

Gadolinium-Based Contrast Media Administration

I. POLICY

The organization has implemented guidelines to be used for all patients before receiving gadolinium-based contrast media in any dose. This is in response to recent FDA warnings about the association between gadolinium-based contrast media (Omniscan, Magnevist, OptiMARK) with nephrogenic systemic fibrosis/nephrogenic fibrosing dermopathy (NSF/NFD). The guidelines ensure the appropriate and safe use of gadolinium-based contrast media during diagnostic and therapeutic imaging procedures. These guidelines will remain in effect until more definitive information is available on the relationship between gadolinium and NSF/NFD.

II. SCOPE

Personnel: Professional staff and referring physicians and their representatives

III. DEFINITIONS

Estimated Glomerular Filtration Rate (eGFR): The eGFR by the Modification of Diet in Renal Disease (MDRD) formula* is based on serum creatinine, age, sex, and ethnicity.

NSF/NFD: Nephrogenic systemic fibrosis/nephrogenic fibrosing dermopathy, which is a rare, irreversible, and often fatal multisystem disorder characterized by collagen deposition in the skin and organs resulting in thickening and hardening of the skin and joints leading to immobility. It was first described in 2000. The number of people with the disorder has grown to a reported 215 worldwide according to an international NSF registry at Yale University (New Haven, Connecticut.) An ongoing survey of some of these patients revealed that 95% (n = ~100) had been exposed to a gadolinium chelate 2 to 3 hours before the onset of NSF/NFD. Of 57 cases reported to FDA, most were associated with Omniscan, but both Magnevist and OptiMARK have been implicated as well. Currently, the only known way to stabilize disease progression is through rapid correction of renal function by surgical or medical means. (Kuo PH, Kanal E, Abu-Alfa AK, Cowper SE. Gadolinium-based MR contrast agents and nephrogenic systemic fibrosis. *Radiology*. 2007;242(3): 647-9.)

IV. PROCEDURE

Action	Responsibility
A. Evaluation of Patient Prior to Administration of Gadolinium	
1. Patients who have normal renal function determined by history or who are at low risk for renal insufficiency may have gadolinium administered per routine institutional protocol <i>without</i> obtaining serum creatinine.	Radiology technicians/ radiology management
2. For patients with known renal problems, or at moderate to high risk for renal insufficiency; follow the protocol (refer to B & C).	Radiology technicians/ radiology management
<i>Note:</i> Patients are considered moderate to high risk if one or more of the following applies:	
- age over 65	
- diabetic	
- hypertensive	
- prior abnormal creatinine clearance	
- family history of kidney disease	

B. Baseline Creatinine

1. Estimated glomerular filtration rate (eGFR): All patients considered moderate to high risk for renal insufficiency and who are to receive gadolinium-based contrast media must have a baseline creatinine drawn within 60 days prior to administration/procedure.
2. Using the baseline creatinine, eGFR will be calculated.
3. If the creatinine was drawn at an outside facility, the results are to be brought to the performing facility the date of exam.

C. Protocol for Safe Administration of Gadolinium

Action	Responsibility
1. If the eGFR is <30 mL/min/1.73m ² , then the review and approval of either the radiologist and/or the referring physician will be required with regard to the risk to benefit ratio of the exam performed with gadolinium.	
2. If the eGFR is >30 mL/min/1.73m ² , then the technologist may proceed with the exam.	Radiology technician
3. If the eGFR is <30 and it is determined that gadolinium is needed, informed consent will be obtained from the patient or patient's legal representative by a radiologist or nephrologist.	Radiologist or nephrologist
4. Consent will be signed by the patient or patient's legal representative and witnessed by personnel.	Radiologist or nephrologist
5. Patients on hemodialysis are to be dialyzed within 18 hours after gadolinium administration.	Nephrology/ hemodialysis department
6. For patients on peritoneal dialysis, the use of gadolinium should be carefully considered. If the need for a gadolinium-based exam outweighs its potential risk, then it should be administered only after consultation with nephrology, who will determine the patient's case-specific post-gadolinium dialysis protocol. The patient or legal representative will be informed of risks, benefits, and alternatives before the exam is performed.	Nephrologist, radiologist, and ordering physician

V. **ATTACHMENT:** N/A

VI. **DISTRIBUTION:** Hospital and medical group

VII. **POLICY RESPONSIBILITY:**

AVP, Radiology Services

In Coordination With:
Nephrology Division
Patient Care Services
Professional Staff
Radiology Department
Pharmacy & Therapeutics
Committee

VIII. REFERENCES:

Internal

External

None

Kuo PH, Kanal E, Abu-Alfa AK, Cowper SE. Gadolinium-based MR contrast agents and nephrogenic systemic fibrosis. *Radiology*. 2007; 242(3): 647-9.

IX. REVISION:

The organization reserves the right to unilaterally revise, modify, review, or alter the terms and conditions of the policy within the constraints of law, with or without reasonable notice.

X. APPROVAL:

_____	President, Professional Staff	_____
Signature	Title	Date
_____	Chief Nursing Officer	_____
Signature	Title	Date
_____	Chairman, Radiology	_____
Signature	Title	Date
_____	AVP, Radiology	_____
Signature	Title	Date

XI. DATES:

Origination: _____ Last Review: _____ Next Review: _____