Ochsner | LSU Health Shreveport	**POLICY #: Rad Proc 6.14.**
SUBJECT Use of Gadolinium Contrast	**Effective: 10/1/2018** **Revised: 2/2019**
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Purpose: **To provide guidelines for the safe use of gadolinium based contrast in imaging.**

Background: In 2006, FDA alerted the public about cases of nephrogenic systemic fibrosis (NSF) reported in patients who received gadolinium based contrast agents (GBCA). The information below provides a brief overview of NSF.

Nephrogenic systemic fibrosis, *originally named nephrogenic fibrosing dermopathy because it was thought to involve only the skin, is a systemic disease that involves the skin, lungs, skeletal muscles, heart, and other organs. Fibrosis and calcification of the diaphragm and renal tubules, fibrosis of the myocardium and lungs, thickening of tendons, and an increased frequency of thrombotic events have all been reported. Manifestations of the disease resemble those of scleroderma, with patients exhibiting thickening and discoloration of the skin, particularly in the extremities. This thickening can progress to the point of limiting joint movement, often resulting in contractures. In addition, patients with NSF can develop pruritus, muscle weakness, and diffuse pain. In some patients, NSF has contributed to death by means of ventilatory restriction or mobility impairment leading to falls.*

In 2007, the FDA asked manufacturers to include a boxed warning on the product labeling of all gadolinium-based contrast agents. Subsequently in September of 2010 the agency mandated that GBCAs carry warnings on their labels about the risk of NSF if the drug is administered to patients with kidney disease. The following recommendations were also provided as a part of the 2010 update.

- ☐ Do not use Magnevist, Omniscan, and Optimark in patients with Acute Kidney Injury (AKI) or with chronic severe kidney disease. These three GBCA drugs are contraindicated in these patients.
- ☐ Screen patients prior to administration of a GBCA to identify those with AKI or chronic severe, kidney disease.
- ☐ Use the clinical history to screen patients for features of AKI or risk factors for chronically reduced kidney function.
    - o Features of AKI consist of rapid (over hours to days) and usually reversible decrease in kidney function, commonly in the setting of surgery, severe infection, injury, or drug-induced kidney toxicity. Serum creatinine levels and estimated GFR may not reliably assess kidney function in the setting of AKI.
    - o For patients at risk for chronically reduced kidney function (such as patients over age 60 years, patients with high blood pressure, or patients with diabetes), estimate the kidney function (GFR) through laboratory testing.

- ☐ Avoid use of GBCAs in patients suspected or known to have impaired drug elimination unless the need for the diagnostic information is essential and not available with non-contrasted MRI or other alternative imaging modalities.
- ☐ Monitor for signs and symptoms of NSF after a GBCA is administered to a patient suspected or known to have impaired elimination of the drug.
- ☐ Do not repeat administration of any GBCA during a single imaging session.

In accordance with these recommendations, the following policies and procedures will be used for MR imaging at LSUHSC Shreveport.

Policy/Procedure:

Selection of a GBCA:

The ACR recognizes three categories of gadolinium-containing contrast media with respect to risk of NSF

- ☐ Agents associated with the greatest number of NSF cases
  - Gadoterate meglumine (Dotarem)
  - Gadodiamide (Omniscan)
  - Gadopentetate dimeglumine (Magnevist)
  - Gadoversetamide (OptiMARK)
- ☐ Agents associated with few, if any, cases of NSF
  - Gadobenate dimeglumine (MultiHance)
  - Gadoteridol (ProHance)
- ☐ Agents which have only recently appeared on the market in the US
  - Gadofosveset (Ablavar)
  - Gadoxetic acid (Eovist)
  - Gadoterate meglumine (Dotarem)

Based on this categorization, OCS/LSU has chosen Gadoterate meglumine (Dotarem) for use on all patients. Also based on this approach, the department will retain (**Omniscan**) to be used only when requested by a Radiologist.

Patient Screening:

All patients with an order to receive gadolinium contrast must have current laboratory data that meets the following criteria:

- ☐ **Minimum Analysis – Serum creatinine and an estimated glomerular filtration rate (eGFR).** The eGFR must be based on the Schwartz equation as provided by the National Kidney Foundation (NKF). The OLSU Shreveport clinical lab reports contain the eGFR value for an adult that is based on this equation.
- ☐ **Timeframe -** Every patient scheduled for a magnetic resonance exam with contrast must have a recent (within 60 days of exam for outpatients or within 48 hours for inpatients) laboratory data.

GBCA use with Normal Lab Results (eGFR > 60 ml/min/1.73m^2)

The technologist will proceed with the exam and use the recommended dose of Dotarem. Under no circumstances is more than a single dose of the GBCA to be administered. Contrast will not be administered to any patient less than 2 years of age unless approved and administered by a **STAFF** radiologist.

GBCA use with Abnormal Lab Results - **If a patient has abnormal laboratory results** the following **guidelines** will be used:

The risk to benefit of a GBCA in patients AKI or chronic severe kidney disease should be carefully considered by the referring physician and radiologist with input from Nephrology as needed. The technologist will review the imaging order and eGFR prior to administering any GBCA. If the eGFR is less than 60 ml/min/1.73m^2 the following procedure will be used.

- ☐ ***eGFR < 60 mL/min/1.73m^2 but >30 mL/min/1.73m^2***

  The technologist will **not** perform the exam until approved by a **staff** radiologist. The technologists will notify the radiologist and the decision to choose an alternative imaging method or continue with a gadolinium-based contrast agent should be made by the staff

radiologist and the ordering physician. If the decision is to proceed with the exam, the radiologist will provide an order for the technologist to proceed.

The GBCA Dotarem will be used at the lowest dose possible as approved by the staff radiologist. The technologist will record the dose given in the RIS.

☐ ***eGFR <30 mL/min/1.73m^2***

In addition to the requirements listed above the following steps must be taken.

- The ordering physician must review the risks with the patient and completes an informed consent.

Hemodialysis will be performed immediately after the MR exam is complete. Prompt dialysis of these patients will eliminate circulating gadolinium-based contrast agent. From the first to the third hemodialysis sessions, average gadolinium-based contrast clearance rates were 78%, 96%, and 99%, respectively. The Nephrology **Staff** must be contacted

- prior to the exam so dialysis equipment and personnel will be ready. The Radiology resident after consultation with a staff Radiologist will contact the **Staff Nephrologist**.
- The GBCA Dotarem will be used at the lowest dose possible as ordered by a staff radiologist.

Patients with Multiple Sclerosis and Suspected Inflammatory Processes

Dotarem will be used in patients with multiple sclerosis and suspected inflammatory processes. These patients will undergo screening as previously described and the laboratory result guidelines also apply.

Pediatric Patients

Pharmacokinetic and pharmacodynamic studies have not been systematically conducted to determine the optimal gadolinium dose and optimal imaging time in pediatric patients with immature renal

function. Pediatric population for the purpose of this policy is defined as 2 to 16 years of age. Since the OCS LSU clinical lab is currently unable to provide the eGFR for pediatric patients, the **Pediatric Service must** provide the eGFR when ordering the exam. The eGFR must be calculated using the following Schwartz equation:

GFR = (A x height (cm))/ (Plasma creatinine concentration)

A = 0.33 for prematurely born infants less than 1 year old, 0.45 for term children less than 1 year old, 0.55 for children ages 1-12 years, 0.55 for girls ages 13-21, 0.65 for boys ages 13-21

The calculated eGFR must be recorded in RIS along with the person's name that provided the value. **Patients under 2 years of age will not receive contrast without approval from the radiologist**. If a child is at high risk of renal insufficiency and potentially toxic drugs are being used, more precise measures of GFR should be considered. If possible, levels of medications should be obtained as well.

Additional Considerations

- ☐ The **Kidney Disease Education Program** presently recommends reporting estimated GFR values ***above 60 mL/min/1.73 m^2*** simply as "above 60 mL/min/1.73 m^2", not an exact number.
- ☐ The MDRD Study equation normalizes or adjusts eGFR to a typical body size (body surface area = 1.73 m^2). Thus, the eGFR itself is larger in large people and smaller in small people. This approach allows for calculation without knowing weight or height. In general, drug dosing is based on eGFR levels that are not adjusted for body surface area. In practice, adjusted eGFRs are adequate except in patients with body size that is very different than average. these patients, unadjusted eGFR can be computed by the following formula:

GFR estimate (mL/min/1.73 m^2) x BSA

For further information on GBCA please go to the National Kidney Foundation (NKF) webpage:
http://www.kidney.org