DOTAREM®
(gadoterate meglumine) Injection

Reimbursement Information

Radiology Reimbursement Information Setting: Freestanding Facility/Independent Diagnostic Testing Facility (IDTF)

About DOTAREM®:

DOTAREM is a gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.[1]

IMPORTANT SAFETY INFORMATION[1]

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- The risk for NSF appears highest among patients with:
  - Chronic, severe kidney disease (GFR < 30 mL/min/1.73m²), or
  - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (e.g. age > 60 years, hypertension, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended DOTAREM dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Important Safety Information continued onto the following pages.

For more information on Dotarem, please see Full Prescribing Information including Boxed Warning and Medication Guide

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Coding for DOTAREM		
Payer Type	Medicare	Commercial
HCPCS Code	A9575	A9575
Code Descriptor	Injection, gadoterate meglumine, 0.1 mL	Injection, gadoterate meglumine, 0.1 mL

DOTAREM (gadoterate meglumine), having received FDA approval for use in magnetic resonance imaging (MRI) of the brain, spine and associated tissues in adult and pediatric patients (including term neonates), has a distinct Healthcare Common Procedural Coding System (HCPCS) code, A9575 Injection, gadoterate meglumine, 0.1 mL.

The code descriptor for A9575 is per 0.1 mL and when billing, it is important to remember to multiply the amount of DOTAREM used by 10 in order to list the correct number of units on the claim form. Samples of unit conversions are:

- 2 mL = 20 units
- 7.5 mL = 75 units
- 15 mL = 150 units
- 20 mL = 200 units

This component of billing is different from using the older contrast codes which are per 1 mL. The lower mL designation allows providers to accurately report the appropriate amount of DOTAREM is used and reduce the potential for over- or under-billing.

Contrast agents are subject to the required use of the -JW modifier for claims with unused drugs or biologicals from single-use vials or single-use packages that are appropriately discarded (except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals). Make sure to document the discarded drug or biological in the patient's medical record when submitting claims with the -JW modifier.

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An example of proper use of the -JW modifier, with a 10 mL single-use vial as example, where 7 mL is administered and 3 mL is waste:

- A9575 70 units
- A9575-JW 30 units

To facilitate appropriate billing of DOTAREM, the following information should be added to the facility charge file:

° Product name: DOTAREM (gadoterate meglumine) injection with National Drug Code (NDC) number
° Price per mL
° HCPCS code: A9575 (Injection, gadoterate meglumine, 0.1 mL)
° Appropriate revenue code unique to your hospital's contrast cost center

All requirements of HIPAA 5010 must be met. These include the NDC and cost information noted above plus dose and route of administration (e.g., IV).

Reimbursement for Contrast by Payer

Medicare: In the freestanding facility/IDTF setting, Medicare reimburses contrast agents separate from the related procedure. Reimbursement will be based on Average Sales Price (ASP) updated on a quarterly basis by the Centers for Medicare and Medicaid Services (CMS). For a copy of the most current ASP Pricing File, please contact DOTAREM Reimbursement Support.

Commercial: Most commercial payers, including Medicare Advantage and Managed Medicaid payers, will reimburse separately for contrast when billed with a corresponding MR procedure CPT code that states, "with contrast."

Please consult the Reimbursement Helpline for payer specific coverage and guidance of compliant coding and billing.

**For asistance, please contact DOTAREM Reimbursement Support at 1-855-368-2736,
Monday - Friday, 7am - 7pm ET.
The Helpline can provide payer-specific coverage information as well as guidance
on securing prior authorization and appeal of denial claims.**

*Reimbursement information provided is for illustrative purposes only and does not constitute legal advice. Information provided is gathered from third party sources and is subject to change without notice due to frequently changing laws, rules and regulations. Guerbet makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service. The provider of service has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Please contact your local payers, reimbursement specialists and/or legal counsel for interpretation of coding, coverage, and payment policies. Guerbet does not promote the use of its products outside FDA-approved labeling.

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Indications and Usage

DOTAREM® (gadoterate meglumine) injection is a prescription gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI) in brain (intracranial), spine and associated tissues in adult and pediatric patients (including term neonates) to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity.

Contraindications

History of clinically important hypersensitivity reactions to DOTAREM.

Warnings and Precautions

- Hypersensitivity Reactions: Anaphylactic and anaphylactoid reactions have been reported with DOTAREM, involving cardiovascular, respiratory, and/or cutaneous manifestations. Some patients experienced circulatory collapse and died. In most cases, initial symptoms occurred within minutes of DOTAREM administration and resolved with prompt emergency treatment.
- Before DOTAREM administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to DOTAREM.
- Administer DOTAREM only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, including personnel trained in resuscitation.
- Gadolinium Retention: Gadolinium is retained for months or years in several organs. The highest concentrations have been identified in the bone, followed by brain, skin, kidney, liver and spleen. The duration of retention also varies by tissue, and is longest in bone. Linear GBCAs cause more retention than macrocyclic GBCAs.
- Consequences of gadolinium retention in the brain have not been established. Adverse events involving multiple organ systems have been reported in patients with normal renal function without an established causal link to gadolinium retention.
- Acute Kidney Injury: In patients with chronically reduced renal function, acute kidney injury requiring dialysis has occurred with the use of GBCAs. The risk of acute kidney injury may increase with increasing dose of the contrast agent; administer the lowest dose necessary for adequate imaging.
- Extravasation and Injection Site Reactions: Ensure catheter and venous patency before the injection of DOTAREM. Extravasation into tissues during DOTAREM administration may result in tissue irritation.

Adverse Reactions

- The most common adverse reactions associated with DOTAREM in clinical trials were nausea, headache, injection site pain, injection site coldness and rash.
- Serious adverse reactions in the Postmarketing experience have been reported with DOTAREM. These serious adverse reactions include but are not limited to: arrhythmia, cardiac arrest, respiratory arrest, pharyngeal edema, laryngospasm, bronchospasm, coma and convulsion.

Use in Specific Populations

- **Pregnancy:** GBCAs cross the human placenta and result in fetal exposure and gadolinium retention. Use only if imaging is essential during pregnancy and cannot be delayed.
- **Lactation:** There are no data on the presence of gadoterate in human milk, the effects on the breastfed infant, or the effects on milk production. However, published lactation data on other GBCAs indicate that 0.01 to 0.04% of the maternal gadolinium dose is present in breast milk.
- **Pediatric Use:** The safety and efficacy of DOTAREM at a single dose of 0.1 mmol/kg has been established in pediatric patients from birth (term neonates ≥ 37 weeks gestational age) to 17 years of age based on clinical data. The safety of DOTAREM has not been established in preterm neonates. No cases of NSF associated with DOTAREM or any other GBCA have been identified in pediatric patients age 6 years and younger.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see the full Prescribing Information, including the patient Medication Guide, for additional important safety information.

References: 1. Dotarem [package insert]. Princeton, NJ: Guerbet LLC; Oct 2019.

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