

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.

CPT® copyright 2023 American Medical Association (AMA). All rights reserved. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

CPT is a registered trademark of the American Medical Association.

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 surrounding 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-contrast 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 ≥ 0.5%) are injection site pain (0.7%), and headache (0.7%).

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 click [here](#) 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.

VUEWAY is a registered trademark of Bracco Imaging S.p.A.

All other trademarks and registered trademarks are the property of their respective owners.

No Compromise in MRI4

CPT Coding Charts 5-7

Coding Nomenclature8

Coding Information9

Example of Billing11

Hospital In-Patient Billing and Coverage13

Ordering Information14

Reimbursement Hotline.....15

References16

Consider the product attributes of VUEWAY® (gadopichlenol) 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}

Gadopichlenol:
the highest
RELAXIVITY
of all GBCAs today²

ACR GROUP II AGENT*

Gadopichlenol is classified
by the American College
of Radiology as a
Group II agent*

Allows use at
**HALF
GADOLINIUM DOSE**

compared to other
macrocyclic GBCAs
in approved indications
in the U.S.^{1,3-6}

ESTABLISHED SAFETY PROFILE

in adults and children
(2 years and older)^{1,7-9}

A GENERAL-USE GBCA

approved across a range
of indications for multiple
areas of the body and CNS¹

*Group II agents are associated with few, if any, unconfounded cases of NSF.¹⁰

MRI CPT CODING CHART¹²

ORBIT, FACE & NECK

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

BRAIN

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

TMJ

70336

THORACIC SPINE

72146 - Without contrast
72147 - With contrast
72157 - 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

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

MRI

UNLOCKING THE
INVISIBLE



MRA CPT CODING CHART¹²

NECK

70547 - Without contrast
70548 - With contrast
70549 - With & without contrast

HEAD

70544 - Without contrast
70545 - With contrast
70546 - With & without contrast

SPINAL CANAL AND CONTENTS

72159 - With or without contrast

CHEST

71555 - With or without contrast

UPPER EXTREMITY

73225 - With or without contrast

ABDOMEN

74185 - With or without contrast

LOWER EXTREMITY

73725 - With or without contrast

PELVIS

72198 - With or without contrast

MRA

UNLOCKING THE
INVISIBLE



CPT CODING CHART

C Codes¹²

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/payment/fee-schedules/physician/lookup-tool>.

VUEWAY[®] (gadopichlenol) solution for injection, 485.1 mg/mL HCPCS Code¹³: A9573, Injection, gadopichlenol, 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 Milliliters (mL)
Pounds (lb)	Kilograms (kg)	
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

[illegible]

Sample health insurance claim form CMS-1500 Contrast enhanced MRI

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

Form Locator 24D. (HCPCS/Rates/HIPPS Code)
Enter CPT® or HCPCS code for procedure and radiopharmaceutical
70552 Contrast enhanced MRI
A9573 VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL

Form Locator 24G. (Units of Service)
Enter number of units based on the HCPCS descriptor

JW Modifier: Discarded drug not administered, wastage
JZ Modifier: Zero drug wasted

Bracco Diagnostics Inc. cannot guarantee coverage or payment for products or procedures at any particular level. For more specific information, please contact your Medicare contractor or the patient's insurer.

Clear Form

UNLOCKING THE INVISIBLE

BRACCO
LIFE FROM INSIDE

Please see Important Safety Information, including BOXED WARNING, on page 2.

12

Hospital in-patient billing: Medicare Severity Adjusted Diagnosis Related Groups (MS-DRG)¹⁴

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:

<https://www.cms.gov/medicare-coverage-database/search.aspx>.

How to Order VUEWAY[®] (gadopichlenol) 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



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:



1-800-349-1388

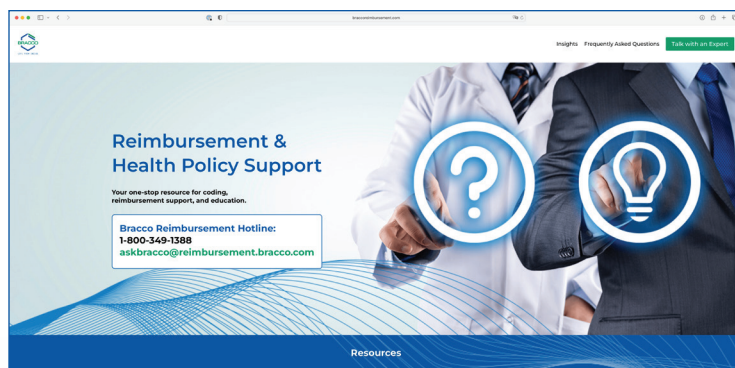


askbracco@reimbursement.bracco.com

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



1. VUEWAY® (gadopiclenol) solution for injection, 485.1 mg/mL Full Prescribing Information and Patient Medication Guide. Monroe Twp., NJ: Bracco Diagnostics Inc.; January 2024.
2. Robic C, Port M, Rousseaux O, et al. Physicochemical and pharmacokinetic profiles of gadopiclenol: a new macrocyclic gadolinium chelate with high T1 relaxivity. *Invest Radiol*. 2019 Aug;54:475-484.
3. GADAVIST® (gadobutrol) Injection. Full Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ; April 2022.
4. DOTAREM® (gadoterate meglumine) Injection. Full Prescribing Information. Guerbet LLC. Princeton, NJ; April 2022.
5. CLARISCAN™ (gadoterate meglumine) injection for intravenous use. Full Prescribing Information. GE Healthcare. Chicago, IL; November 2020.
6. ProHance® (Gadoteridol) Injection, 279.3 mg/mL Full Prescribing Information and Patient Medication Guide. Monroe Twp., NJ: Bracco Diagnostics Inc.; January 2024.
7. Bendszus M, Roberts D, Kolumban B, et al. Dose finding study of gadopiclenol, a new macrocyclic contrast agent, in MRI of central nervous system. *Invest Radiol*. 2020 Mar;55(3):129-137.
8. Jurkiewicz E, Tsvetkova S, Grinberg A, Pasquiers B. Pharmacokinetics, safety, and efficacy of gadopiclenol in pediatric patients aged 2 to 17 Years. *Invest Radiol*. 2020 Aug;57(8):510-516.
9. Hao J, Bourrinet P, Desché P. Assessment of pharmacokinetic, pharmacodynamic profile, and tolerance of gadopiclenol, a new high relaxivity GBCA, in healthy subjects and patients with brain lesions (Phase I/IIa Study). *Invest Radiol*. 2019 Jul;54(7):396-492.
10. ACR Manual on Contrast Media, Updated May 2023. Accessed May 3, 2023 https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf
11. American Medical Association. 2022 Professional Edition CPT® Current Procedural Terminology. Chicago, IL: American Medical Association; 526-562.
12. Centers for Medicare & Medicaid Services. HCPCS Quarterly Update: October 2023 Alpha-Numeric HCPCS Files. Accessed September 13, 2023. <https://www.cms.gov/medicare/coding/hcpcsrleasecodesets/hcpcs-quarterly-update>
13. Centers for Medicare & Medicaid Services (CMS) healthcare common procedure coding system (HCPCS) application summaries and coding recommendations. Centers for Medicare & Medicaid Services. Published July 25, 2023. <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Prior-Years-CMS-HCPCS-LevelIII-Coding-Decisions-Narrative-Summary>
14. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Washington, DC: Centers for Medicare & Medicaid Services, Department of Health and Human Services. Published December 2022. Accessed January 5, 2023. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c03.pdf>

Bracco Diagnostics Inc.
259 Prospect Plains Road, Building H
Monroe Township, NJ 08831 USA
Phone: 609-514-2200
Toll-Free: 1-877-272-2269 (U.S. only)
Fax: 609-514-2446

© 2024 Bracco Diagnostics Inc. All Rights Reserved. US-VW-2300031 02/24

**UNLOCKING THE
INVISIBLE**