



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2025

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Vueway gadopiclenol

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Vueway. The marketing authorisation holder for this medicinal product is Bracco Imaging S.p.A.

The CHMP adopted an extension to the existing indication as follows:²

This medicinal product is for diagnostic use only.

Vueway is indicated in adults and children **from birth** ~~aged 2 years and older~~ for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and visualization of pathologies with disruption of the blood-brain-barrier (BBB) and/or abnormal vascularity of:

- the brain, spine, and associated tissues of the central nervous system (CNS);
- the liver, kidney, pancreas, breast, lung, prostate, and musculoskeletal system.

It should be used only when diagnostic information is essential and not available with unenhanced MRI.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold, removed text as strikethrough

