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| **Medication Standing Order** |

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| **ADULT** | **Macrocyclic gadolinium containing MRI contrast agent**  *Standing order for the intravenous administration of gadobutrol (Gadavist® or Gadovist® 1.0) as an example for magnetic resonance imaging (MRI) studies in ADULTS* |
| **Applicable areas** | Public health organisation imaging departments |
| **Validity and areas where standing order NOT applicable** | Validity:  This standing order has been approved by the (insert name of hospital district), Drug and Therapeutics Committee (DTC) and is only valid until (insert the date).   * Changes to this standing order must be approved by a radiologist or another medical officer with final approval required by the relevant hospital/district DTC. This standing order only applies in public health organisation imaging departments using the *MRI gadolinium contrast administration* form.   Non applicable areas:   * **All other areas outside of public health organisation imaging departments** (local health district (LHD) to determine).   This standing order is not applicable when:   * Patient is less than 16 years of age. * There are identified contraindications. For example: * No contrast for epilepsy unless for first seizure. * Peritoneal dialysis: Avoid all gadolinium-based MRI contrast agents in patients receiving peritoneal dialysis. Patients on peritoneal dialysis have both reduced clearance of gadolinium and increased volume of distribution.1 * The patient or their authorised representative is unable to provide information as required by the *MRI gadolinium contrast administration* form(e.g. patient is unconscious, has cognitive impairment or during a medical emergency). * It is unclear from the medical imaging request whether a protocol using intravenous (IV) contrast should be followed (refer to supervising radiologist).   In all the cases above an electronic or paper-based prescription by a radiologist or medical officer must be obtained prior to MRI contrast administration and documented on the *MRI gadolinium contrast administration* form. |
|  | In order to be authorised to administer IV gadobutrol MRI (or other macrocyclic gadolinium-containing agent) contrast under this standing order, accredited medical radiation scientists and registered nurses must:   * meet Australian Health Practitioner Regulation Agency (AHPRA) registration requirements * have successfully completed HETI My Health Learning education module – *Contrast Administration*, HETI Course Code: 172277411 * have successfully completed HETI My Health Learning education module – *Aseptic Technique*, HETI Course Code: 40027445 * have current basic life support accreditation   **AND**   * have been regularly assessed and deemed to be competent to administer and check IV contrast (according to LHD requirements).   In accordance with [Policy Directive: Medication Handling in NSW Public Health Facilities PD2022\_0](https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2022_032.pdf)32  Section 7.4:  “In the absence of an authorised prescriber, medication administration (or supply for administration where applicable) during routine procedures and under certain programs conducted at or by a facility may be carried out under a standing order.”2  Section 7.1 outlines who can administer contrast agents; that is:  ”registered nurses, enrolled nurses (certified), but only in accordance with any practice conditions imposed by the person’s place of employment and the endorsements, notations and conditions on the person’s registration.  Other appropriately trained and accredited staff members may be authorised to administer certain medications and/or diagnostics agents within their context of practice at the particular facility in accordance with local protocols.”2  There must always be a medical officer (MO) immediately available in all situations where an IV macrocyclic gadolinium-containing agent is administered by an authorised clinician, to respond to an adverse event.1 |
| **Standing order applies to** | Gadobutrol *(*or other macrocyclic gadolinium-containing agent) is a chelate with a cyclic structure which is more stable than linear molecules such as gadobenate, gadodiamide, gadopentetate, and gadoversetamide.  Suitable for adult patients (16 years and older) requiring intravenous gadolinium-based contrast MRI studies (e.g. cardiac, breast, central nervous system, musculoskeletal and magnetic resonance angiography applications) with no identified contraindications or ‘red flags’ on the *MRI gadolinium contrast administration* form.  N.B. This order may only be activated under the specific circumstances set out in the section ‘indications for use under this standing order’ and provided there are no contraindications present.  This standing order is to be used in conjunction with any additional clinical business rules (insert name of your intravenous macrocyclic gadolinium-containing contrast) or product information links for example:  <https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2012-CMI-01912-3>  **If a ‘red flag’ is noted in the *MRI gadolinium contrast administration* form*,* NH700649, this standing order does not apply.** |
| **Indications for use under this standing order** | For use where IV injection of gadolinium-based contrast agents (or other macrocyclic gadolinium-containing agent) can improve tissue visualisation for contrast MRI studies.  The Bayer product information (PI) for gadobutrol (Gadovist®) outlines indications for use of gadobutrol as:  Gadobutrol “is indicated in adults for:   * contrast enhancement in cranial and spinal MRI * contrast enhancement in whole body MRI including head and neck region, thoracic space, breast, abdomen (pancreas, liver and spleen), pelvis (prostate, bladder and uterus), retroperitoneal space (kidney), extremities and musculoskeletal system * use in first-pass MRI studies of cerebral perfusion (see ‘Precautions’ section of this standing order) * contrast enhancement in magnetic resonance angiography (CE MRA).”3   Gadobutrol should only be used:   * when no absolute or relative contraindications are identified on the *MRI gadolinium contrast administration* form (change to relevant name at LHD) * if relative contraindications or clinically relevant conditions have been identified on the *MRI gadolinium contrast administration* form (change to relevant name for LHD), a radiologist or medical officer has been consulted and approved administration.   In circumstances where the patient or their authorised representative has not been able to provide information to complete the *MRI gadolinium contrast administration* form (change to relevant name for LHD), the referrer provides a written or electronic request for a MRI examination that includes sufficient information to demonstrate the medical necessity of the examination, including signs and symptoms and/or relevant history.  Additional information regarding the specific reason for the examination or a provisional diagnosis should also be provided to ensure that the correct protocol is followed, including the need for a gadolinium-based contrast agent.1 Administration of contrast media (CM) to unconscious patients should be in consultation with the radiologist. |
| **Presentation** | Gadobutrol is a clear, colourless-pale yellow, preservative-free solution with each mL containing 604.72mg (1.0mmol) of gadobutrol.  Gadobutrol is available as:   * glass vials of 15mL * glass prefilled syringes with various volumes: 5mL, 7.5mL, 10mL.   <*Please amend this section for other macrocyclic gadolinium-containing agent>* |
| **Contra-indications** | Intravenous gadobutrol must not be administered under this standing order to patients with:   * known significant hypersensitivity * previous allergic reactions to contrast agents.   <Please amend this section for other macrocyclic gadolinium-containing agent> |
| **Precautions** | For specific precautions please refer to product information based on product used <Insert your LHD/department specific product information hyperlink here>.  See Royal Australian and New Zealand College of Radiologists (RANZCR) [*Guideline on the use of Gadolinium-containing MRI Contrast Agents in Patients with Renal Impairment*](https://www.ranzcr.com/college/document-library/gadolinium-containing-mri-contrast-agents-guidelines), Version 3, released 2019.1  The RANZCRhave identified patients with increased risk of adverse reaction as those who:   * have had a previous reaction to a gadolinium chelate * have had a previous reaction to iodinated contrast * have had a previous reaction to other medical or non-medical substances * have asthma * are pregnant * are lactating * are patients with end-stage, severe and (possibly) moderate renal failure.4   Risk stratification is performed according to clinical assessment and reported estimated glomerular filtration rate (eGFR).1, 5  eGFR risk levels should be considered. See Table 1 below.  **Table 1. eGFR Risk levels**  eGFR Risk Action   |  |  |  | | --- | --- | --- | | 30-60mL/min | Small risk of nephrogenic systemic fibrosis (NSF), caution with the use of higher risk gadolinium-based contrast agents (GBCA) particularly in pregnant or lactating patients. | Refer to local business rules | | 15-30mL/min | Low risk of NSF (~0.1% per dose). High risk GBCA contraindicated and other agents should only be used after careful consideration. | Refer to local business rules | | <15mL/min | Significant risk of NSF (~1% per dose). High risk GBCA contraindicated and other agents should only be used after careful consideration. | Refer to radiologist/MO |   “Biochemical screening of patients for renal impairment is not thought warranted**, in the absence of relevant symptoms or history. Specific questions about renal disease should be included in the contrast administration checklist.” 4(p23)**  In patients with no risk factors and eGFR >60mL/min there is no recognised risk factors for kidney disease and risk of contrast-induced nephropathy (CIN) is negligible.  **Patients with severe or end-stage renal impairment, have often been defined as an eGFR of <30mL/min/1.73msq, MRI examination without a gadolinium-based contrast agent, or with another modality, should be considered.**4   * Patients undergoing haemodialysis are at high risk of NSF (>1% per dose). For these patients, a computerised tomography (CT) scan with iodinated contrast should be considered if appropriate, especially if the patient is anuric as there is no longer a risk of nephrotoxicity. * If absolutely necessary a low-risk gadolinium-based contrast agent at the lowest possible dose should be used and haemodialysis should be scheduled immediately post the MRI examination, ideally with a second session within 24 hours and a third session considered. * Patients undergoing peritoneal dialysis should avoid all gadolinium-based contrast agent.4 |
| **Adverse effects** | **Example for gadobutrol <**Please amend this section for other macrocyclic gadolinium-containing agent>  **Summary of the safety profile**  The overall safety profile of gadobutrol is based on data from more than 6,300 patients in clinical trials, and from post-marketing surveillance.  The most frequently observed adverse drug reactions (>0.5%) in patients receiving gadobutrol are headache, nausea and dizziness.  The most serious adverse drug reactions in patients receiving gadobutrol are cardiac arrest and severe anaphylactoid reactions. Delayed allergic reactions (hours later up to several days) have been rarely reported. Frequency **of adverse reactions can be seen in the table below.**3  **Table 2: Adverse drug reactions based on clinical trial data and post-marketing surveillance**3   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **System organ class** | **Common**  **(≥1/100 to <1/10)** | **Uncommon**  **(≥1/1,000 to <1/100)** | | **Rare**  **(<1/1,000)** | | **Immune system disorders** |  | Hypersensitivity/anaphylactoid reaction  (e.g. hypotension, urticaria, face oedema, eyelid oedema, flushing) | | | | **Nervous system disorders** | Headache | Dizziness  Dysgeusia  Paraesthesia | Loss of consciousness  Convulsion  Parosmia | | | **Cardiac disorders** |  | Tachycardia  Palpitations | | | | **Respiratory, thoracic and mediastinal disorders** |  | Dyspnoea | | | | **Gastrointestinal disorders** | Nausea | Vomiting | | Dry Mouth | | **Skin and subcutaneous tissue disorders** |  | Erythema  Pruritus (including generalised pruritus)  Rash (including generalised, macular, popular, pruritic rash) | | | | **General disorders and administration site conditions** |  | Injection site reaction  Feeling hot | | Malaise  Feeling cold |      * No harmful effects of gadolinium retention in the brain have been identified by the Therapeutic Goods Association (TGA). 6   Studies in the last 10 years have suggested that some gadolinium may be retained in the brain and other tissues such as the bone. Multiple studies have shown that gadolinium deposits can be seen as hyper-intensities on the dentate nucleus on unenhanced T1-weighted MRI images of patients with repeat exposure to linear gadolinium-based contrast agents. Patients exposed only to macrocyclic gadolinium-based contrast agents show no such association. The increased signal intensity happens in patients with normal renal function and the signal intensity changes may be a consequence of the number of previous gadolinium-based contrast agent administrations.6  To date no adverse effects have been proven to be caused by this gadolinium retention however very little is known about how and why this happens or the long-term consequences. It is not yet known what the likely time of retention for gadolinium is. It is not known what chemical form it has when retained but this is likely to vary depending on the different contrast agent.6, 7, 8  Bayer’s Gadavist*®* product information (last updated March 2021) states:  While clinical consequences of gadolinium retention have not been, established in patients with normal renal function, certain patients might be at higher risk. These include patients requiring multiple lifetime doses, pregnant and paediatric patients, and patients with inflammatory conditions. Consider the retention characteristics of the agent and minimise repetitive gadolinium-based contrast agents studies when possible.3  **Allergic reaction**  Obtain a history of allergy or hypersensitivity reactions to contrast agents and always have emergency resuscitation equipment and trained personnel available prior to contrast agent administration.  Monitor all patients for hypersensitivity reactions. Some of the symptoms of an allergic reaction may include:   * shortness of breath * wheezing or difficulty breathing * swelling of the face, lips, throat, tongue or other parts of the body * rash, itching or hives on the skin.9   **There is an increased risk in patients with a history of a previous reaction to contrast agent, and known allergies (e.g. bronchial asthma,** **drug or food allergies) or other hypersensitivities.**  Premedication with antihistamines or corticosteroids does not prevent serious life-threatening reactions but may reduce both their incidence and severity.10  **Asthma**  A risk benefit analysis should be done for any poorly controlled asthma. |
| **Adverse effects** | **Contrast-induced acute kidney injury**  On a volume for volume basis, MRI contrast agents can be just as nephrotoxic as those used for computerised tomography (CT) scans. Staff should therefore **be aware of current nephrotoxic drugs being taken by the patient.** Renal impairment has been reported in the literature.10  Severe renal impairment and liver transplant patients:   * No impairment of renal function has so far been observed. * Prior to administration of gadobutrol all patients should be screened for renal dysfunction by obtaining a history and/or laboratory tests. * In patients with severely impaired renal function the benefits must be weighed carefully against the risks, since contrast medium elimination is delayed in such cases.   Because gadobutrol is renally excreted, a sufficient period of time for elimination of the contrast agent from the body prior to any re-administration in patients with renal impairment should be ensured. Usually, complete recovery in the urine was seen in patients with mild or moderate renal impairment within 72 hours. In patients with severely impaired renal function at least 80% of the administered dose was recovered in the urine within 5 days.3  **Nephrogenic systemic sclerosis**  Please see the MRI contrast agents by the RANZCR:  “Patients with severe renal disease who receive MRI contrast agents are at risk of ‘nephrogenic systemic sclerosis’, a rare, recently recognised fibrosing disorder which can be crippling, and can contribute to death…. For this reason, it is very important that MRI sites be informed if the patient has known significant (eGFR <30 mL/min/1.73m2) renal impairment. If risk factors for potential renal impairment are present, a recent (<3 months old) eGFR result will be required before administration of an MRI contrast agent will be considered.  For patients with significant medical illness in the three months preceding MRI, and for hospital inpatients, a more recent eGFR (timing will be related to the nature, severity and timing of the illness) is a wise precaution.”5  **Severe cardiovascular disease**  In patients with severe cardiovascular disease, gadobutrol should only be administered after careful risk-benefit assessment because to date only limited data are available.  Patients taking beta blockers who experience hypersensitivity reactions may be resistant to treatment with beta agonists.  **Seizure disorders**  As with other gadolinium-chelate-containing contrast media, special precaution is necessary in patients with a low threshold for seizures.  Extravasation and injection site reactions  Extravasation of contrast media during intravascular injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure intravascular placement of catheters prior to injection. Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.  **Breastfeeding**  Breastfeeding is not a contraindication to MRI or MRI contrast agents.9 The amount of MRI contrast agent excreted into breast milk is extremely small, and little of it is absorbed from the infant gut. Therefore, it is not necessary for lactating women to stop breastfeeding before or after having a MRI, nor does breast milk need to be manually expressed and discarded after the MRI scan.  **Pregnancy**  Although pregnancy is not an absolute contraindication to gadolinium-based contrast agent administration, it is approached with great caution. The safety of the fetus cannot be confirmed but the current evidence suggests that although small amount of gadolinium-based contrast agent does appear to cross the placental barrier and circulate within the fetus, this contrast is excreted by the kidneys into the bladder of the fetus soon after. Studies in rats have shown high clearance rates so it is believed that the gadolinium-based contrast agent diffuses back across the placenta to the mother. No carcinogenic or mutagenic effects have been documented and studies of mice in utero show no teratogenic or other long-term effects to gadolinium-based contrast agent exposure.11  If the pregnancy status of the patient is in doubt, a pregnancy test (serum Beta hCG) should be conducted to help determine the risk-benefit analysis. If the MRI study is deemed important to the health of the mother, the referring specialist and supervising radiologist need to consult. The decision to recommend contrast is at their discretion and the patient also needs to consent after being informed of the risks and benefits.12  **Important drug interactions**  Delayed reactions (from hours up to several days) have been rarely observed. Most of these reactions occur within half an hour of administration. Therefore, post-procedure observation of the patient is recommended.  For the management of adverse events please refer to local procedures.13, 14 |
| **Dosage guideline** | <Contrast agent name>: XXX Milligram/mL (based on product information)  <Specific procedures may have specific amounts – to be defined by LHD>  In the event the dose given to the patient exceeds the limits set by this standing order, a verbal order for the additional volume can be performed by the radiologist. This should be followed by electronic or paper confirmation of contrast dose and volume within the patient’s health record within 24 hours by the ordering radiologist.  The following sections provide an example of the dosage information for the standing order from the *Gadovist® 1.0 Gadbutrol Australian Product Information*, revised 12 February 2020:  **Dosage**  **Adults**  Dosage depends on indication. A single intravenous injection of 0.1mmol Gadovist® 1.0 per kg body weight (equivalent to 0.1mL Gadovist® 1.0 per kg body weight) is generally sufficient. A total amount of 0.3mmol Gadovist 1.0 per kg body weight (equivalent to 0.3mL Gadovist® 1.0 per kg body weight) may be administered at maximum.  **Cranial and spinal MRI**  0.1mmol Gadovist® 1.0 per kg body weight (equivalent to 0.1mL Gadovist® 1.0 per kg body weight), given intravenously at a rate of 2mL per second.  In some investigations use of further doses of 0.1mmol Gadovist® 1.0 per kg body weight (equivalent to 0.2mL Gadovist® 1.0 per kg body weight) or 0.2mmol Gadovist® 1.0 per kg body weight (equivalent to 0.3mL Gadovist® 1.0 per kg body weight) may yield additional information.  **CE MRI of the whole body**  0.1 mL/kg body weight of the 1.0 mmol/mL Gadovist® 1.0 solution (equivalent to 0.1 mmol/kg body weight) is recommended and is generally sufficient to answer clinical questions.  **Cerebral perfusion studies**  For gradient echo sequences, 0.1-0.3 mmol Gadovist® 1.0 per kg of body weight (equivalent to 0.1-0.3mL Gadovist® 1.0 per kg body weight) Gadovist® 1.0 given intravenously at a rate of 5mL per second using a powered injector is recommended.  **Contrast-enhanced magnetic resonance angiography (CE MRA)**  Imaging of one field of view:  7.5mL for body weight less than 75kg  10mL for body weight of 75kg or more  (Corresponding to 0.1-0.15mmol per kg body weight)  Imaging of more than one field of view:  15mL for body weight less than 75kg  20mL for body weight of 75kg or more  (Corresponding to 0.2-0.3 mmol per kg body weight)  **CE myocardial perfusion imaging and delayed enhancement**  The recommended dose is 0.05mL/kg body weight during pharmacological stress and 0.05mL/kg body weight at rest of the 1.0 mmol/mL Gadovist® 1.0 solution (equivalent to a total dose of 0.1mL/kg body weight or 0.1mmol/kg body weight).  For delayed enhancement only, a total dose of 0.1 mL/kg body weight is also recommended.  Determine the volume of gadobutrol injection to be used taking into account factors such as:   * age * body weight * size of the vessel and the rate of blood flow within the vessel * extent of opacification required * structure(s) or area to be examined * disease processes affecting the patient * and equipment and technique to be employed.   <Please amend this section for other macrocyclic gadolinium-containing agent> |
| **Duration of therapy** | Each DOSE is individually ordered (once only). |
| **Administration instructions** | Prepare immediately before administration.  Administration should be according to the product information for the gadobutrol <or other macrocyclic gadolinium containing agent>  The below information is an example:  Visually inspect <contrast agent> for particulate matter and/or discolouration, whenever solution and container permit. Do not administer <contrast agent name> if particulate matter and/or discolouration is observed.  The rate of administration will be determined by patient weight, scan type, venous access device and patency of peripheral intra venous cannula (PIVC). For patient safety, the aim is to administer at the lowest possible rate (volume/dose) necessary to provide optimum image quality.  Flushing of the cannula should be performed between administrations of <contrast agent name> and other drugs with sodium chloride 0.9%. This should be an aseptic technique. Please check product information.  **You must not administer gadobutrol contrast after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.** |
| **Compatibilities** | Although no incompatibility has been found, IV gadobutrol <or other macrocyclic gadolinium-containing agent> should not be directly mixed with other drugs. A separate syringe should be used and the IV cannula should be flushed between administrations of <contrast agent name> and other drugs with sodium chloride 0.9%. |
| **Standing order**  **The following table is to be completed by individual sites/LHD:**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Scan region | Medication | Dose  (mL) | Rate  (mL/s) | Route | Frequency | |  | <contrast media name> (gadobutrol) | <Insert> | <Insert> | IV | <insert> | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | |  |  |  |  |  |  | | |
| **Monitoring requirements** | The patient must be monitored for adverse effects for at least 15 minutes after the administration of IV contrast **before** the removal of the cannula, as most adverse reactions occur in this time.  Patients identified to be at a greater risk of reaction require extended monitoring of up to 15-30 minutes, depending on the procedure. |
| **Management of complications** | Management of complications should be determined by LHD and according to the product information for the product used.  **Allergic or anaphylactic reactions**  Allergic and anaphylactic reactions should be assessed and treated on their severity in accordance with the relevant local guidelines.  **Adverse reactions**  If any adverse reactions are observed during administration:   1. Cease administration immediately (if in progress). 2. Call for assistance including request for urgent medical assistance. 3. Leave the cannula in situ. 4. Provide basic life support.   The full management of anaphylactic contrast reaction is also described in the RANZCR *Iodinated Contrast Media Manual*:  “R55. Adrenaline is potentially life-saving and must be used promptly. Withholding adrenaline due to misplaced concerns of possible adverse effects can result in deterioration and death of the patient.“4(p29) |

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| **Management of complications** | **Delayed reactions**  Delayed allergic reactions (hours later up to several days) have been rarely observed. Most reactions occur in the first 30 minutes post injection.  **Extravasation**  Extravasation of a contrast medium during intravascular injection may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease. Ensure intravascular placement of catheters prior to injection.  Monitor patients for extravasation.  If contrast media extravasation occurs, conservative treatment with limb elevation, cold or warm compresses and monitoring for compartment syndrome is recommended. Surgical referral is required if compartment syndrome should develop. Specific documentation of the adverse event is required as per LHD policy/procedure.  Further information: [Contrast agent product information sheets](https://www.radiologysolutions.bayer.com/products/contrast-agents/gadavist-injection-pi),[NICE guidelines](http://www.nice.org.uk/guidance/cg169/evidence)or other product information.3, 9, 15  **Renal impairment**  This may occur after leaving the medical imaging department. Manage as per local procedures/protocols.13, 14 |
| **MRI documentation requirements** | Documentation must be undertaken as per legal requirements and LHD policy.  Record the administration on *MRI Gadolinium Contrast Administration form* including:   * dose * batch number * volume * route of administration * performing staff member.   The *MRI gadolinium contrast administration* formis to be placed in the paper file and/or scanned into the patient’s electronic health record at completion of the examination. The paper file can act as a contingency when networks are down.  Any adverse events must be:   * notified to the prescriber * documented in the alerts in the clinical information system * documented in the radiology report and/or patient health care record * entered into incident management system (IMS+) as a clinical incident with principal incident type – medication * reported to the TGA by completing a ‘*Blue card’ form* from Adverse Drug Reactions Advisory Committee (ADRAC) and a copy provided to pharmacy * reported to the pharmaceutical company.   A letter should be provided to the GP/referrer including the radiologist report and any adverse reactions. |
| **Standing order review and approval** | The information in the standing order must be dated and **reviewed annually** by the DTC to ensure currency. |
| **References** | 1. Royal Australian and New Zealand College of Radiologists. Guideline on the use of Gadolinium-containing MRI Contrast Agents in Patients with Renal Impairment, Version 3 [Internet]. Sydney: RANZCR; 2019 [cited 24 September 2021]. Available from: [Gadolinium-containing MRI Contrast Agents Guidelines | RANZCR](https://www.ranzcr.com/college/document-library/gadolinium-containing-mri-contrast-agents-guidelines) 2. NSW Ministry of Health. Medication Handling (PD2022\_032) [Internet]. Sydney: NSW Ministry of Health; 2022 [cited 26 October 2022]. Available from: <https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2022_032> 3. Bayer Pharmaceuticals. Gadavist® (gadobutrol) injection 1mmol/mL [Internet]. USA: Bayer Pharmaceuticals; 2021 [cited 10 November 2021]. Available from: <https://www.radiologysolutions.bayer.com/products/contrast-agents/gadavist-injection-pi> 4. The Royal Australian and New Zealand College of Radiologists, Faculty of Clinical Radiology. MRI Safety Guidelines. Sydney: RANZCR; 2013. Guidance for GP Referrals for MRI Studies. 5. NSW Agency for Clinical Innovation. CIN - Risk Assessment and Prevention Strategies [Internet]. Sydney: ACI; 3 Dec 2020 [cited 24 September 2021]. Available from: <https://aci.health.nsw.gov.au/networks/eci/clinical/clinical-tools/renal/contrast-induced-nephropathy/cin---risk-assessment-and-prevention-strategies> 6. Clinical Excellence Commission. Safety Information 002/17 Gadolinium-based contrast agents for MRI scans [Internet]. Sydney: NSW Ministry of Health; 15 August 2017 [cited 24 September 2021]. Available from: <https://www.health.nsw.gov.au/sabs/Documents/2017-si-002.pdf> 7. McDonald RJ, Levine D, Weinreb J, et al. Gadolinium Retention: A Research Roadmap from the 2018 NIH/ACR/RSNA Workshop on Gadolinium Chelates. Radiology. 2018;289(2):517-534. 8. McDonald RJ, [McDonald](https://pubs.rsna.org/author/McDonald%2C+Jennifer+S) JR, [Kallmes](https://pubs.rsna.org/author/Kallmes%2C+David+F" \o "David F. Kallmes) DF, et al. Intracranial Gadolinium Deposition after Contrast-enhanced MR Imaging. Radiology. 2015 Jun;275(3):772-82. 9. New Zealand Medicines and Medical Devices Safety Authority. Gadovist® 1.0 Consumer Medicine Information (CMI) summary [Internet] NZ: Medsafe; December 2020 [cited 17 October 2019]. Available from: <http://medsafe.govt.nz/consumers/cmi/g/gadovist.pdf>   American College of Radiology Committee on Drugs and Contrast Media. ACR Manual on Contrast Media [Internet]. USA: ACR; 2021 [cited 24 September 2021]. Available from: <https://www.acr.org/-/media/ACR/files/clinical-resources/contrast_media.pdf>  [Garcia-Bournissen](https://scholar.google.com.au/citations?user=2yswuAMAAAAJ&hl=en&oi=sra) F, Shrim A, [Koren](https://scholar.google.com.au/citations?user=CrO0R1kAAAAJ&hl=en&oi=sra) G. [Safety of gadolinium during pregnancy.](https://www.cfp.ca/content/52/3/309.short) Canadian family physician. 2006 Mar 1;52(3):309-10.  Sotamba Jimenez JJ. [Analysis of the patient risk, evaluation of the internal regulations and generation of national normative of security](https://201.159.223.86/handle/123456789/192). Magnetic Resonance Imaging. 2020.   1. <Enter any other contrast media product information based on LHD-nominated product, using the referencing format: Author. Page or document title [Internet]. Place of the sponsor of the source: publisher; date page/site was created [date source was cited]. Available from: <URL> 2. <Enter any LHD specific protocol sites, using referencing format: Author. Page or document title [Internet]. Place of the sponsor of the source: publisher; date page/site was created [date source was cited]. Available from: <URL> 3. National Institute for Health and Care Excellence. Clinical guideline: Acute kidney injury: prevention, detection and management [Internet]. United Kingdom: NICE; 28 August 2013 [cited 25 May 2019]. Available from: <http://www.nice.org.uk/guidance/cg169/evidence> |

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| **Authorisation** | | |
| **Author** |  | |
| **Position** |  | |
| **Department/service/clinical network or stream** |  | |
| **Department/service/clinical network or stream contact** |  | |
| **Date authorised by department/service/clinical network or stream position/committee** |  | |
| **Governance** | | |
| **Enactment date** |  | |
| **Review date** |  | |
| **Ratification by Quality Use of Medicines Committee/Drug and Therapeutics Committee** |  |  |
| **Previous version of guideline removed** | Date: Not applicable | |
| **Approved guideline distributed** | Date: | |
| **Location** | MRI unit in radiology/medical imaging departments, or other MRI facilities (e.g. radiation oncology, nuclear medicine or cardiology) | |
| **Guideline number** |  | |
| **Replaces existing document? (If Yes, list previous registration numbers and dates of approval** |  | |
| **Version number** | 1.1 | |

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