an estimated glomerular filtration rate (eGFR) of <math>&lt; 30\text{mL}/\text{min}/1.73\text{m}^2</math></li> <li>• Any history documented in the radiology/imaging referral/request of: <ul style="list-style-type: none"> <li>○ Manifest thyrotoxicosis</li> <li>○ Congestive heart failure, severe cardiac disease or pulmonary hypertension</li> <li>○ Homocystinuria</li> <li>○ Sickle cell disease</li> <li>○ Severe liver impairment or peri-operative liver transplant period</li> <li>○ Asthma which is poorly controlled at the time of procedure</li> <li>○ Myeloma.</li> </ul> </li> </ul>   |
| <b>Precautions and Special Warnings</b>   | <ul style="list-style-type: none"> <li>• <b>Previous history of any adverse drug reaction to an intravascular contrast agent not listed in the exclusion criteria.</b> Caution should be exercised where there is a known previous moderately severe reaction to intravascular contrast such as bronchospasm or urticaria requiring treatment or severe reactions (e.g. laryngeal or angioneurotic oedema, severe bronchospasm or collapse) to intravascular contrast. Any individual known to have had a previous moderately severe or severe reaction to contrast agent should be discussed with the supervising Radiologist, Clinical Oncologist (or other medically qualified imaging expert) prior to administration of contrast agents under this PGD. If the practitioner acting under this PGD decides to continue to administer the named agent under the PGD a full record of the decision must be made in the individual's clinical record.</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

| <b>Iohexol (Omnipaque®) 140mg I/mL, 240mg I/mL, 300mg I/mL or 350mg I/mL solution for injection</b> |   |
|---|---|
|   | <ul style="list-style-type: none"> <li>• Any history documented in the radiology referral/request of paraproteinaemias (multiple myeloma and Waldenstrom’s macroglobulinaemia– increased risk of renal impairment) or hypercalcaemia.</li> <li>• Breastfeeding.</li> <li>• History of severe/multiple allergy including food allergies, hay fever and urticaria that has required medical intervention.</li> <li>• Dehydration – General assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake).</li> <li>• Care should be taken in individuals with serious cardiac disease /cardio-circulatory disease and pulmonary hypertension</li> <li>• Like with other contrast agents special precaution is necessary in individuals with a low threshold for seizures. Precautionary measures should be taken, e.g. close monitoring.</li> <li>• The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis.</li> <li>• In patients with phaeochromocytoma caution is advised as these patients may be at risk of developing hypertensive crisis following large doses of Iohexol.</li> <li>• There is a risk of the development of lactic acidosis when iodinated contrast agents are administered to diabetic individuals treated with metformin, particularly in those with impaired renal function.</li> <li>• Individuals treated with interleukin-2 and interferons less than two weeks previously have been associated with an increased risk for delayed reactions. A specific risk of delayed skin rash is associated with Interleukin-2 therapy.</li> <li>• The concomitant use of certain neuroleptics or tricyclic antidepressants can reduce the seizure threshold and thus increase the risk of contrast medium-induced seizures.</li> <li>• Treatment with <math>\beta</math>-blockers may lower the threshold for hypersensitivity reactions, as well as necessitating higher doses of <math>\beta</math>-agonists when treating hypersensitivity reactions.</li> </ul> |
| <b>Legal Status</b>   | Iohexol (Omnipaque®) 140mg I/mL, 240mg I/mL, 300mg I/mL or 350mg I/mL solution for injection are Prescription-only Medicines (POM).   |

## Radiographers Contrast Agent PGD Formulary

### Iohexol (Omnipaque®) 140mg I/mL, 240mg I/mL, 300mg I/mL or 350mg I/mL solution for injection

**Dose/Maximum total dose**

The following are dose guidelines for intravenous use as set out in the SmPC for Iohexol (Omnipaque® 140, 240, 300 and 350):

**Note:** I/mL stands for iodine concentration per mL. The term b.w in the table below denotes body weight.

| Indication                             | Concentration  | Volume   |
|--|--|--|
| <b>Urography</b>                       |  |  |
| Adults                                 | 300mg I/mL or 350mg I/mL                             | 40-80 mL   |
| Children <7 kg                         | 240mg I/mL or 300mg I/mL                             | 4mL/kg b.w.or 3mL/kg b.w.                            |
| Children >7kg                          | 240mg I/mL or 300mg I/mL                             | 3 mL/kg b.w. or 2 mL/kg b.w                          |
| <b>Phlebography (leg)</b>              | 240mg I/mL or 300mg I/mL                             | 20-100 mL/leg  |
| <b>Digital subtraction angiography</b> |  |  |
| Adults                                 | 300mg I/mL or 350mg I/mL                             | Up to 3mL per kg b.w (20 - 60mL/inj)                 |
| Children                               | 140mg I/mL   | Dependent upon age, weight and pathology.            |
| <b>CT enhancement</b>                  |  |  |
| Adults                                 | 140mg I/mL or 240mg I/mL or 300mg I/mL or 350 mgI/mL | 100-400 mL<br>100-250 mL<br>100-200 mL<br>100-150 mL |

The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.

## Radiographers Contrast Agent PGD Formulary

| <b>Iohexol (Omnipaque®) 140mg I/mL, 240mg I/mL, 300mg I/mL or 350mg I/mL solution for injection</b> |  |
|---|--|
|   | <b>Maximum total dose allowed under this PGD should be as per manufacturer's guidelines and local Board protocols.</b>   |
| <b>Frequency of dose/Duration of treatment</b>  | <p>Single dose for procedure indicated. However, repeated doses may be given under PGD in line with the following guidance (as a separate episode of care):</p> <ul style="list-style-type: none"> <li>• Individuals with normal or moderately reduced renal function (eGFR &gt;30 and &lt;60 mL/min/1.73 m<sup>2</sup>) - 75 % of iodine-based contrast medium is excreted by 4 hours after administration. Therefore, there should be 4 hours between injections of iodine-based contrast medium.</li> </ul>   |
| <b>Maximum or minimum treatment period</b>  | See Frequency of dose/Duration of treatment section above.   |
| <b>Route/Method of Administration</b>   | Intravenous injection by hand or by pump in accordance with local protocol.  |
| <b>Quantity to be administered</b>  | Dependent on clinical requirement.   |
| <b>Potential Adverse Reactions</b>  | <p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects. The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <ul style="list-style-type: none"> <li>• Feeling hot/flushed</li> <li>• Feeling of urination</li> <li>• Nausea</li> <li>• Pain</li> <li>• Vomiting</li> <li>• Transient change in respiratory rate/respiratory distress.</li> </ul> <p><b>Note:</b> There is a risk of the development of lactic acidosis when iodinated contrast agents are administered to diabetic patients treated with metformin, particularly in those with impaired renal function.</p> |
| <b>Advice</b>   | <ul style="list-style-type: none"> <li>• Individuals should be informed that they may experience a metallic taste, hot flush or a sensation of passing urine during administration and that this is normal &amp; transient.</li> </ul>   |



## Radiographers Contrast Agent PGD Formulary

| <b>Iohexol (Omnipaque®) 140mg I/mL, 240mg I/mL, 300mg I/mL or 350mg I/mL solution for injection</b> |   |
|---|---|
|   | <ul style="list-style-type: none"> <li>• Individuals should be advised to drink plenty of fluid following the procedure if possible</li> <li>• If relevant advise on the management of injection site/s and any infection control or self-management required.</li> <li>• Individual should be informed that whilst uncommon a mild allergic reaction such as a rash, itchiness, feeling hot or cold, runny nose, watery eyes can occur and that they must inform a healthcare professional if they experience these symptoms.</li> </ul> |
| <b>Follow up (If applicable)</b>  | <ul style="list-style-type: none"> <li>• Individuals should be assessed prior to being discharged from the department for any adverse effects from the administered agent or for any signs of extravasation.</li> <li>• Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.</li> </ul>   |
| <b>Storage</b>  | <ul style="list-style-type: none"> <li>• Store below 30°C and store in outer carton to protect from light.</li> <li>• Stock must be securely stored in a lockable cupboard and be protected from light.</li> <li>• Contrast agent should be warmed to body temperature prior to administration.</li> </ul>  |

## Radiographers Contrast Agent PGD Formulary

| <b>Iomeprol (Iomeron®) 400 solution for injection</b> |   |
|---|---|
| <b>Indication</b>                                     | <p>Imaging procedures within the Radiology/ Radiotherapy Department to allow the visualisation of blood vessels, solid organs and other organs.</p> <p><b>NOTE:</b> Follow local individual Board protocols.</p>  |
| <b>Inclusion Criteria</b>                             | <p>As per main PGD inclusion criteria and additionally;</p> <ul style="list-style-type: none"> <li>• Individuals 2 years of age and over</li> <li>• Individuals with an estimated glomerular filtration rate (eGFR) of <math>\geq 30\text{mL}/\text{min}/1.73\text{m}^2</math>.</li> </ul>  |
| <b>Exclusion Criteria</b>                             | <p>As per main PGD exclusion criteria and additionally:</p> <ul style="list-style-type: none"> <li>• Previous adverse drug reaction (allergic, hypersensitivity or other) after administration of a contrast agent</li> <li>• Known renal impairment with an estimated glomerular filtration rate (eGFR) of <math>&lt; 30\text{mL}/\text{min}/1.73\text{m}^2</math></li> <li>• Pregnancy</li> <li>• Any history documented in the radiology/imaging referral/request of:               <ul style="list-style-type: none"> <li>○ Manifest thyrotoxicosis</li> <li>○ Congestive heart failure, severe cardiac disease or pulmonary hypertension</li> <li>○ Homocystinuria</li> <li>○ Sickle cell disease</li> <li>○ Severe liver impairment or peri-operative liver transplant period</li> <li>○ Asthma which is poorly controlled at the time of procedure</li> <li>○ Myeloma.</li> </ul> </li> </ul>  |
| <b>Precautions and Special Warnings</b>               | <ul style="list-style-type: none"> <li>• <b>Previous history of any adverse drug reaction to an intravascular contrast agent not listed in the exclusion criteria.</b> Caution should be exercised where there is a known previous moderately severe reaction to intravascular contrast such as bronchospasm or urticaria requiring treatment or severe reactions (e.g. laryngeal or angioneurotic oedema, severe bronchospasm or collapse) to intravascular contrast. Any individual known to have had a previous moderately severe or severe reaction to contrast agent should be discussed with the supervising Radiologist, Clinical Oncologist (or other medically qualified imaging expert) prior to administration of contrast agents under this PGD. If the practitioner acting under this PGD decides to continue to administer the named agent under the PGD a full record of the decision must be made in the individual's clinical record.</li> </ul> |

## Radiographers Contrast Agent PGD Formulary

### **Iomeprol (Iomeron®) 400 solution for injection**

- Any history documented in the radiology referral/request of paraproteinaemias (multiple myeloma and Waldenstrom's macroglobulinaemia– increased risk of renal impairment) or hypercalcaemia.
- Breastfeeding.
- History of severe/multiple allergy including food allergies, hay fever and urticaria that has required medical intervention.
- Dehydration – General assessment of the individual should be undertaken to ensure they are not dehydrated (e.g. acute/recent vomiting or diarrhoea reported or reduced fluid intake).
- Care should be taken in individuals with serious cardiac disease /cardio-circulatory disease and pulmonary hypertension
- In patients with phaeochromocytoma caution is advised as these patients may be at risk of developing hypertensive crisis following large doses of Iomeron.
- Like with other contrast agents special precaution is necessary in individuals with a low threshold for seizures. Precautionary measures should be taken, e.g. close monitoring.
- The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis.
- There is a risk of the development of lactic acidosis when iodinated contrast agents are administered to diabetic individuals treated with metformin, particularly in those with impaired renal function.
- Individuals treated with interleukin-2 and interferons less than two weeks previously have been associated with an increased risk for delayed reactions. A specific risk of delayed skin rash is associated with Interleukin-2 therapy.
- The concomitant use of certain neuroleptics or tricyclic antidepressants can reduce the seizure threshold and thus increase the risk of contrast medium-induced seizures.
- Treatment with  $\beta$ -blockers may lower the threshold for hypersensitivity reactions, as well as necessitating higher doses of  $\beta$ -agonists when treating hypersensitivity reactions.
- It has been reported that cardiac and/or hypersensitive individuals under treatment with diuretics, ACE-inhibitors, and/or beta blocking agents are at higher risk of adverse reactions when administered Iomeprol (Iomeron® 400).

## Radiographers Contrast Agent PGD Formulary

| <b>Iomeprol (Iomeron®) 400 solution for injection</b> |   |             |                                    |                    |          |                     |       |         |              |
|---|---|-------------|------------------------------------|--------------------|----------|---------------------|-------|---------|--------------|
| <b>Legal Status</b>                                   | Iomeprol (Iomeron®) 400 solution for injection is a Prescription-only Medicines (POM).  |             |                                    |                    |          |                     |       |         |              |
| <b>Dose/Maximum total dose</b>                        | <p>The following are dose guidelines for intravenous use as set out in the SmPC for Iohexol (Iomeron® 400):</p> <p><b>CT enhancement in adults</b> (according to body weight, size and examination being done)</p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th style="text-align: left;">Examination</th> <th style="text-align: left;">Volume of Iomeron® 400 (25-150mLs)</th> </tr> </thead> <tbody> <tr> <td>Cardiac test bolus</td> <td>25-35mLs</td> </tr> <tr> <td>Cardiac acquisition</td> <td>75mLs</td> </tr> <tr> <td>BMI &gt;30</td> <td>Up to 150mLs</td> </tr> </tbody> </table> <p>The lowest dose that provides sufficient enhancement for diagnostic purposes should be used.</p> <p><b>Maximum total dose allowed under this PGD is 150mLs.</b></p> | Examination | Volume of Iomeron® 400 (25-150mLs) | Cardiac test bolus | 25-35mLs | Cardiac acquisition | 75mLs | BMI >30 | Up to 150mLs |
| Examination   | Volume of Iomeron® 400 (25-150mLs)  |             |                                    |                    |          |                     |       |         |              |
| Cardiac test bolus                                    | 25-35mLs  |             |                                    |                    |          |                     |       |         |              |
| Cardiac acquisition                                   | 75mLs   |             |                                    |                    |          |                     |       |         |              |
| BMI >30   | Up to 150mLs  |             |                                    |                    |          |                     |       |         |              |
| <b>Frequency of dose/Duration of treatment</b>        | <p>Single dose for procedure indicated. However, repeated doses may be given under PGD in line with the following guidance (as a separate episode of care):</p> <ul style="list-style-type: none"> <li>Individuals with normal or moderately reduced renal function (eGFR &gt;30 and &lt;60 mL/min/1.73 m<sup>2</sup>) - 75 % of iodine-based contrast medium is excreted by 4 hours after administration. Therefore, there should be 4 hours between injections of iodine-based contrast medium.</li> </ul>  |             |                                    |                    |          |                     |       |         |              |
| <b>Maximum or minimum treatment period</b>            | See Frequency of dose/Duration of treatment section above.  |             |                                    |                    |          |                     |       |         |              |
| <b>Route/Method of Administration</b>                 | Intravenous injection by hand or by pump in accordance with local protocol.   |             |                                    |                    |          |                     |       |         |              |
| <b>Quantity to be administered</b>                    | Dependent on clinical requirement.  |             |                                    |                    |          |                     |       |         |              |

## Radiographers Contrast Agent PGD Formulary

| <b>Iomeprol (Iomeron®) 400 solution for injection</b> |   |
|---|---|
| <b>Potential Adverse Reactions</b>                    | <p>Refer to the product Summary of Product Characteristics (<a href="#">SmPC</a>) for full details of known adverse effects.</p> <p>The below list details only commonly reported adverse effects (&gt;1 in 100) and does not represent all the product's known adverse effects:</p> <ul style="list-style-type: none"> <li>• Feeling hot/flushed.</li> </ul>   |
| <b>Advice</b>   | <ul style="list-style-type: none"> <li>• Individuals should be informed that they may experience a metallic taste, hot flush or a sensation of passing urine during administration and that this is normal &amp; transient.</li> <li>• Individuals should be advised to drink plenty of fluid following the procedure if possible</li> <li>• If relevant advise on the management of injection site/s and any infection control or self-management required.</li> <li>• Individual should be informed that whilst uncommon a mild allergic reaction such as a rash, itchiness, feeling hot or cold, runny nose, watery eyes can occur and that they must inform a healthcare professional if they experience these symptoms.</li> </ul> |
| <b>Follow up (If applicable)</b>                      | <ul style="list-style-type: none"> <li>• Individuals should be assessed prior to being discharged from the department for any adverse effects from the administered agent or for any signs of extravasation.</li> <li>• Advise of the possible adverse effects and where to seek advice in the event of a suspected adverse reaction developing.</li> </ul>   |
| <b>Storage</b>  | <ul style="list-style-type: none"> <li>• Stock must be securely stored in a lockable cupboard and be protected from light.</li> <li>• Contrast agent should be warmed to body temperature prior to administration.</li> </ul>   |