Bracco Delivers 6 Million VUEWAY® (gadopiclenol) Injection Doses Worldwide as Its MRI Portfolio Continues to Evolve

Milestone reflects growing global adoption of VUEWAY® injection and Bracco's continued expansion across contrast media, delivery systems, and AI-enabled imaging solutions

PRINCETON, N.J., Nov. 20, 2026 -- Bracco, a global leader in diagnostic imaging, today announced that more than 6 million doses1 of VUEWAY® (gadopiclenol) injection for intravenous use have been administered worldwide, a milestone for its magnetic resonance imaging (MRI) contrast agent. Building on this achievement, Bracco continues to advance its broader MRI portfolio with innovations spanning contrast media, delivery systems and AI-enabled technologies designed to address evolving clinical and operational needs.

VUEWAY injection is a highly stable macrocyclic gadolinium-based contrast agent (GBCA) that provides effective contrast enhancement at a low gadolinium (Gd) dose of 0.05 mmol/kg.2,3 Its molecular design contributes to its highest Gd-based relaxivity of FDA-approved GBCAs with similar indications in the U.S.4 Since its first regulatory approval in 2022, VUEWAY injection has expanded into international markets. In 2026, regulatory approvals in the EU and U.S. extended the approved pediatric indications to include neonates and infants, expanding access to low-dose contrast-enhanced MRI for the youngest patients.2,3

"*Six million VUEWAY injection doses administered worldwide is an important milestone, reflecting its growing role in helping radiologists make informed decisions for their patients,*" said **Cosimo De Pinto, Executive Vice President of Marketing & Commercial Operations at Bracco Americas**. "*For patients who require repeated imaging over time, gadolinium dose is a key consideration. The unique molecular design of VUEWAY injection contributes to its highest relaxivity per gadolinium ion among FDA-approved GBCAs with similar indications in the U.S.,4 allowing us to offer a low-dose option across a broad patient population, including neonates and infants. Building on this progress with the Max 3™ Injector and AiMIFY® Software, we're continuing to expand our MRI solutions to address evolving clinical needs and advance patient-centered care.*"

Bracco's expanding MRI portfolio includes complementary solutions designed to address additional needs across the imaging pathway:

- **Max 3™ Rapid-Exchange, Syringeless MR Injector – Streamlining workflow and contrast delivery**: Designed for efficient contrast delivery and streamlined workflows, its cable-free, closed-system design helps optimize contrast use and minimize waste. Automatic air detection, particle filtration and SafeConnect touch protection support safety and aseptic technique. Its expanded U.S. indication includes use with the VUEWAY Imaging Bulk Package, offering more contrast-delivery options.

- **AiMIFY® Software – Bringing AI into image evaluation**: Developed with Subtle Medical, this AI-enabled solution is designed to amplify existing contrast enhancement in post-contrast brain MRI images, supporting improved visualization of enhancing lesions and providing radiologists with additional imaging information. AiMIFY was recently named Best New Radiology Software in AuntMinnie.com's 2026 Minnies Awards.

The milestone of 6 million VUEWAY injection doses administered worldwide represents both progress to date and a foundation for continued innovation. Building on nearly a century of diagnostic imaging expertise, Bracco remains focused on advancing its MRI portfolio in collaboration with the radiology community, so clinicians can give patients clear answers today and in the future.

Please see Important Safety Information for VUEWAY® injection below.

VUEWAY® (gadopiclenol) injection for intravenous use

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 BIPSO GmbH, 78224 Singen (Germany).

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

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ulricheasyINJECT Max 3™ (the Bracco-branded Max 3™, a Rapid Exchange and Syringeless MR Injector System) is distributed by Bracco Diagnostics Inc.

Indications for use
ulricheasyINJECT Max 3 (XD 10180) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications.

ulricheasyINJECT Max 3 (XD 10180) is specifically indicated for use in MRI procedures for the delivery of the following contrast media:

- Gadobutrol Injection in single-dose (SD) container or Imaging Bulk Package (IBP)
- Gadopiclenol Injection in SD container or IBP
- Gadobenate dimeglumine Injection in SD container
- Gadoterate meglumine Injection in SD container

Easy-Click-Cassette – flex Max 3 is used for a maximum time of twenty-four (24) hours or a maximum of 96 bottles of contrast media, whichever comes first.

Use time expiration per SD container is a maximum of four (4) hours, unless otherwise stated by the contrast media labeling.

Use time expiration per IBP or saline container is a maximum of twenty-four (24) hours, unless otherwise stated by the media labeling.

Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure.

ulricheasyINJECT Max 3 (XD 10180) is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The ulricheasyINJECT Max 3 (XD 10180) is not intended for injection of contrast media (CM) for high-pressure angiography.

Contraindications
The ulricheasyINJECT Max 3 injectors are not intended for the administration of contrast medium during high-pressure angiography or other applications that do not comply with the intended use.

The injector is not protected against the effects of defibrillation. Before a defibrillator is used, the patient must be disconnected from ulricheasyINJECT Max 3 injector.

Do not add any disposables (i.e. connector tubing or valves) to the ulricheasyINJECT Max 3 disposables or in conjunction with the patient tubing that are not provided by ulrich medical.

No valves or other connectors may be placed in-line between the patient tubing and the patient cannula. The disposables identified in this IFU are designed, manufactured, and tested for connection with cannulas for pressure injections.

Do not use ulricheasyINJECT Max 3 injectors with any other contrast media (other than those described in this IFU). Any other contrast media are inappropriate and should not be used.

Do not operate the injector and terminal, including any accessories, in potentially explosive atmospheres or in the vicinity of combustible materials (especially anesthetic drugs, detergents, and oxygen-enriched environments).

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ulricheasyINJECT Max 3 is distributed as the Bracco-branded Max 3, a Rapid Exchange and Syringeless MR Injector System, by Bracco Diagnostics Inc.; 510 Carnegie Center, Suite 300, Princeton, NJ 08540 USA; Phone: (800) 631-5245; Fax: (609) 514-2424; Customer Service: 1-877-BRACCO 9 (1-877-272-2269); Scientific Information: 1-800-257-5181 (Option 2); Website: https://braccomr.com/max-3/

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AiMIFY® Software

Indications for Use

AiMIFY® is an image processing software that can be used for image enhancement in MRI images. It can be used to increase contrast-to-noise ratio (CNR), contrast enhancement (CEP), and lesion-to-brain ratio (LBR) of enhancing tissue in brain MRI images acquired with a gadolinium-based contrast agent. It is intended to enhance MRI images acquired using standard approved dosage per the contrast agent's instructions for use.

Cautions

AiMIFY-enhanced images should not be used alone to assist patient diagnosis. The standard post-contrast image must always be reviewed first before using AiMIFY-enhanced images for patient diagnosis.

Please be aware that AiMIFY is not intended for artifact reduction, such as metal artifact and motion artifact. Enhanced images may have similar artifacts as input images.

AiMIFY may enhance intensity differences between pre-and post-contrast images that are caused by 1) registration errors between the sequences or 2) image artifacts in either sequence.

AiMIFY may enhance vessel conspicuity more than standard acquired post-contrast images. In cases where vessel conspicuity interferes with or delays diagnosis, the standard post-contrast image should be used for adjudication.

AiMIFY-enhanced images may contain false lesions due to enhancement of image quality issues in either input sequences, due to being introduced by the AiMIFY algorithm, or both. The standard post-contrast image should be used to rule out false lesions.

Please be aware that AiMIFY has only been trained and tested on head MRI for contrast enhancement. Using the AiMIFY software in other anatomies or use cases not defined in this user manual could result in unknown image enhancement performance.

The internal morphology of tissue in input sequences have been tested to be moderately preserved by AiMIFY processing both for lesion tissue and parenchyma tissue. Internal morphology may appear to be missing due to window leveling of the image, and can be obtained by adjusting the window levels.

Please be aware that AiMIFY is intended for use only with standard of care quality images. Standard approved dose contrast images should be acquired per the contrast agent's instructions for use. The standard of care should not be adjusted in preparation for using AiMIFY.

Please be aware that AiMIFY should not be used for acquiring stat scans or emergent scans, as image processing time may delay diagnosis.

Standard approved dose contrast images should be acquired per the contrast agent's instructions for use. AiMIFY-enhanced images are not fully equivalent to post-contrast images acquired with a higher than recommended actual dosage of contrast. However, the high-dose-like appearance of AiMIFY-enhanced images offers a potentially safer alternative to actually acquiring post-contrast images beyond standard dosing.

Contraindications

AiMIFY is an image processing software that inherently doesn't cause harm to patients of any subpopulation. However, gadolinium-based contrast agents are associated with contraindications, precautions, and warnings for certain subpopulations. Strictly follow the gadolinium-based contrast agent's instructions for use, including but not limited to contraindicated patient populations, prior to processing with AiMIFY.

Limitations

AiMIFY has been trained and tested using a diverse DICOM image dataset collected from different MR imaging applications at 0.3T, 1.5T, and 3.0T, including:

- T1 weighted imaging for pre and post-contrast brain scans obtained with gadolinium-based contrast agents in 2D sequences, such as fluid-attenuated inversion recovery (FLAIR) and fast spin echo (FSE).
- T1 weighted imaging for pre and post-contrast brain scans obtained with gadolinium-based contrast agents in 3D sequences, such as BRAin VOlume (BRAVO) inversion-recovery-prep fast split echo (SPGR) and Magnetization Prepared Rapid Gradient Echo (MPRAGE).
- Acquisition in axial, coronal, and sagittal orientations.
- Images acquired with GE Medical Systems, Philips Medical Systems, Siemens Healthineers, and Hitachi scanners (see separate Scanner List for models).
- Images (for performance testing) spanning a variety of pathologies including patients with Cerebritis, Glioma, Inflammation, Lymphoma, Meningioma, Metastatic lesions, Multiple sclerosis, Neuritis, other tumor-related lesions (e.g., resection/radiation necrosis / suspected cyst / etc.), and other abnormalities.
- Patients aged 7 to 86 years old with an even distribution of females and males in the test dataset.
- Lesions in the dataset were small (<1 cc) and large (>1 cc).

Any imaging sequences/applications outside the above list may result in prolonged processing time and/or unreasonable results.

AiMIFY is manufactured for Bracco Diagnostics Inc. by Subtle Medical Inc. – Menlo Park, CA, USA 94025.

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

About Bracco
Bracco Group, founded in 1927, is a global leader in diagnostic imaging committed to advancing healthcare and improving people's lives by shaping the future of prevention and precision medicine. The company operates in the healthcare sector in more than 100 countries, with a workforce of over 4,000 employees and consolidated annual revenues of approximately €2 billion, with a global footprint.

With a strong commitment to innovation, investing around 9% of its reference turnover in research and development, Bracco develops and provides a broad portfolio of pharmaceutical products for diagnostic imaging, including contrast agents for X-ray, computed tomography and magnetic resonance imaging, as well as microbubbles for contrast-enhanced ultrasound and molecular imaging agents such as radioactive tracers and novel positron emission tomography imaging agents, alongside artificial intelligence-based solutions. It is also a global market leader in advanced contrast management technologies for cardiovascular angiography and radiology imaging.

Discover more at www.bracco.com.

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1 Data on file. Bracco Diagnostics Inc.: September 2026.
2 European Medicines Agency VUEWAY® (gadopiclenol). EPAR Product Information. 2026.
3 VUEWAY® (gadopiclenol) injection for intravenous use. Full Prescribing Information and Patient Medication Guide. Princeton, NJ: Bracco Diagnostics Inc.; February 2026.
4 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;54(8):475–484.