Vueway®
(gadopiclenol) injection
485.1 mg/mL

REIMBURSEMENT RESOURCE KIT

VUEWAY® (gadopiclenol) injection for intravenous use

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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Dosage Forms
VUEWAY® is available in single-dose vials, single-dose prefilled syringes, pharmacy bulk packages, and imaging bulk packages.

The VUEWAY Imaging Bulk Package (IBP) is for intravenous use and not for direct infusion. IBP is used for dispensing multiple single doses of gadopiclenol injection for multiple patients, using an automated contrast injection system, or contrast management system approved or cleared for use with this contrast agent in this Imaging Bulk Package. See drug and device labeling for information on devices indicated for use with this Imaging Bulk Package and techniques to help assure safe use.

Indications
VUEWAY injection is indicated in adults and children, including term neonates, 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 ≥ 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.
- General Disorders and Administration Site Conditions: Fatigue, asthenia, pain syndromes, and heterogeneous clusters of symptoms in the neurological, cutaneous, and musculoskeletal systems with variable onset and duration after GBCA administration.
- Respiratory, Thoracic and Mediastinal Disorders: Acute respiratory distress syndrome, pulmonary edema.
- Skin Disorders: Gadolinium-associated plaques.

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) injection for intravenous use including BOXED WARNING on Nephrogenic Systemic Fibrosis.

Manufactured for Bracco Diagnostics Inc. by by BIPSO GmbH, 78224 Singen (Germany).

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CONTENTS

Consider the product attributes of VUEWAY® (gadopiclenol) injection for intravenous use

For MRI, choose the low-dose contrast agent with the highest relaxivity:

VUEWAY injection, a unique macrocyclic gadolinium-based contrast agent (GBCA).[1,2]

Gadopiclenol: the highest **RELAXIVITY** of all GBCAs today[2]

ACR GROUP II AGENT*
Gadopiclenol is classified by the American College of Radiology as a Group II agent*

A LOW GADOLINIUM DOSE
compared to other macrocyclic GBCAs in approved indications in the U.S.[1,3-6]

EXTENSIVE SAFETY DATA
882,550 administrations in the U.S. from February 2023 to March 2024 reported no serious adverse events[7]

GENERAL-USE GBCA
approved across a range of indications for multiple areas of the body and CNS in patients of all ages, including neonates[1]

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

MRA CPT CODING CHART[9]

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

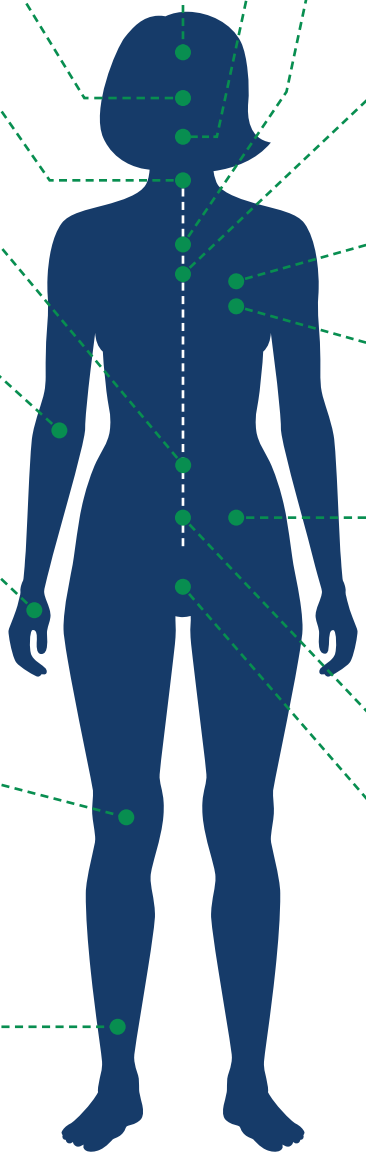
HUMERUS, FOREARM, AND/OR HAND (Upper Extremity, Non-Joint)
73218 - Without contrast
73219 - With contrast
73220 - With & without contrast

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

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

TMJ
70336



MRI

THORACIC SPINE
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

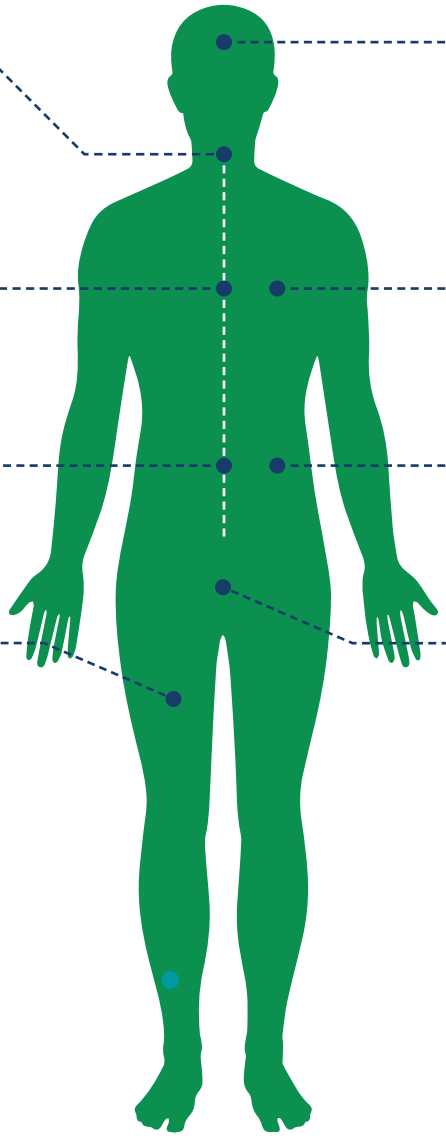
MRA CPT CODING CHART[9]

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

SPINAL CANAL AND CONTENTS
72159 - With or without contrast

UPPER EXTREMITY
73225 - With or without contrast

LOWER EXTREMITY
73725 - With or witnout contrast



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

CHEST
71555 - With or without contrast

ABDOMEN
74185 - With or without contrast

PELVIS
72198 - With or without contrast

MRA

C Codes[10]

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)

CODING NOMENCLATURE

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) injection for intravenous use 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) injection for intravenous use HCPCS Code[11]: 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) injection for intravenous use by Body Weight

For patients <22 lbs (10 kg) the dose of VUEWAY injection is calculated using 0.1 mL/kg

BODY WEIGHT		VOLUME
Pounds (lb)	Kilograms (kg)	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

For patients >330 lbs (150 kg) the dose of VUEWAY injection is calculated using 0.1 mL/kg

Sample hospital setting billing form UB-04 CMS-1450

Contrast enhanced MRI

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES
0483	MRI, brain, w & w/o contrast	70553	5/01/26	1	XXXX.XX	
0636	VUEWAY injection	A9573	5/01/26	10	XXX.XX	

Form Locator 42 (Rev. CD)

Enter Revenue Code:

0254 Drugs incident to diagnostic service
0636 Drugs requiring detailed coding

(Verify Revenue Code with Hospital Billing Department and Insurance Providers)

Form Locator 44 (HCPCS/Rates/HIPPS Code)

Enter CPT© or HCPCS code for procedure and radiopharmaceutical

[A9573, Injection, gadopiclenol, 1 mL]

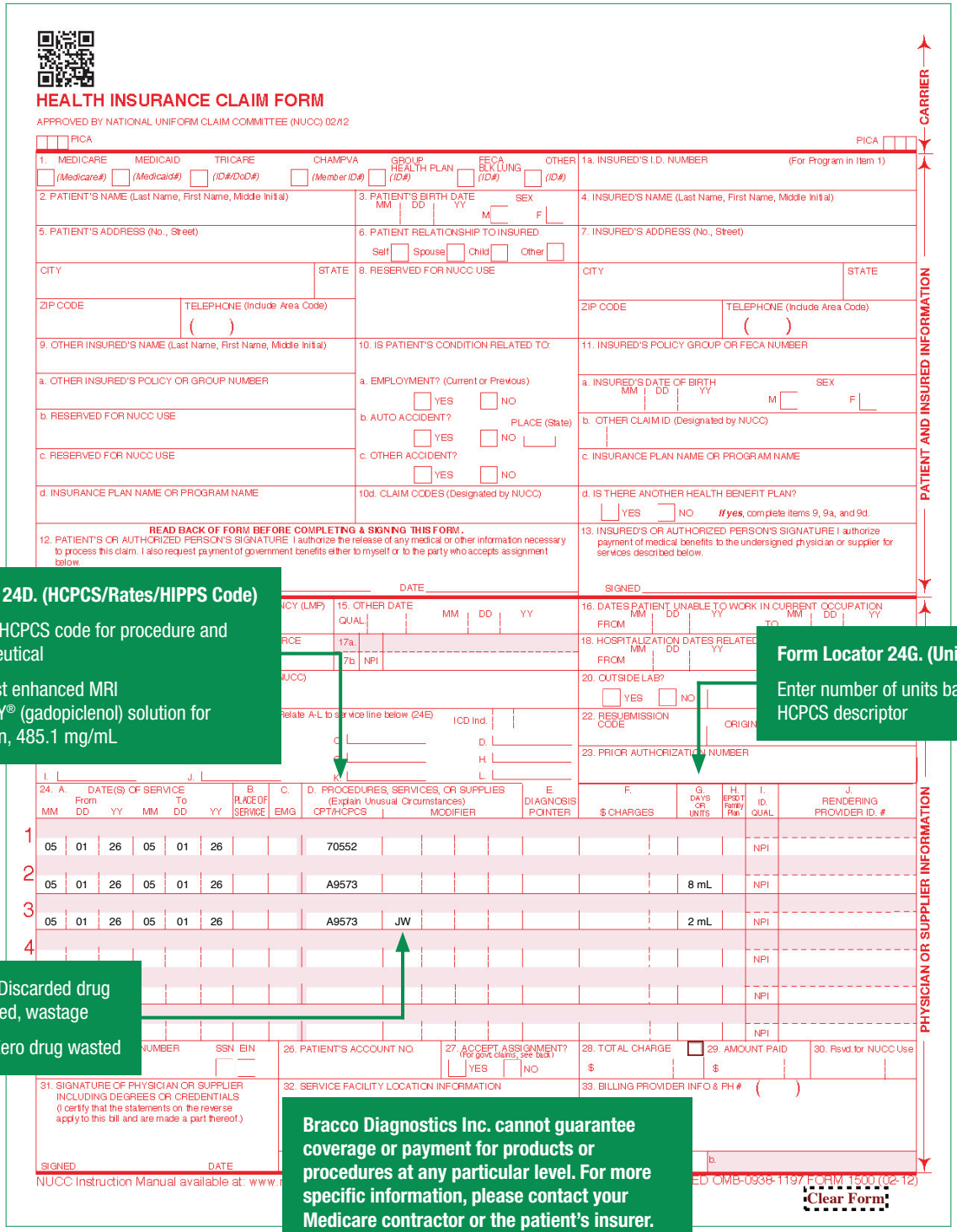
Form Locator 46 (Units of Service)

Enter number of units based on the HCPCS descriptor

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.

Sample health insurance claim form CMS-1500

Contrast enhanced MRI



HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

DATE SIGNED

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED MM DD YY FROM

20. OUTSIDE LAB? YES NO

22. RESUBMISSION CODE ORIGIN

ICD Ind.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1	05	01	26	05	01	26			70552					NPI	
2	05	01	26	05	01	26			A9573			8 mL		NPI	
3	05	01	26	05	01	26			A9573	JW		2 mL		NPI	
4														NPI	
														NPI	
														NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd. for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH #

SIGNED DATE

a. b.

NUCC Instruction Manual available at: www.n

ED OMB-0938-1197 FORM 1500 (02-12)

Clear Form

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

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.

HOSPITAL IN-PATIENT BILLING AND COVERAGE

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

ORDERING INFORMATION

How to Order VUEWAY® (gadopiclenol) injection for intravenous use

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

REIMBURSEMENT HOTLINE

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

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