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

PATIENT GROUP DIRECTION (PGD)

**Administration of contrast material in Speech and Language Therapy led Videofluoroscopic Swallowing Studies (VFSS) at \_\_\_\_\_\_**

**EZ-HD, EZ-Paque and Omnipaque**

Version Number 1.0

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| **Change History** | |
| **Version and Change details**  **Date** | |
| 1 | New PGD |

Patient Group Directions (PGDs) are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. The Directions are reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

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

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**PGD DEVELOPMENT GROUP**

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| Date PGD comes into effect: | Month/Year |
| Review date: | Month/Year |
| Expiry date: | Month/Year |

This PGD has been peer reviewed by the following staff and approved by the MIC Divisional Quality and Safety Committee.

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| **Name** | **Designation** |
|  | Clinical Service Lead Adult SLT |
|  | Therapy Lead |
|  | Clinical Lead Specialist SLT (Paediatrics) |
|  | Chief AHP |
|  | Deputy Chief Pharmacist |
|  | Consultant Radiologist |
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**Glossary**

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**ORGANISATIONAL AUTHORISATIONS**

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|  | **Name and Job title** | **Signature** | **Date** |
| **Senior doctor (for** | Consultant |  |  |
| **clinical area)** | Radiologist (GI} |  |
|  | Consultant |  |
|  | Radiologist (Paediatrics) |  |
| **Senior pharmacist (for**  **clinical area)** | Deputy Chief  Pharmacist |  |  |
| **Senior representative of professional group using the PGD** | Clinical Service Lead Adults & Professional Lead Speech & Language Therapy |  |  |
| **Chair of Non-Medical**  **Prescribing Committee** | Trust lead for advancing practice and NM prescribing |  |  |
| **Chair of Drugs and**  **Therapeutics Committee** |  |  |  |

1. **Characteristics of staff**

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| **Qualifications and professional registration** | Speech & Language Therapists employed by\_\_\_\_\_  , via agency, bank or other contracted routes such as an outsourcing service, with HCPC registration working in the department who have the appropriate and up to date skills and competencies for video fluoroscopy. |
| **Initial training** | The registered healthcare professional authorised to operate under  this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical diagnostic assessment of individuals with oropharyngeal dysphagia using a VFSS assessment.  They must have reviewed the purpose of a PGD as per information on this website: [https://www.gov.uk/government/publications/patient­](http://www.gov.uk/government/publications/patient) group-directions-pgds/patient-group-directions-who-can-use-them; and be aware of the guidance within The Medicines Administration Policy |
| **Competency assessment** | Staff operating under this PGD are encouraged to review their  competency using the NICE Competency Framework for health professionals using patient group directions  All SLTs working within the VFSS clinics should complete the appropriate competencies for their level of experience (Basic or Lead) as per the defined guidance within the SLT team. |
| **Ongoing training and competency** | Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.  Self-assessment of PGD competence will be completed on an annual basis as part of wider VFSS competencies recorded within the \_\_\_\_ SLT central competency log, which is reviewed and updated by the Clinical Service Lead Adult Speech & Language Therapy, within the wider Integrated Care Q&S governance structure.  All staff must maintain up to date Basic Life Support training |
| ***The decision to supply any medication rests with the individual registered health***  ***professional who must abide by the PGD and any associated organisation policies.*** | |

1. *Medicine 1 (Repeat* as *necessary for each condition included in PGD)*
   1. **Clinical condition or situation to which this PGD applies**

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| **Clinical condition or situation to which this PGD applies** | Assessment of oropharyngeal swallow via Videofluoroscopic  Swallow Study (VFSS) - Modified Barium Swallow Study. |
| **Criteria for inclusion**  Use BNF/BNFC/SPC,  considering any clinical guidelines or policies that are available locally or nationally, e.g.  BASHH/NICE/JCVI | All inpatients and outpatients accepted for a diagnostic VFSS by a  Speech and Language Therapist (SLT), in accordance with Trust VFSS guidelines (Adult and Paediatric versions). |
| **Criteria for exclusion** | Exclusions for use of barium sulfate patient would require  assessment with Omnipaque:   * Known or suspected perforation of the gastrointestinal tract. * Known or suspected trachea-oesophageal fistula (oral administration). * Gastrointestinal haemorrhage. * Gastrointestinal ischemia. * Megacolon or toxic megacolon. * Necrotising enterocolitis. * Severe ileus.   Other exclusions relating to clinical decision making around suitability for VFSS include the following, as outlined in Trust VFSS guidelines:   * Unable to tolerate at least a 5ml bolus orally. * Unable to comply with the demands of the swallow assessment, due to reduced level of alertness, impaired cognitive function, extreme pain, distress, fatigue or behavioural difficulties. * Unable to be positioned in appropriate seating, to maintain safe posture for swallowing. * Dysphagia of purely oesophageal aetiology, which has not been investigated with radiographic imaging or manometry. * Known or suspected adverse reaction to contrast media. * Nil by mouth (NBM) under medical/surgical team direction   e.g. for surgery. |
| **Cautions including any relevant action to be taken** | As per local VFSS guidelines, high risk patients may include the following:   * Suspicion of large volume aspiration. * Suspicion of undiagnosed cancers of head and neck, trachea or oesophagus. * Recent history of respiratory distress/arrest due to aspiration. * Presence of tracheostomy.   Please refer to the interactions section for full details of caution required. |

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| **Action to be taken if the individual is excluded** | Contrast required to perform the study, so if patient unable to have  contrast the study cannot be offered and an alternative objective assessment of swallowing should be considered, for example, Flexible Endoscopic Swallow Study (FEES) or Pharyngeal High­ Resolution Manometry (pHRM). This advice will be documented in the patient record and onward referrals, for example to community SLT will be made as appropriate. |
| **Action to be taken if the individual or carer declines treatment** | Contrast is required for the study, so if a patient declines treatment  they will be discharged from this pathway and an alternative assessment option (FEES or pHRM) offered if appropriate. This advice will be documented in the patient record and onward referrals, for example to community SLT will be made as appropriate. |
| **Arrangements for referral for medical advice** | Refer to the appropriate clinician or prescriber in the care pathway. |

* 1. **Description of treatment**

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| **Name, strength** &  **formulation of drug** | OMNIPAQUE 180/240/300 mg I per ml (lohexol) |
| **Legal category** | Omnipaque is a Prescription-only medicine (POM). |
| **Route** / **method of administration** | Oral |
| **Indicate any off-label use (if relevant)** | N/A |
| **Dose and frequency of administration** | Ominpaque will be offered as an oral solution, maximum dose  thresholds (per patient) are as follows: Omnipaque 300/180/240:  <3 months: Omnipaque 180: 5-30ml 3m-3 years: up to 60 ml  4-10 years: up to 100 ml  10+: up to 100 ml |
| **Duration of treatment** | The contrast material will be offered to a patient only as part of the diagnostic/therapeutic VFSS clinic. |
| **Quantity to be supplied** | **N/A** |
| **Storage** | Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk/) |
| **Drug interactions** | **Omnipaque** interactions are as follows (taken from [www.medicines.org.uk):](http://www.medicines.org.uk/)  Use of iodinated contrast media may result in a transient impairment |

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|  | of renal function, and this may precipitate lactic acidosis in diabetics  who are taking metformin.  Patients treated with interleukin-2 and interferons less than two weeks previously have been associated with an increased risk for delayed reactions (erythema, flu-like symptoms or skin reactions).  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 13 -blockers may lower the threshold for hypersensitivity reactions, as well as necessitating higher doses of 13  -agonists when treating hypersensitivity reactions.  Beta-blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists may reduce efficacy of cardiovascular compensation mechanisms of blood pressure changes.  All iodinated contrast media may interfere with tests on thyroid function; thus the iodine binding capacity of the thyroid may be reduced for up to several weeks.  High concentrations of contrast media in serum and urine can interfere with laboratory tests for bilirubin, proteins or inorganic substances (e.g. iron, copper, calcium and phosphate). These substances should therefore not be assayed on the day of examination. |
| **Identification** & **management of adverse reactions** | The following possible adverse effects have been reported with oral administration of **Omnipaque:**   * Gastrointestinal disorders:   + Very common: Diarrhoea.   + Common: Nausea, vomiting.   + Uncommon: Abdominal pain.   The following possible adverse effects have been reported with all uses of Omnipague (but may not reflect all reported adverse effects):   * Headache. * Mild to moderate pain including backache, neckache and stiffness. * Nausea, and vomiting. * Neuralgia . * Rash. * Erythema. * Pruritus. * Urticaria. * Skin discoloration .   A detailed list of adverse reactions for both contrast materials is available in the SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk/) |

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| **Management of and reporting procedure for adverse reactions** | * ***Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk*** * ***Record all adverse drug reactions (ADRs) in the individual's clinical record.*** * ***Report via organisation incident policy.*** * *If anaphylaxis management may be required the resuscitation team or nearby medical team in Imaging would be called.* |

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| **Name, strength** &  **formulation of drug** | E-Z-HD 98 % w/w barium powder for oral suspension  E-Z-Paque 96 % w/w barium powder for oral suspension |
| **Legal category** | E-Z-HD is a pharmacy medicine  E-Z-Paque is a pharmacy medicine |
| **Route** *I* **method of administration** | Oral |
| **Indicate any off-label use (if relevant)** | **N/A** |
| **Dose and frequency of administration** | All contrast materials (EZ-HD, EZPaque) must be administered  orally.  The EZ powders must be reconstituted prior to administration. Different liquid and solid textures are prepared to a specific recipe as per table below, to conform to the IDDSI texture descriptions (International Dysphagia Diet Standardisation Initiative). The volumes and textures offered may be discontinued if aspiration is witnessed.  The dose table below explains the prepared volume per VFSS clinic for adults and prepares enough contrast for a clinic involving up to 6 patients. Where fewer patients are assessed, the volume is reduced by the appropriate ratio: |

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|  | Dose guidance below provides information for paediatric VFSS using EZ-Paque:  Under 1's, immune-suppressed or if medically indicated   1. Shake the dry barium in the container first and tap the bottom to break up the barium. 2. Pour in 2 X 90ml containers of sterile water 3. Shake well ensuring all the barium is mixed   Over 1's   1. Shake the dry barium in the container first and tap the bottom to break up the barium. 2. Pour in tap water (provided by radiology) to the level of groove in the container 3. Shake well ensuring all the barium is mixed   Tap bottle on a hard surface (right side up) several times to compact the product in the bottle.   * Add water to the blue line marked 'Initial Fill Line' on the bottle. |

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|  | * Replace cap securely on the bottle. * Invert bottle and tap with fingers to mix contrast into the water. * Shake vigorously for 30 seconds; wait 5 minutes. * Add more water as needed to achieve the desired % w/v concentration using the fill lines marked on the bottle. Then, re-shake vigorously for 30 seconds. * To use with straw, remove adhesive label on top of cap. * Remove cap and use straw to push out cap liner; replace cap.   For paediatric VFSS using EZ-HD:  The dosage will be dependent on the size, age, health state and anatomical region to be imaged of the child. Individual requirements should be determined, from experience, by the SLT. |
| **Duration of treatment** | The contrast material will be offered to a patient only as part of the  diagnostic/therapeutic VFSS clinic. |
| **Quantity to be supplied** | **N/A** |
| **Storage** | Stock must be securely stored according to organisation medicines  policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk/) |
| **Drug interactions** | Barium sulfate is biologically inert and there are no known interactions with other medicinal products. However, the presence of barium sulfate formulations in the gastrointestinal tract may alter the absorption of therapeutic agents taken concomitantly. To minimise any potential change in absorption, the separate administration of barium sulfate from that of other medicines should be considered.  ***A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website:*** [***www.medicines.org.uk***](http://www.medicines.org.uk/) |
| **Identification** & **management of adverse reactions** | ***A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website:*** [***www.medicines.org.uk***](http://www.medicines.org.uk/) ***and BNF*** [***www.bnf.org***](http://www.bnf.org/)  The following possible adverse effects have been reported with use of Barium Sulfate (but may not reflect all reported adverse effects):  Skin and subcutaneous disorders together with immune system disorders, reflecting allergic reactions either to barium sulfate or the product excipients, are among the most commonly reported effects; for example, urticaria, erythema and rash.  Gastrointestinal disorders are also one of the most frequently reported class of undesirable effects; for example, diarrhoea, nausea, abdominal pain/distention, constipation.  A detailed list of adverse reactions for both contrast materials is |

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|  | available in the SPC, which is available from the electronic  Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk/) |
| **Management of and reporting procedure for adverse reactions** | * ***Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk*** * ***Record all adverse drug reactions (ADRs) in the individual's clinical record.*** * ***Report via organisation incident policy.*** * *If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team details)* |

1. **Key references**

* *Electronic Medicines Compendium* [*http://www.medicines.org.ukl*](http://www.medicines.org.ukl/)
* *Electronic BNF https:llbnfnice.org.ukl*
* *NICE Medicines practice guideline "Patient Group Directions"* [*https://www.nice.org.uk/guidance/mpg2*](http://www.nice.org.uk/guidance/mpg2)

**Key references**

**Appendix A- Registered health professional authorisation sheet (example** - **local versions/electronic systems may be used)**

**PGD Administration of contrast material in Speech and Language Therapy led Videofluoroscopic Swallowing Studies (VFSS) at XXX**

**Valid from: January 2025 Expiry: January 2028**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

**Registered health professional**

By signing this Patient Group Direction, you are indicating that you agree to its contents and that you will work within it.

Patient Group Directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

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| I **confirm that** I **have read and understood the content of this Patient Group Direction and that** I **am willing and competent to work to it within my professional code of conduct.** | | | |
| **Name** | **Designation** | Signature | Date |
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Authorising manager

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| I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of XXX for the above named health care professionals who have signed the PGD to work under it. | | | |
| Name | Designation | Signature | Date |
|  |  |  |  |

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

# Patient Group Direction Audit Tool

1. **Operational audit**

To be completed once for each service using the PGD

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|  | **Questions** | **Yes/No** |
| **1.1** | I Do staff always have access to a copy of the latest version of the PGD they are working under available for reference at the time of the  consultation? |  |
| **1.21** | Have all staff working under the PGD signed the latest version of that PGD? |  |
| **1.3** | Are all staff working under the PGD competent to work under that PGD? (Either signed off by their senior clinician/manager or self-  certified.) |  |
| **1.4** Are all staff authorised to work under the PGD employed as one of the registered health professions listed in the PGD? | |  |
| **1.5** Is there an up-to-date list held within the service, of all staff authorised to work under each PGD in use? | |  |
| **1.6** Have all staff completed the necessary training and continuing professional development specified in the PGD/s they are authorised to  work under? | |  |
| **1.7** I Is there an up-to-date record within the service of all staff who have attended any required specific PGD training? | |  |

# Patient level audit

To be completed for a sample of 10 patients

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|  | **Questions** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
| **2.1** | I Is there a statement/record or order in the patient's electronic record that supply  and/or administration of the medicine was made using a PGD? |  |  |  |  |  |  |  |  |  |  |
| **2.2** | I Does the Patient Record contain details of the medicine supplied or  administered (name, strength, dose, quantity, route)? |  |  |  |  |  |  |  |  |  |  |
| **2.3** Does the patient's condition fit with the condition criteria of the PGD? | |  |  |  |  |  |  |  |  |  |  |
| **2.4** Was the drug administration/supply documented in accordance with the PGD? | |  |  |  |  |  |  |  |  |  |  |
| **2.5** Was the right drug strength administered/supplied? | |  |  |  |  |  |  |  |  |  |  |
| **2.6** Was there any adverse reaction? | |  |  |  |  |  |  |  |  |  |  |
| **2.7** Is there a record of any written or verbal information/advice that was given to the  patient when supplying/administering any medicine under any given PGD? | |  |  |  |  |  |  |  |  |  |  |
| **2.8** I Did the patient need any follow up? E.g. was the patient referred to a doctor for  further advice or after a stat dose as per the PGD? If so, why? | |  |  |  |  |  |  |  |  |  |  |
| **2.9** I Is the person administering or supplying included in the list held locally by the  senior nurse? | |  |  |  |  |  |  |  |  |  |  |

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| PGD audit completed by |  | Date |  |