Introduction

Bayer HealthCare Inc. offers this billing guide to freestanding imaging center customers as part of its comprehensive educational program on the reimbursement process. We understand that medical practice today requires working with health insurers that finance the care of your patients. Bayer is committed to providing you with up-to-date reimbursement information for the entire Bayer suite of diagnostic imaging contrast agents for enhanced magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), and computed tomography (CT) procedures.

This billing guide provides information about general coverage, coding, and payment information for Bayer imaging agents and associated diagnostic imaging procedures in the freestanding imaging center and physician office settings. Because providers face a multitude of Current Procedural Terminology (CPT) coding options for imaging procedures, we also provide CPT codes for MRI, MRA, X-ray, and CT procedures beginning on page 10 in this brochure.

In the sections that follow, we present an overview of the major public and private insurers’ general coverage and reimbursement policies for diagnostic radiology services.

Reimbursement Process

Bayer HealthCare also operates the Reimbursement Helpline to answer coverage, coding, and payment questions about its products and associated diagnostic imaging procedures.

The toll-free Bayer Helpline number is 1-800-423-7539 and e-mail is imaging@prgweb.com.

Helpline hours are Monday through Friday, 9:00 am to 5:00 pm, Eastern time.

Information provided in this resource is for informational purpose only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource nor the Bayer Healthcare Reimbursement Helpline is intended as a legal advice or as a substitute for a provider’s independent professional judgment.
Coverage

Coverage refers to the decision by an insurer to provide program benefits for a specific product or medical service. Coverage policies, which vary by payer, typically specify whether a proposed course of treatment is medically necessary and, therefore, eligible for reimbursement under a patient's healthcare plan.

When considering whether a product or service is covered, it is important to distinguish between coverage and payment. It is possible for a service or product to be bundled, which means that it is covered but not paid separately. An example would be a service that falls under an all-inclusive payment mechanism like diagnosis-related groups (DRGs) or per diems.

Medicare

Medicare typically covers diagnostic radiology procedures and imaging agents when they are considered reasonable and necessary for the diagnosis or treatment of an illness or injury. Medicare often bases its coverage decisions on information submitted on claim forms, including diagnosis codes and procedure codes. In some cases, Medicare may also look at accompanying documentation that is submitted with a claim. Medicare has developed the following specific coverage policies for MRI and CT procedures:

- In general, Medicare covers non-investigational uses of MR that are reasonable and necessary when performed on approved MR units
- Medicare generally covers reasonable and necessary CT scans when performed using approved CT equipment, provided that the medical and scientific literature and opinion support the effective use of a scan for the patient’s condition

Medicare’s complete national coverage determinations for MR and CT procedures are available at:
http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd

Medicare’s national coverage determination for CT does not make reference to specific CT procedures. In the absence of a national policy, each local Medicare carrier has established a local coverage determination (LCD) for their jurisdiction that provides coverage guidelines for CT. The LCDs provide specific guidelines and requirements, ranging from patient diagnosis to equipment technology.

Because of variations in each carrier’s local policy, it is important to be familiar with the LCD for CT procedures in your state. LCDs are available for review on each carrier’s website, or contact the Reimbursement Helpline for more information.

Private Insurers

Like Medicare, most private insurers cover MRIs, CT scans, other diagnostic radiology procedures, and imaging agents when determined to be medically necessary and appropriate; however, benefits vary from payer to payer and also depend on the specific contract terms that a provider negotiates with a given plan. Some private insurers have medical criteria for coverage similar to those used by Medicare, while others have developed their own policies. As a condition of coverage, some managed care plans may also require that providers obtain prior authorization before providing diagnostic imaging services.

Check your patient’s policy or call the Reimbursement Helpline for help determining specific policy limits or requirements that might apply to Bayer products or related diagnostic imaging procedures.

Medicaid

Because decisions regarding Medicaid benefits generally are left to the states, Medicaid coverage policies will be determined on a state-by-state basis. While some state Medicaid programs may utilize coverage guidelines for contrast agents and associated diagnostic imaging procedures that mirror Medicare’s policies, other programs may provide more limited benefits for diagnostic services. Additionally, some states may have prior authorization requirements for such services.

For more specific information, check your state’s Medicaid coverage policies, or call the Reimbursement Helpline if you need help researching specific guidelines or restrictions.
Coding

Coding systems provide a uniform language for describing medical, surgical, and diagnostic services, as well as patient conditions and certain drugs and supplies. Correct coding of all components of a service is necessary to obtain appropriate reimbursement.

Freestanding imaging centers and physician offices bill for services and items using the CMS-1500 claim form, which is also used to report physicians’ professional services in other settings of care. Although specific coding requirements vary by insurer, Medicare and many other payers require the following codes on claims for diagnostic radiology services furnished in freestanding imaging centers:

- International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis code(s) to describe the patient’s condition
- CPT code(s) to accurately identify the procedure(s) performed, including the imaging service
- Healthcare Common Procedure Coding System (HCPCS) code(s) for certain contrast agents and other drugs and supplies

We describe each type of code below.

All codes must be supported with adequate documentation in the medical record; such documentation may be requested in the event of an audit or a retrospective claims review.

ICD-10-CM Diagnosis Codes

All claim forms must include at least one ICD-10-CM diagnosis code to describe the patient’s condition as it relates to the service(s) provided. Because there are many possible circumstances that may require diagnostic imaging services, such services can be billed with a variety of diagnosis codes. Some payers have coverage policies that list specific covered diagnosis codes for MRI, MRA, X-ray, and CT procedures; these codes will vary from payer to payer.

Providers should consult a complete listing of current ICD-10-CM diagnosis codes to determine which code(s) best reflect the condition of any specific patient for whom a claim is submitted. Additionally, providers always should select the appropriate ICD-10-CM diagnosis code(s) with the highest level of specificity.

CPT Codes

CMS-1500 claims for freestanding imaging centers and physician office services (as well as physicians’ professional services in other settings of care) must include appropriate CPT codes to describe the services performed. An entire section of the CPT book is dedicated to radiology; this section includes codes for MRI, MRA, and CT scans, as well as other diagnostic imaging services. Many CPT codes specify whether an imaging technique is performed without contrast material, with contrast material, or without contrast material followed by contrast material.

For a listing of CPT codes for MRI, MRA, and CT procedures, please see pages 10–21 in this brochure. However, providers also should consult a complete listing of current CPT codes to determine if an alternative code may be appropriate. The American Medical Association (AMA)—the organization that updates and maintains CPT codes—instructs providers to select a CPT code with a descriptor “that accurately identifies the service performed,” rather than a code “that merely approximates the service provided.” In the absence of a specific code that accurately identifies a service, providers should “report the service using the appropriate unlisted procedure or service code.”

Please contact Bayer’s Reimbursement Helpline at 1-800-423-7539 if you need assistance with determining whether these codes are covered for your non-Medicare payers.

All codes must be supported with adequate documentation in the medical record; such documentation may be requested in the event of an audit or a retrospective claims review.
Coding (continued)

Modifiers
In many instances, it may be appropriate to use modifiers in conjunction with CPT codes. Modifiers are two-digit numeric or alphanumeric codes that are appended to CPT codes to provide additional detail or to indicate that a service has been altered in some way.

Under the Medicare physician fee schedule, many diagnostic procedures, including imaging services, include professional and/or technical components. When reporting services on the CMS-1500 claim form, freestanding imaging centers, physicians, and physician offices sometimes use modifiers to indicate that a procedure involves only one of these components. Specifically, for certain procedures, these providers may bill for only the professional component (reflecting just the physician’s professional services) or only the technical component (reflecting the equipment, supplies, office expenses, and non-physician staff performing the service) by attaching one of the following modifiers to the appropriate CPT code:

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
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<tbody>
<tr>
<td>-26</td>
<td>Professional component</td>
</tr>
<tr>
<td>-TC</td>
<td>Technical component</td>
</tr>
</tbody>
</table>

A freestanding imaging center or physician office that performs both the technical and professional components of an imaging procedure for a non-hospital patient may bill for the global service by reporting the applicable CPT code(s) with neither the -26 nor the -TC modifier.

Modifiers -26 and -TC are not appropriate for all CPT codes, as many services (especially non-diagnostic procedures) are not broken down into technical and professional components. Providers should determine whether the use of a modifier(s) is appropriate for a particular case and should select modifier(s) that—when reported in conjunction with the corresponding CPT code(s)—accurately describe the service(s) rendered to the patient.

HCPCS Codes
Medicare, as well as many private payers and Medicaid plans, requires that freestanding imaging centers and physician offices report many drugs, supplies, and other items using alpha-numeric HCPCS codes, which often are highly specific in nature.

Please note that the availability of a HCPCS code for a particular product does not necessarily indicate that the product is separately reimbursable. Depending on the insurer and the particular service and agent provided, reimbursement for contrast materials may be included within the payment for the associated imaging procedure.

In situations that warrant the use of HCPCS codes, providers should consult a complete listing of current HCPCS codes and select the appropriate HCPCS code(s) with the highest level of specificity to describe the product(s) or service(s) furnished.

Below, we briefly discuss some of the differences between Medicare’s HCPCS coding requirements and the requirements of other payers. Because billing policies for contrast materials often are complex and payer-specific, we encourage you to contact your payers to verify their particular coding requirements for the imaging agents used at your facility. The Reimbursement Helpline also is available to research payer-specific billing information; please contact us if you would like our assistance in this area.
Medicare
Freestanding imaging centers and physician offices may bill Medicare for reasonable and necessary uses of LOCM with Q-codes Q9965, Q9966, Q9967, and Q9951. Providers may also bill Medicare for reasonable and necessary uses of MR contrast with HCPCS code A9579. The Final Rule to the Medicare Physician Fee Schedule, published in December 2006, allows for the separate reimbursement of various contrast materials. Prior to January 1, 2007, Medicare paid separately for MR contrast only in very limited circumstances. We provide more information on this issue in the Payment section of this billing guide.

Private Insurers and Medicaid
The coding requirements of non-Medicare payers likely will vary. Some insurers may not require providers to bill imaging agents with HCPCS codes for many contrast-enhanced diagnostic radiology procedures. Please see page 9 for appropriate HCPCS codes.

If you are unsure whether a particular payer accepts contrast agent HCPCS codes, we encourage you to contact the payer directly or call Bayer’s Reimbursement Helpline at 1-800-423-7539.
Payment methodologies often vary depending on where a procedure is performed. This is especially true of the Medicare program. Here, we outline the payment systems that different payers use to reimburse services furnished in the freestanding imaging center and physician office settings.

**Medicare**

Medicare reimburses freestanding imaging centers and physician office services based on the resource-based relative value scale (RBRVS) physician fee schedule. This payment system also applies to physicians' professional services furnished in other settings of care.

Payment levels under the Medicare Physician Fee Schedule (MPFS) are calculated separately for each covered CPT code. RBRVS payment calculations take into account the average time, effort, practice expense, and malpractice cost associated with a procedure, as well as geographic cost differences. For each separately payable procedure, Medicare pays 80% of the fee schedule amount, and the patient (or the patient’s secondary insurser) is responsible for the remaining 20% as co-insurance.

**Diagnostic Imaging Procedures**

Under the physician fee schedule, each diagnostic imaging CPT code is assigned relative value units (RVUs), which are used to calculate a payment amount. In general, imaging procedures whose CPT descriptors specify “with contrast” are assigned higher RVU values than those procedures whose CPT descriptors specify only “without contrast,” which results in higher payment rates for contrast-enhanced procedures.

The RVUs for imaging CPT codes with descriptors that specify “without contrast followed by with contrast” reflect payment levels for two procedures: the first scan without contrast, and the second scan with contrast. Because these descriptors include “further sequences” (for MR) or “further sections” (for CT), Medicare generally does not provide additional payment if a third procedure is performed on the same area of the body.

**Multiple-procedure payment reduction**—When multiple imaging procedures within the same family are performed during the same session, Medicare will make full payment for the technical component (TC) of the procedure with the highest payment amount. Medicare will then make payment at 50% (or a 50% reduction) of the applicable rate for the TC of additional procedures. This policy to reduce payments became effective on January 1, 2006, and was based on CMS's belief that there are certain efficiencies associated with conducting multiple studies using the same imaging modality in contiguous body areas. The enactment of the Deficit Reduction Act (DRA) on January 1, 2007 set the multiple-procedure reductions at 25%. CMS proposed to further reduce payment to these families, and on July 31, 2010 they increased the reduction to 50%.

It is important to note that this payment reduction will apply only to multiple services described by codes within the same family, not across families. For example, if an MRI of the brain (Family 5) is performed in the same session as an MRI of the spine (Family 6), the payment reduction would not apply because the CPT codes would be from different families.

Also, the reduction will be applied only to the technical (non-physician) component of the MPFS payment and not to the professional (physician) component; therefore, physicians will continue to receive the full payment rates for their professional services, even when multiple procedures are performed.

**Cap on the Technical Component (TC) of Imaging Procedures**

This policy limits the TC payment for certain imaging procedures performed in freestanding facilities that are paid under the MPFS to the amount paid for the same service in the hospital outpatient department under the outpatient prospective payment system (OPPS). This cap is applicable only when the MPFS TC payment amount is greater than the OPPS TC payment amount for the same service.
The imaging services that are affected by the OPPS payment cap include X-ray, ultrasound, MRI, MRA, CT, positron emission tomography (PET) and nuclear medicine, and fluoroscopy. The OPPS payment cap does not affect the professional component associated with the procedures, nor does it apply to mammography services. Medicare carriers adjust the cap fee schedule to reflect the Geographic Practice Cost Indices, so individual carriers should be consulted to determine local payment caps. For help with determining carrier-specific caps, call the Reimbursement Helpline.

For imaging procedures that are subject to both the multiple-procedure payment reduction policy and the OPPS payment cap, CMS will apply the multiple-procedure reductions first, followed by the OPPS imaging cap, if applicable.

**Bayer Imaging Agents**

Medicare provides separate payment for certain imaging agents (as well as physician-administered drugs and biologicals) when furnished in freestanding imaging centers and physician offices. These agents are reimbursed outside of the physician fee schedule and are reported on physician CMS-1500 claim forms using HCPCS codes.

The current basis of Medicare payment for imaging agents is average sales price (ASP). This is the same reimbursement methodology that also applies to most physician-administered drugs and biologicals under Medicare Part B. CMS calculates an ASP-based payment amount for each HCPCS code based on sales data submitted by manufacturers, and ASP amounts are updated quarterly. Because the ASP-based payment rates for imaging agents are set at the HCPCS code level, these amounts apply to—and reflect the aggregate sales data of—all products that fall under each HCPCS code.

All reasonable and necessary uses of LOCM and gadolinium-based MR contrast are eligible for separate Medicare payment in the freestanding imaging center and physician office settings.

For a current status on carrier notification, implementation instructions, or claims submissions, contact the Reimbursement Helpline.

**Private Insurers**

Some private insurers use RBRVS-based or other fee schedules to pay for services provided in freestanding imaging centers and physician offices, while others may base reimbursement on discounted charges or capitated rates.

Whether a freestanding imaging center receives separate reimbursement for contrast material will depend on the plan in question, the particular agent and imaging service furnished, and the contract that the facility has negotiated with the plan. Facing increasing pressures to control costs, many private insurers are adopting bundled payment arrangements for services like contrast-enhanced diagnostic radiology studies.

**Medicaid**

Although Medicaid payment methods for freestanding imaging centers and physician office services may vary by state, many state Medicaid programs reimburse these services based on fee schedules. There is significant variation in Medicaid payment amounts among states; however, Medicaid programs typically pay less than other insurers. State-specific policies will determine whether imaging agents are paid separately in freestanding imaging centers.

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# Summary of Medicare

## Components of Reimbursement

<table>
<thead>
<tr>
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<th>Imaging Agent</th>
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</tr>
<tr>
<td><strong>LOCM CT/X-ray Contrast</strong></td>
<td><strong>Gadolinium-based MR Contrast</strong></td>
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</tbody>
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### CPT Codes

- **Specific codes for MR and CTs**
  - See codes listed inside this piece
  - Many codes specify without contrast, with contrast, or without contrast followed by with contrast

### HCPCS Codes

- Generally not used to report imaging procedures in freestanding imaging center

### Payment

- Based on physician fee schedule
  - Each procedure assigned RVUs that are used to calculate payments
  - Procedures with contrast generally paid at a higher rate than those without contrast
  - Payment generally limited to two procedures on same area of body
  - 50% discount applies to additional procedures within same imaging “family”

- Reasonable and necessary uses of LOCM eligible for separate payment
  - Payment based on ASP
  - ASP-based rates updated quarterly

- Reasonable and necessary uses of MR contrast eligible for separate payment
  - Payment based on ASP
  - ASP-based rates updated quarterly

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For information regarding the Bayer portfolio of diagnostic imaging agents, please call your Bayer HealthCare Sales Consultant at 1-888-842-2937, option 5. For customer service or purchasing information regarding any Bayer diagnostic imaging agent, please call 1-877-229-3750.

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CPT Codes

Gadavist-specific MRI Codes

A9585  injection, gadobutrol, 0.1 mL

MRI, Breast
77058  MRI, breast, without and/or with contrast material(s); unilateral
77059  MRI, breast, without and/or with contrast material(s); bilateral

MRI, Brain (Including Brain Stem)
70552  with contrast material(s)
70553  without contrast material(s), followed by contrast material(s) and further sequences

MRI, Spinal Canal and Contents, Thoracic
72147  with contrast material(s)
72157  without contrast material(s), followed by contrast material(s) and further sequences

MRI, Spinal Canal and Contents, Cervical
72142  with contrast material(s)
72156  without contrast material(s), followed by contrast material(s) and further sequences

MRI, Spinal Canal and Contents, Lumbar
72149  with contrast material(s)
72158  without contrast material(s), followed by contrast material(s) and further sequences

Gadavist-specific MRA Codes

A9585  injection, gadobutrol, 0.1 mL

MRA, Abdomen
74185  with or without contrast material(s)

MRA, Neck
70548  with contrast material(s)
70549  without contrast material(s) followed by with contrast material(s) and further sequences

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Indications and Usage
Gadavist® (gadobutrol) injection is a gadolinium-based contrast agent indicated for use with magnetic resonance imaging (MRI):

- To detect and visualize areas with disrupted blood brain barrier (BBB) and/or abnormal vascularity of the central nervous system in adult and pediatric patients (including term neonates)
- To assess the presence and extent of malignant breast disease

Gadavist® is indicated for use in magnetic resonance angiography (MRA):

- To evaluate known or suspected supra-aortic or renal artery disease in adult and pediatric patients (including term neonates)

Please see Important Safety Information on following page.

10 Please note that the MR C-codes apply only to Medicare hospital outpatient claims; providers should use the standard CPT codes when submitting claims for the above services to non-Medicare payers.
Important Safety Information

**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 of 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 (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended GADAVIST dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

**Contraindication and Important Information about Hypersensitivity Reactions:** Gadavist® is contraindicated in patients with history of severe hypersensitivity reactions to Gadavist®. Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory, or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following Gadavist® administration. Before Gadavist® 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 Gadavist®.

**Acute Kidney Injury:** In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

**Extravasation and Injection Site Reactions:** Ensure catheter and venous patency before the injection of Gadavist®. Extravasation into tissues during Gadavist® administration may result in moderate irritation.

**Overestimation of Extent of Malignant Disease in MRI of the Breast:** Gadavist® MRI of the breast overestimated the histologically confirmed extent of malignancy in the diseased breast in up to 50% of the patients.

**Low Sensitivity for Significant Arterial Stenosis:** The performance of Gadavist® MRA for detecting arterial segments with significant stenosis (>50% renal, >70% supra-aortic) has not been shown to exceed 55%. Therefore, a negative MRA study alone should not be used to rule out significant stenosis.

**Adverse Reactions:** The most frequent (≥0.5%) adverse reactions associated with Gadavist® in clinical studies were headache (1.5%), nausea (1.1%) and dizziness (0.5%).

Please click here to see the Gadavist® Full Prescribing Information (Vials & Syringes).

Please click here to see the Gadavist® Full Prescribing Information (Pharmacy Bulk Package).

Learn more about Gadavist at gadavist.com
CPT Codes

Magnevist-specific MRI Codes

A9579 injection, gadolinium-based MR contrast agent, NOS, per 1.0 mL

MRI, Orbit, Face, and/or Neck
- 70542 with contrast material(s)
- 70543 without contrast material(s), followed by contrast material(s) and further sequences

MRI, Brain (Including Brain Stem)
- 70552 with contrast material(s)
- 70553 without contrast material(s), followed by contrast material(s) and further sequences

MRI, Chest (e.g., for Evaluation of Hilar and Mediastinal Lymphadenopathy)
- 71551 with contrast material(s)
- 71552 without contrast material(s), followed by contrast material(s) and further sequences

MRI, Abdomen
- 74182 with contrast material(s)
- 74183 without contrast material(s), followed by contrast material(s) and further sequences

MRI, Spinal Canal and Contents, Cervical
- 72142 with contrast material(s)
- 72156 without contrast material(s), followed by contrast material(s) and further sequences

MRI, Spinal Canal and Contents, Thoracic
- 72147 with contrast material(s)
- 72157 without contrast material(s), followed by contrast material(s) and further sequences

MRI, Spinal Canal and Contents, Lumbar
- 72149 with contrast material(s)
- 72158 without contrast material(s), followed by contrast material(s) and further sequences

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Indications and Usage

Central Nervous System: Magnevist® (gadopentetate dimeglumine) injection is indicated for the use with magnetic resonance imaging (MRI) in adults and pediatric patients (2 years of age and older) to visualize lesions with abnormal vascularity in the brain (intracranial lesions), spine and associated tissues. Magnevist® has been shown to facilitate visualization of intracranial lesions including but not limited to tumors.

Extracranial/Extraspinal Tissues: Magnevist® is indicated for use with MRI in adults and pediatric patients (2 years of age and older) to visualize lesions with abnormal vascularity in the head and neck.

Body: Magnevist® is indicated for use with MRI in adults and pediatric patients (2 years of age and older) to visualize lesions with abnormal vascularity in the body.

Please see Important Safety Information on following pages.
**Important Safety Information**

**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-contrast MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- Do not administer MAGNEVIST to 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 (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.

Do not exceed the recommended MAGNEVIST dose and allow a sufficient period of time for elimination of the drug from the body prior to re-administration.

**Contraindications:**

Magnevist® is contraindicated in patients with:

- Chronic, severe kidney disease (glomerular filtration rate, GFR <30 mL/min/1.73m²), or
- Acute kidney injury, or
- History of severe hypersensitivity reactions to Magnevist®.

**Hypersensitivity Reactions:** Anaphylactoid and anaphylactic reactions with cardiovascular, respiratory and/or cutaneous manifestations rarely resulting in death have occurred. The risk of hypersensitivity reactions is higher in patients with a history of reaction to contrast media, bronchial asthma, or allergic disorders. Hypersensitivity reactions can occur with or without prior exposure to GBCAs.

**Renal Failure:** In patients with renal impairment, acute renal failure (acute kidney injury) requiring dialysis or worsening renal function has occurred, mostly within 48 hours of Magnevist® Injection. The risk of acute renal failure is higher with increasing dose of contrast. Use the lowest possible dose, evaluate renal function in patients with renal impairment, and allow sufficient time for contrast elimination before re-administration. Elimination half-life in patients with mild or moderate renal impairment is 3 to 4 hours. Elimination half-life in patients with severe renal impairment is about 11 hours. Magnevist® is cleared by glomerular filtration and is dialyzable. After 3 dialysis sessions of 3 hours each, about 97% of the administered dose is eliminated from the body; each dialysis session removes about 70% of the circulating drug.

Please see additional Important Safety Information on following page.
Magnevist®
(gadopentetate dimeglumine) injection
0.5 mmol/mL

Magnevist Important Safety Information (continued)

**Injection Site Reaction:** Skin and soft tissue necrosis, thrombosis, fasciitis, and compartment syndrome requiring surgical intervention (e.g., compartment release or amputation) have occurred very rarely at the site of the contrast injection or the dosed limb. Total volume and rate of Magnevist® Injection, extravasation of contrast agent, and patient susceptibility might contribute to these reactions. Phlebitis and thrombophlebitis may be observed generally within 24 hours after Magnevist® Injection and resolve with supportive treatment. Determine the patency and integrity of the intravenous line before administration of Magnevist® Injection. Assessment of the dosed limb for the development of injection site reactions is recommended.

**Interference with Visualization of Lesions with Non-Contrast MRI:** As with any paramagnetic contrast agent, Magnevist® Injection might impair the visualization of lesions seen on non-contrast MRI. Therefore, caution should be exercised when Magnevist® MRI scans are interpreted without a companion non-contrast MRI scan.

**Adverse Reactions:** In clinical trials, the most frequently reported adverse reactions (≥1%) included headache (4.8%), nausea (2.7%), injection site coldness/localized coldness (2.3%) and dizziness (1%).

Please see additional Important Safety Information on previous page.

Please click here to see the Magnevist® Full Prescribing Information (Vials & Syringes).

Please click here to see the Magnevist® Full Prescribing Information (Pharmacy Bulk Package).

Learn more about Magnevist at magnevist.com
Eovist®
(gadoxetate disodium) injection
0.25 mmol/mL

CPT Codes

Eovist-specific MRI Codes

A9581 injection, gadoxetate disodium, per 1.0 mL

MRI, Abdomen (for Liver MRI)
74182 with contrast material(s)
74183 without contrast material(s), followed by contrast material(s) and further sequences

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Indication and Usage

Eovist® (gadoxetate disodium) injection is indicated for intravenous use in magnetic resonance imaging (MRI) of the liver to detect and characterize lesions in patients with known or suspected focal liver disease.

Important Safety Information

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 (for example, age >60 years, hypertension or diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
• For patients at highest risk for NSF, do not exceed the recommended EOVIST dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Contraindication and Important Information about Hypersensitivity Reactions: Eovist® is contraindicated in patients with history of severe hypersensitivity reactions to Eovist®. Anaphylactic and other hypersensitivity reactions with cardiovascular, respiratory and cutaneous manifestations, ranging from mild to severe, including shock have uncommonly occurred following Eovist® administration. Before Eovist® administration, assess all patients for any history of a reaction to contrast media, bronchial asthma and allergic disorders. These patients may have an increased risk for a hypersensitivity reaction to Eovist®.

Please see additional Important Safety Information on following page.
Eovist®
(gadoxetate disodium) injection
0.25 mmol/mL

Eovist Important Safety Information (continued)

Acute Kidney Injury: In patients with chronic renal impairment, acute kidney injury sometimes requiring dialysis has been observed with the use of some GBCAs. The risk of acute kidney injury might be lower with Eovist® due to its dual excretory pathways. Do not exceed the recommended dose; the risk of acute kidney injury may increase with higher than recommended doses.

Extravasation and Injection Site Reactions: Ensure catheter and venous patency before the injection of Eovist®. Extravasation into tissues during Eovist® administration may result in local tissue reactions. Strictly avoid intramuscular administration of Eovist® because it may cause myocyte necrosis and inflammation.

Interference with Laboratory Tests: Serum iron determination using complexometric methods (for example, ferrocene complexation method) may result in falsely high or low values for up to 24 hours after the examination with Eovist® because of the caloxetate trisodium excipients.

Interference with Visualization of Liver Lesions: Severe renal or hepatic failure may impair Eovist® imaging performance. In patients with end-stage renal failure, hepatic contrast was markedly reduced and was attributed to elevated serum ferritin levels. In patients with abnormally high (>3 mg/dL) serum bilirubin, reduced hepatic contrast was observed. If Eovist® is used in these patients, complete MRI no later than 60 minutes after Eovist® administration and use a paired non-contrast and contrast MRI set for diagnosis.

Adverse Reactions: The most frequent (≥0.5%) adverse reactions associated with Eovist® are nausea (1.1%), headache (1.1%), feeling hot (0.8%), dizziness (0.6%), and back pain (0.6%).

Please see additional Important Safety Information on previous page.

Please click here to see the Eovist® Full Prescribing Information.

Learn more about Eovist at eovist.com
CPT Codes

Ultravist-specific CT Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q9966</td>
<td>low osmolar contrast media 200-299 mg/mL iodine, per 1.0 mL</td>
</tr>
<tr>
<td>Q9967</td>
<td>low osmolar contrast media 300-399 mg/mL iodine, per 1.0 mL</td>
</tr>
</tbody>
</table>

**CT, Head or Brain**
- 70460 with contrast material(s)
- 70470 without contrast material(s), followed by contrast material(s) and further sections

**CT, Orbit, Sella, or Posterior Fossa or Outer, Middle, or Inner Ear**
- 70481 with contrast material(s)
- 70482 without contrast material(s), followed by contrast material(s) and further sections

**CT, Maxillofacial Area**
- 70487 with contrast material(s)
- 70488 without contrast material(s), followed by contrast material(s) and further sections

**CT, Thorax**
- 71250 without contrast material(s)
- 71260 with contrast material(s)
- 71270 without contrast material(s), followed by contrast material(s) and further sections

**CT, Pelvis**
- 72193 with contrast material(s)
- 72194 without contrast material(s), followed by contrast material(s) and further sections

**CT, Abdomen**
- 74160 with contrast material(s)
- 74170 without contrast material(s), followed by contrast material(s) and further sections

**CT, Abdomen and Pelvis**
- 74177 with contrast material(s)
- 74178 without contrast material(s), followed by contrast material(s) and further sections

Information provided in this resource is for informational purpose only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource nor the Bayer Healthcare Reimbursement Helpline is intended as a legal advice or as a substitute for a provider's independent professional judgment.

**Indications and Usage**

Ultravist® (iopromide) injection is an iodinated contrast agent indicated for:

**Intra-arterial Procedures**: 300 mg Iodine per mL for cerebral arteriography and peripheral arteriography; 370 mg Iodine per mL for coronary arteriography and left ventriculography, visceral angiography, and aortography.

**Intravenous Procedures**: 240 mg Iodine per mL for peripheral venography; 300 mg Iodine per mL for excretory urography; 300 mg Iodine per mL and 370 mg Iodine per mL for contrast Computed Tomography (CT) of the head and body (intrathoracic, intraabdominal and retroperitoneal regions) for the evaluation of neoplastic and non-neoplastic lesions. The usefulness of contrast enhancement for the investigation of the retrobulbar space and of low grade or infiltrative glioma has not been demonstrated.

* For information on the concentrations and doses for the Pediatric Population [see Dosage and Administration (2.3) and Use in Specific Populations (8.4) in the Full Prescribing Information].

Please see Important Safety Information on following pages.
WARNING: NOT FOR INTRATHECAL USE

Inadvertent intrathecal administration may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema.

Contraindications: Ultravist® injection is contraindicated for intrathecal use.

Preparatory dehydration (e.g. prolonged fasting and the administration of a laxative before Ultravist® injection) is contraindicated in pediatric patients because of risk of renal failure.

Anaphylactoid Reactions: Life‐threatening or fatal anaphylactoid reactions may occur during or after Ultravist® administration, particularly in patients with allergic disorders. Increased risk is associated with a history of previous reaction to a contrast agent, a known sensitivity to iodine and known allergic disorders or other hypersensitivities. Exercise extreme caution when considering the use of iodinated contrast agents in patients with these histories or disorders. Emergency facilities and personnel trained in the treatment of anaphylactoid reactions should be available for at least 30 to 60 minutes after Ultravist® administration.

Contrast Induced Acute Kidney Injury: Acute kidney injury, including renal failure, may occur after intravascular administration of Ultravist®. Risk factors include: pre‐existing renal insufficiency, dehydration, diabetes mellitus, congestive heart failure, advanced vascular disease, elderly age, concomitant use of nephrotoxic or diuretic medications, multiple myeloma/paraproteinemia, repetitive and/or large doses of Ultravist®. Use the lowest necessary dose of Ultravist® in patients with renal impairment. Adequately hydrate patients prior to and following Ultravist® administration.

Cardiovascular Reactions: Hemodynamic disturbances including shock and cardiac arrest may occur during or shortly after administration of Ultravist®. Observe patients with preexisting cardiovascular disease for several hours following Ultravist® administration.

Thromboembolic Complications: Angiography may be associated with local and distal organ damage, ischemia, thromboembolism and organ failure. In angiographic procedures, consider the possibility of dislodging plaques or damaging or perforating the vessel wall. The physicochemical properties of the contrast agent, the dose and the speed of injection can influence the reactions. Monitor electrocardiograms and vital signs throughout the procedure. Exercise care when performing venography in patients with suspected thrombosis, phlebitis, severe ischemic disease, local infection, venous thrombosis or a totally obstructed venous system. Clotting may occur when blood remains in contact with syringes containing iodinated contrast agents. Avoid angiography whenever possible in patients with homocystinuria because of the risk of inducing thrombosis and embolism.

Reactions in Patients with Hyperthyroidism, Pheochromocytoma, or Sickle Cell Disease: Thyroid storm has occurred after the intravascular use of iodinated contrast agents in patients with hyperthyroidism, or with autonomously functioning thyroid nodule. Evaluate the risk in such patients before use of any iodinated contrast agent. Administer iodinated contrast agents with extreme caution in patients with known or suspected pheochromocytoma. Inject the minimal amount of contrast necessary. Contrast agents may promote sickling in individuals who are homozygous for sickle cell disease when administered intravascularly.

Extravasation: Extravasation of Ultravist® may cause tissue necrosis and/or compartment syndrome, particularly in patients with severe arterial or venous disease.

Please see additional Important Safety Information on following page.
**Ultravist®**  
({{iopromide}}) injection  
240 | 300 | 370 mg I/mL

**Ultravist Important Safety Information (continued)**

**Increased Radiation Exposure:** The decision to use contrast enhancement is associated with risk and increased radiation exposure.

**Interference with Image Interpretation:** The use of Ultravist® Injection may obscure some lesions which were seen on non-contrast CT scans. Calcified lesions are less likely to enhance. The enhancement of tumors after therapy may decrease. The opacification of the inferior vermis following contrast agent administration has resulted in false-positive diagnosis. Cerebral infarctions of recent onset may be better visualized with contrast enhancement. However, older infarctions may be obscured by the contrast agent. In patients with normal blood-brain barriers and renal failure, iodinated contrast agents have been associated with blood-brain barrier disruption and accumulation of contrast in the brain. Accumulation of contrast in the brain also occurs in patients where the blood-brain barrier is known or suspected to be disrupted.

**Severe Cutaneous Adverse Reactions:** Severe cutaneous adverse reactions (SCAR) may develop from 1 hour to several weeks after intravascular contrast agent administration. These reactions include Stevens-Johnson syndrome and toxic epidermal necrolysis (SJS/TEN), acute generalized exanthematous pustulosis (AGEP) and drug reaction with eosinophilia and systemic symptoms (DRESS). Reaction severity may increase and time to onset may decrease with repeat administration of contrast agent; prophylactic medications may not prevent or mitigate severe cutaneous adverse reactions. Avoid administering Ultravist® to patients with a history of a severe cutaneous adverse reaction to Ultravist®.

**Most Common Adverse Reactions:** Most common adverse reactions (>1%) are headache, nausea, injection site and infusion site reactions, vasodilatation, vomiting, back pain, urinary urgency, chest pain, pain, dysgeusia, and abnormal vision.

Please see additional Important Safety Information on previous page.

**Please click here to see the Ultravist® Full Prescribing Information (Vials and Syringes).**

**Please click here to see the Ultravist® Full Prescribing Information (Pharmacy Bulk Package).**

Learn more about Ultravist at ultravist.com
Bayer HealthCare Inc. also provides additional information on non-reimbursement topics.

For information regarding Bayer's portfolio of diagnostic imaging agents, please call your Bayer HealthCare Sales Consultant at 1-888-842-2937, option 5.

For customer service or purchasing information regarding any Bayer diagnostic imaging agent, please call 1-877-229-3750.

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