

Bracco Receives Health Canada Approval for VUEWAY® injection (gadopiclenol), Advancing Lower-Dose MRI Contrast Imaging

Approval marks a major milestone in reducing gadolinium exposure while maintaining diagnostic performance, aligning with clinical guidance to use the lowest effective dose

17 APRIL 2026, MONTREAL, CANADA — Bracco Imaging, a global leader in diagnostic imaging, today announced that on April 10, 2026, Health Canada approved VUEWAY® injection (gadopiclenol), a macrocyclic gadolinium-based contrast agent (GBCA), for use in contrast-enhanced magnetic resonance imaging (CE-MRI).

VUEWAY® injection is a highly kinetically stable, macrocyclic GBCA with the highest values of longitudinal relaxivity (r1) among macrocyclic GBCAs approved in major global markets.¹ In clinical studies, VUEWAY® injection has demonstrated effective contrast enhancement at a dose of 0.05 mmol/kg—half of the 0.1 mmol/kg dose used with other GBCAs—resulting in reduced gadolinium exposure for patients.^{2,3,4} This approach aligns with clinical guidance from radiology societies, which emphasizes the use of the lowest effective GBCA dose when contrast-enhanced imaging is required.⁴

“Reducing gadolinium exposure is not only a clinical priority but increasingly an environmental one,” said Dr. Kate Hanneman, Radiologist & Deputy Lead for Sustainability at the Joint Department of Medical Imaging, University of Toronto. *“High-relaxivity gadolinium-based contrast agents that deliver diagnostic confidence at half the standard dose represent an important advance for Canadian patients, supporting both patient safety and environmental stewardship.”*

VUEWAY® injection is indicated for use in adults and children 2 years and older for CE-MRI to detect and visualize lesions with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity in:

- the Central Nervous System (CNS), including brain, spine and surrounding tissues
- the Body, including head and neck, thorax (including breast), abdomen (including liver and kidneys), pelvis (including prostate), and musculo-skeletal system.

The approval of VUEWAY® injection in Canada follows successful regulatory milestones in other major markets, including the United States (2022) and the European Union (2023). VUEWAY® injection now approved in 37 countries, has been administered to more than 4 million patients worldwide, further strengthening Bracco Imaging’s position in MRI.

“The Health Canada approval of VUEWAY® injection is a pivotal milestone in Contrast Enhancement MRI procedures as it is meeting radiologists’ goals to reduce exposure to Gadolinium agents to the patient population, such as children and adults who require frequent MRI procedures for surveillance, regression or progression of the disease,” said Mr. Patrice Plourde, Sr. Director Sales & Marketing at Bracco Imaging Canada. *“Alongside radiologists and technologists, we are guided by the ALARA (as low as reasonably achievable) principle to strive to meet the highest standards of safety and efficacy while minimizing the environmental footprint. Today, the entire Bracco organization looks forward to elevating the standard of care in the Canadian diagnostic imaging landscape.”*

About gadolinium-based contrast agents

Gadolinium-based contrast agents (GBCAs) are widely and routinely used to enhance the diagnostic performance of magnetic resonance imaging (MRI) examinations. Gadolinium is a rare earth metal that has unique magnetic properties that make it useful for the use in MRI imaging.

About Bracco Imaging

Bracco Imaging is a global leader in diagnostic imaging, dedicated to improving people's lives by shaping the future of prevention and precision medicine. With a strong passion for innovation, the company develops and provides a broad portfolio of pharmaceutical products for diagnostic imaging: contrast agents for X-ray, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI), as well microbubbles for Contrast Enhanced Ultrasound (CEUS), and Molecular Imaging through radioactive tracers and novel PET imaging agents, alongside specialized medical devices and related services.

The company is committed to advancing diagnostic imaging 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, healthcare professionals, and healthcare systems in over 100 countries.

Discover Bracco Imaging at www.bracco.com.

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

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1. [VUEWAY®. Product Monograph. Bracco Imaging S.p.A. April 2026].

2. Robic C, Port M, Rousseaux O, Louguet S, Fretellier N, Catoen S, Factor C, Le Greneur S, Medina C, Bourrinet P, Raynal I, Idée JM, Corot C. Physicochemical and Pharmacokinetic Profiles of Gadopiclenol: A New Macrocyclic Gadolinium Chelate With High T1 Relaxivity. *Invest Radiol* 2019; 54(8):475-484.

3. Hao J, Pitrou C, Bourrinet P. A Comprehensive Overview of the Efficacy and Safety of Gadopiclenol: A New Contrast Agent for MRI of the CNS and Body. *Invest Radiol* 2024; 59(2):124-130.

4. Kanal E, Maki JH, Schramm P, Marti-Bonmati L. Evolving Characteristics of Gadolinium-Based Contrast Agents for MR Imaging: A Systematic Review of the Importance of Relaxivity. *J Magn Reson Imaging* 2025; 61(1):52-69.