FDA Approves VUEWAY® (gadopiclenol) Solution for Injection, Intravenous Use, for Use in Neonates and Infants

Approval expands low-dose MRI contrast options for the youngest patients and reflects a positive benefit–risk profile of VUEWAY® injection from birth through adulthood

23 FEBRUARY 2026, PRINCETON, NJ – Bracco, a global leader in diagnostic imaging, today announced that the U.S. Food and Drug Administration (FDA) has approved the extension of the current VUEWAY® (gadopiclenol) solution for injection, intravenous use, for use in neonates and infants.

VUEWAY® injection is a macrocyclic gadolinium-based contrast agent (GBCA) that provides effective contrast enhancement at half the gadolinium dose (0.05 mmol/kg) compared with other macrocyclic GBCAs approved in the United States (0.1 mmol/kg), helping reduce cumulative gadolinium exposure without compromising image quality.[1,2,3] Reducing gadolinium exposure while maintaining diagnostic performance is important for all patients undergoing contrast-enhanced MRI, and is particularly critical in neonates and infants, whose brains and body tissues are still developing.[4] Clinical guidance from radiology societies emphasizes the use of the lowest effective GBCA dose when contrast-enhanced imaging is required.[4]

"In the delivery of medical care, and particularly for our care of neonates and young children, we must consider potential long-term implications of our decisions today," said Teresa Chapman, MD, MA, FACR, Director of Fetal and Pediatric MR Imaging, Department of Radiology, University of Wisconsin School of Medicine & Public Health. *"For diagnostic magnetic resonance imaging exams that require intravenous gadolinium contrast, we have a responsibility to achieve high-quality imaging while reducing cumulative exposure to gadolinium. An FDA-approved contrast agent that provides our required diagnostic quality with half the gadolinium dose represents meaningful progress for pediatric MRI. Additionally, limiting gadolinium amounts in production and in medical waste supports responsible contrast stewardship, which is an increasing focus for radiology sustainability efforts."*

VUEWAY® injection is a highly stable macrocyclic GBCA with the highest longitudinal relaxivity (r1) values among currently approved GBCAs. Large, multicenter clinical studies have demonstrated that VUEWAY® injection provides comparable diagnostic efficacy at half the gadolinium dose of gadobutrol, a GBCA widely used in clinical practice.[5,6,7]

"Imaging neonates and infants demands both precision and restraint," said Jeffrey H. Miller, MD, Pediatric Neuroradiologist and Chief of Radiology at Phoenix Children's Hospital. *"The availability of a contrast agent that delivers strong visualization at a lower gadolinium dose gives clinicians another tool to balance diagnostic confidence with thoughtful exposure management. For practices caring for children who may require multiple MRIs over time, this represents a practical and clinically meaningful advancement."*

More than 3.5 million doses of VUEWAY® injection have been administered across approximately 900 customer sites in the U.S., reflecting growing clinical adoption and patient preference for lower-dose contrast agents.[8,9]

"When imaging is needed early in life, families want reassurance that every decision has been made with long-term safety in mind," said Gary Ray, Associate Director, MR Contrast, Bracco Americas. *"This FDA approval provides clinicians with an approved option for contrast-enhanced MRI in neonates and infants that delivers diagnostic*

confidence at a lower gadolinium dose. By extending VUEWAY® injection to patients from birth, we are helping support essential imaging while being intentional about exposure in populations where long-term considerations matter most."

The FDA approval was based on data from study GDX-44-015, which evaluated the safety and efficacy of VUEWAY® injection in pediatric patients. Gadopiclenol was first approved by the FDA in September 2022 and obtained EU approval in December 2023 for use in adult patients and in pediatric patients aged 2 years and older.[10,11] In January 2026, gadopiclenol received EU approval expanding its approved indications to include neonates and infants.[11]

Please see Important Safety Information 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 (children younger than 2 years of age), 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., Princeton, NJ 08540, by BIPSO GmbH, 78224 Singen (Germany): (vials only).

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The company is committed to advancing radiology by sharing knowledge to cultivate future thought leaders, linking today's practice with tomorrow's progress. Since 1927, Bracco Imaging has grown to more than 3,800 employees and now supports patients and radiology professionals in over 100 countries.

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