

RSNA Statement on Gadolinium-Based MR Contrast Agents Reviewed: 5/9/2024

The Radiological Society of North America (RSNA) is committed to excellence in patient care through education and research.

- Radiologists, radiology technologists, radiology nurses and other radiology professionals are committed to appropriate utilization of MRI exams that utilize gadolinium-based contrast agents (GBCA). Radiologists also apply appropriateness criteria in a variety of ways, including consultation with patients' physicians and other providers who order imaging examinations to guide the patient to the best procedure to address the clinical circumstance.
- GBCA have been used for diagnosis and treatment guidance in more than 100 million patients worldwide over the past 25 years. These agents enhance the quality of MR images by altering the magnetic properties of nearby water molecules in the body. By improving the visibility of specific organs, blood vessels or tissues, contrast agents help physicians diagnose and treat a wide variety of medical conditions.
- GBCA are approved by the FDA for use with MRI to provide improved images of body organs and tissues. They are also used for magnetic resonance angiography (MRA), an MRI procedure that is designed to evaluate blood vessels.
- Gadolinium is a paramagnetic metal ion. GBCA are manufactured by a chelating process, a procedure in which large organic molecules form a stable complex around the gadolinium. The chelate reduces the chances of toxicity that could result from exposure to gadolinium. This stable complex is eliminated predominantly via the kidneys. GBCAs are classified as macrocyclic and linear, based on how the drug is formulated.
- Some GBCA are contraindicated in patients with severe acute or chronic renal failure, with a glomerular filtration rate (GFR) < 30, because of the risk of nephrogenic systemic fibrosis (NSF). NSF is a rare but serious systemic disease characterized by fibrosis of the skin and other tissues throughout the body. NSF is thought to be related to deposition of gadolinium in the skin. Linear GBCAs tend to result in more gadolinium retention in the body than macrocyclic GBCAs.
- Several preliminary studies have demonstrated the presence of residual gadolinium concentrations in the bodies of patients with no history of kidney disease. The clinical significance of this observation is unknown at this time, but warrants attention.
- Patients should not be unnecessarily deprived of crucial, sometimes life-saving medical information from gadolinium contrast-enhanced MRI. At the same time, the potential risk associated with residual gadolinium concentrations in the body should be taken into consideration. This risk must be weighed against the clinical benefit of the diagnostic information or treatment result that a MRI may provide for each individual patient.
- On September 8, 2017, the Medical Imaging Drugs Advisory Committee (MIDAC) of the FDA recommended adding a warning to labels about gadolinium retention in various organs, including the brain, for GBCA used during MRI. The FDA highlighted several specific patient populations at greater risk, including children, pregnant women, and those patients requiring multiple lifetime doses of GBCA. On December 19, 2017, the FDA issued a safety announcement requiring a new class warning and other safety measures for all GBCA used for MRI. These include requiring a new patient Medication Guide and a requirement for manufacturers of GBCA to conduct human and animal studies to further assess the

safety of these contrast agents. For further information on this and other FDA statements on GBCA, visit <https://www.fda.gov>.

RSNA is a strong advocate for quality, safety, equity and strict adherence to appropriateness criteria in medical imaging and radiation oncology. Through its peer-reviewed journals, education programs and annual scientific assembly, RSNA continually informs radiologists, medical physicists, radiation oncologists and other radiology professionals of the latest technologies and research developments designed to optimize dose and improve patient safety.