

REIMBURSEMENT RESOURCE KIT

VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL

DISCLAIMERS

The information provided here is general reimbursement information for VUEWAY® injection. It is not legal advice, nor is it advice about how to code, complete, or submit any particular claim for payment. Although we supply this information based on our current knowledge, it is always the provider's responsibility to determine and submit appropriate codes, charges, modifiers, and bills for the services that were rendered. This coding and reimbursement information is subject to change without notice. Payers or their local branches may have their own coding and reimbursement requirements and policies. Before filing any claims, providers should verify current requirements and policies with the payer.

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VUEWAY® (gadopiclenol) solution for injection

Indications

VUEWAY injection is indicated in adults and children aged 2 years and older for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in:

- the central nervous system (brain, spine, and associated tissues),
- the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

IMPORTANT SAFETY INFORMATION WARNING: RISK ASSOCIATED WITH INTRATHECAL USE and NEPHROGENIC SYSTEMIC FIBROSIS

Risk Associated with Intrathecal Use

Intrathecal administration of gadolinium-based contrast agents (GBCAs) can cause serious adverse reactions including death, coma, encephalopathy, and seizures. VUEWAY is not approved for intrathecal use.

NEPHROGENIC SYSTEMIC FIBROSIS

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/1.73 m²), 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 VUEWAY dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

Contraindications

VUEWAY injection is contraindicated in patients with history of hypersensitivity reactions to VUEWAY.

Warnings and Precautions

There are **risks associated with intrathecal use** of GBCAs that can cause serious adverse reactions including death, coma, encephalopathy, and seizures. The safety and effectiveness of VUEWAY have not been established with intrathecal use and VUEWAY is not approved for intrathecal use.

Risk of **nephrogenic systemic fibrosis** is increased in patients using GBCA agents that have impaired elimination of the drugs, with the

highest risk in patients with chronic, severe kidney disease as well as patients with acute kidney injury. Avoid use of GBCAs among these patients unless the diagnostic information is essential and not available with non-contrast MRI or other modalities.

Hypersensitivity reactions, including serious hypersensitivity reactions, could occur during use or shortly following VUEWAY administration. Assess all patients for any history of a reaction to contrast media, bronchial asthma and/or allergic disorders, administer VUEWAY only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, and observe patients for signs and symptoms of hypersensitivity reactions after administration.

Gadolinium retention can be for months or years in several organs after administration. The highest concentrations (nanomoles per gram of tissue) have been identified in the bone, followed by other organs (brain, skin, kidney, liver and spleen). Minimize repetitive GBCA imaging studies, particularly closely spaced studies, when possible.

Acute kidney injury requiring dialysis has occurred with the use of GBCAs in patients with chronically reduced renal function. The risk of acute kidney injury may increase with increasing dose of the contrast agent.

Extravasation and injection site reactions can occur with administration of VUEWAY. Ensure catheter and venous patency before the injection of VUEWAY.

VUEWAY may **impair the visualization of lesions** seen on non-contrast MRI. Therefore, caution should be exercised when VUEWAY MRI scans are interpreted without a companion non-contrast MRI scan.

The most common adverse reactions (incidence $\geq 0.5\%$) are injection site pain (0.7%), and headache (0.7%).

POST-MARKETING EVENTS

The following adverse reactions have been identified during postmarketing use of GBCAs. Gastrointestinal Disorders: Acute pancreatitis with onset within 48 hours after GBCA administration

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

Please click <u>here</u> for full Prescribing Information for VUEWAY (gadopiclenol) solution for injection including BOXED WARNING on Nephrogenic Systemic Fibrosis.

Manufactured for Bracco Diagnostics Inc. by Liebel-Flarsheim Company LLC - Raleigh, NC, USA 27616.

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UNLOCKING THE



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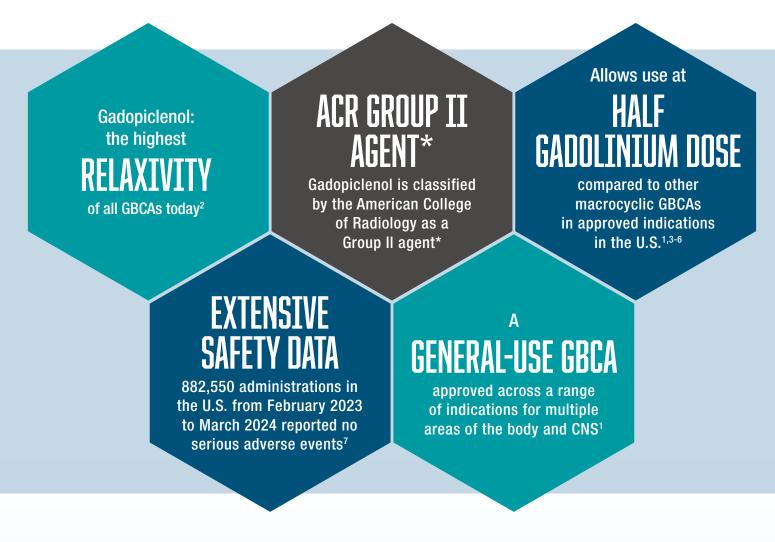






Consider the product attributes of VUEWAY[®] (gadopiclenol) solution for injection, 485.1 mg/mL

For MRI, you've had to choose either clinically relevant higher relaxivity or higher kinetic stability.^{1,2} Why choose one when you can have both? VUEWAY injection: a unique macrocyclic high-relaxivity GBCA.^{1,2}



*Group II agents are associated with few, if any, unconfounded cases of NSF.⁸





MRI CPT CODING CHART⁹

ORBIT, FACE & NECK · - - -

70540 - Without contrast 70542 - With contrast 70543 - With & without contrast

CERVICAL SPINE 72141 - Without contrast 72142 - With contrast 72156 - With & without contrast

FETAL IMAGING (Single or first gestation) 74712

FETAL IMAGING ------(Each additional gestation) 74713

SHOULDER, ELBOW, OR WRIST -(Upper Extremity, Joint) 73221 - Without contrast 73222 - With contrast 73223 - With & without contrast

HUMERUS, FOREARM, AND/OR -----HAND (Upper Extremity, Non-Joint) 73218 - Without contrast 73219 - With contrast 73220 - With & without contrast

HIP, KNEE, AND/OR ANKLE ----(Lower Extremity, Joint) 73721 - Without contrast 73722 - With contrast 73723 - With & without contrast

THIGH, LOWER LEG, AND/OR FOOT (Lower Extremity, Non-Joint) ----73718 - Without contrast 73719 - With contrast 73720 - With & without contrast

UNLOCKING THE



BRAIN

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70551 - Without contrast 70552 - With contrast 70553 - With & without contrast

TMJ 70336 72146 - Without contrast 72147 - With contrast 72157 - With & without contrast

-- CARDIAC FOR MORPHOLOGY & FUNCTION

75557 - Without contrast 75559 - Without contrast, with stress imaging 75561 - Without contrast, followed by contrast and further sequences 75563 - Without contrast, followed by contrast and further sequences; with stress imaging

-- CARDIAC FOR VELOCITY FLOW MAPPING 75565

----- CHEST

71550 - Without contrast 71551 - With contrast 71552 - With & without contrast

----- BREAST

77046 - Without contrast; unilateral 77047 - Without contrast; bilateral 77048 - With & without contrast; including CAD; unilateral 77049 - With & without contrast; including CAD; bilateral

----- ABDOMEN

74181 - Without contrast 74182 - With contrast 74183 - With & without contrast

----- LUMBAR SPINE

72148 - Without contrast 72149 - With contrast 72158 - With & without contrast

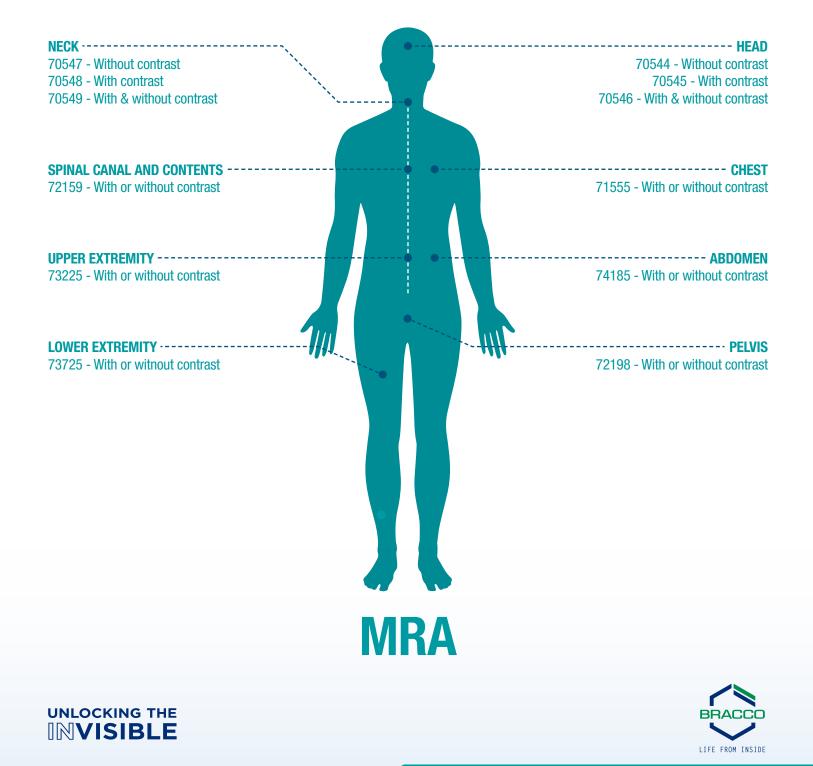
----- PELVIS

72195 - Without contrast 72196 - With contrast 72197 - With & without contrast





MRA CPT CODING CHART⁹



C Codes¹⁰

C Codes are created by Medicare for Patients under HOPPS. In some circumstances, commercial payors may accept these codes in non-hospital settings.

C8900	MRA w/ contrast, abdomen
C8902	MRA w/o followed by w/ contrast, abdomen
C8905	MRI w/o followed by w/ contrast, breast, unilateral
C8906	MRI w/ contrast, breast, bilateral
C8908	MRI w/o fol w/ contrast, breast
C8909	MRA w/ contrast, chest
C8911	MRA w/o fol w/ contrast, chest
C8912	MRA w/ contrast, lower extremity
C8914	MRA w/o contrast fol w/ contrast, lower extremity
C8918	MRA w/ contrast, pelvis
C8920	MRA w/o fol w/ contrast, pelvis
C8931	MRA, w/ contrast, spinal canal
C8933	MRA, w/o & w/ contrast, spinal canal
C8934	MRA, w/ contrast, upper extremity
C8937	MRI, CAD, breast (list separately in addition to code for primary procedure)







CPT[®] (Current Procedural Terminology)

Codes used to report the service or procedure performed.

HCPCS (Healthcare Common Procedure Coding System)

Codes used to report the provision of supplies, materials, injections, and certain services and procedures. For example, the HCPCS code for VUEWAY[®] (gadopiclenol) solution for injection, 485.1 mg/mL is A9573, Injection, gadopiclenol, 1 mL.

Coding Modifiers

Under HOPPS, VUEWAY injection is not separately reimbursable, and therefore the JZ and JW Modifiers do not apply under this billing system. They are required for independent imaging centers billing under the Medicare Physician Fee Schedule.

ICD-10-CM (International Classification of Disease)

Codes used to describe a patient's signs and symptoms that would represent a medically necessary reason for performing the procedure. ICD-10-CM codes need to be entered on the claim form. ICD-10-CM is the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD), a medical classification list by the World Health Organization (WHO).

APC (Ambulatory Payment Classification)

In most cases, the unit of payment under the HOPPS is the APC. CMS assigns individual services HCPCS & CPT codes to APCs based on similar clinical characteristics and similar costs. The payment rate and copayment calculated for an APC apply to each service within the APC.

NDC (National Drug Code)

An NDC code provides a unique identifier for a specific drug. NDCs for VUEWAY injection are on page 14.

Medicare Addendum B

These files are updated quarterly and reflect HOPPS payment rates for HCPCS codes and APC codes. https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.

Medicare Part B ASP (average selling price) file

Quarterly payment files are published for Independent Diagnostic Testing Facilities (IDTFs) and physician offices. This is where the payment value for VUEWAY injection (A9573, Injection, gadopiclenol, 1 mL) can be found: https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files.

Medicare Physician Fee Schedule (MPFS)

Find out physician payment for specific geographic locations in the country for different procedures. This schedule provides: global (G), technical (TC), and professional (26) component payment rates. To find out more information on specific locations visit: https://www.cms.gov/medicare/physician-fee-schedule/search/overview.







CODING INFORMATION

VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL HCPCS Code¹¹: A9573, Injection, gadopiclenol, 1 mL

Medicare Patients: VUEWAY injection is part of a bundled payment under HOPPS and not separately reimbursed. Please code separately with the echocardiography and radiology procedure codes.

Commercially insured patients: The provider must contact their respective insurance providers to include A9573 and establish a reimbursement value.

Medicaid Patients: Medicaid coverage varies by state, please consult your local Medicaid office to find the policies in your area. Bracco does not participate in the Medicaid Rebate Program.

Procedure Codes: Contrast enhanced MRI CPT codes are part of the 70000 series codes. Please refer to the American Medical Association's official CPT book for a complete list.







Volume of VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL by Body Weight

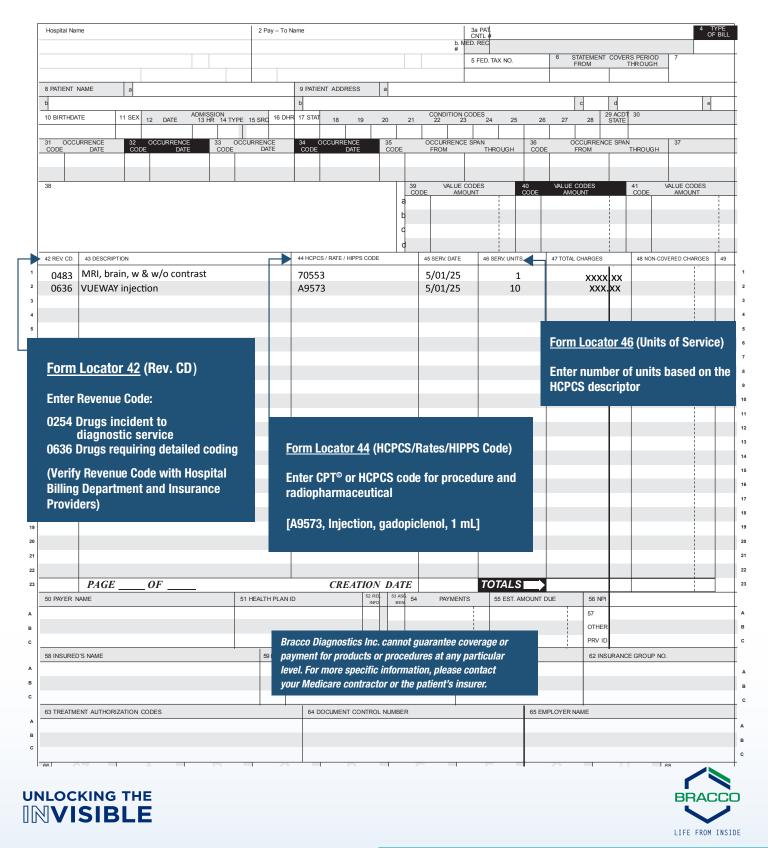
Body Weight		Volume Millilitere (ml.)
Pounds (lb)	Kilograms (kg)	Volume Milliliters (mL)
22	10	1
44	20	2
66	30	3
88	40	4
110	50	5
132	60	6
154	70	7
176	80	8
198	90	9
220	100	10
242	110	11
264	120	12
286	130	13
308	140	14
330	150	15







Sample hospital setting billing form UB-04 CMS-1450 Contrast enhanced MRI





Sample health insurance claim form CMS-1500

Contrast enhanced MRI

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Hospital in-patient billing: Medicare Severity Adjusted Diagnosis Related Groups (MS-DRG)¹²

ICD-10-PCS procedure codes are used for in-patient billing. They indicate the surgical and/or diagnostic procedures performed on the patient. These codes, in combination with diagnosis codes, help determine the assignment to an MS-DRG payment category under Medicare and other payment systems. Payment in the hospital is determined by the MS-DRG. Under this system, a hospital is paid at a predetermined specific rate for each Medicare discharge. Fixed reimbursement is established for hospital services based on the patient diagnosis and is paid regardless of the actual cost the hospital incurs in providing the services. MRI exams and contrast agents are part of the MS-DRG payment.

Coverage: Medicare National Coverage Decisions (NCD)

Though CMS covers MRIs for different parts of the body for many different indications, it is important to remember to only perform the exam when it is necessary.

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A) states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

For more coverage information, please visit the Medicare Coverage Database search tool at: <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>.







How to Order VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL

VIAL (GLASS)			
	Count	SKU	NDC
3 mL vial (filled in 10 mL vial)	10	702038	0270-7020-38
7.5 mL vial (filled in 10 mL vial)	10	702540	0270-7025-40
10 mL vial (filled in 10 mL vial)	10	703042	0270-7030-42

PHARMACY BULK PACKAGE			
	Count	SKU	NDC
30 mL vial (filled in 50 mL vial)	25	701546	0270-7015-46
50 mL vial (filled in 50 mL vial)	25	701548	0270-7015-48

Please Note: For billing purposes, an extra 0 should be added to the beginning of the NDC number.

To order, call Bracco Customer Service at 1-877-BRACCO-9 (1-877-272-2269), option 2 or visit us online at: MyOrders.Bracco.com











How we support you

The Bracco Reimbursement Hotline is here to support you for all your reimbursement needs.

Ask coding and billing questions regarding Bracco Diagnostics products and procedures related to those products.

- HCPCS codes for products
- CPT[®] and HCPCS codes for procedures
- Medicare payments
- Monday-Friday: 9:00 AM-6:00 PM Eastern Time

For more information on reimbursement, contact the Bracco Reimbursement Hotline at:





askbracco@reimbursement.bracco.com

Please visit us at www.braccoreimbursement.com for more information

On our website, you may sign up to:

- Receive educational emails
- Access our complimentary reimbursement webinars
- 🕑 Get the latest updates on:
 - Coding
 - Coverage
 - Payment







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