SUMMARY

gadopiclenol

VUEWAY 0.5 mmol/mL

solution for injection

First listing

Adopted by the Transparency Committee on 25 September 2024

Summary of opinion

Favourable opinion for reimbursement "for diagnostic use only, in adults and children aged 2 years and older for contrast-enhanced magnetic resonance imaging (MRI) to improve detection and visualisation 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.**

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

Transparency Committee's conclusions

Clinical Benefit

- The seriousness of the condition is only known following MRI investigation.
- This is a diagnostic medicinal product. It can be used to improve contrast during MRI to increase detection of structural or functional abnormalities.
- The efficacy/adverse effects ratio is high.
- This product is a first-line treatment in the same way as other macrocyclic gadolinium-based contrast agents.

Public health benefit

Considering:

- the seriousness of the condition, which is defined on the basis of the results of the investigation,
- the prevalence and incidence, which depend on the condition being investigated by MRI,
- the partially met medical need,
- the contribution of MRI with VUEWAY (gadopiclenol) in terms of meeting this medical meet, given:

- evidence of its non-inferiority versus gadobutrol in terms of visualisation of lesions of the CNS and body but with no evidence of an additional impact on morbidity and mortality and/or quality of life,
- the lack of evidence of an impact on the organisation of care.

VUEWAY (gadopiclenol) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of VUEWAY (gadopiclenol) 0.5 mmol/mL solution for injection is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion of VUEWAY (gadopiclenol) 0.5 mmol/mL solution for injection in the list of covered drugs for inpatients approved for use in the MA indications and at the MA dosages.

Clinical Added Value

Considering:

- evidence of a non-inferiority of MRI with injection of VUEWAY (gadopiclenol) at a dose of 0.05 mmol/kg compared to injection of gadobutrol at a dose of 0.1 mmol/kg, on 3 coprimary endpoints for visualisation of lesions in the CNS and body, in the PICTURE and PROMISE studies conducted in adults,
- the pharmacokinetic profile in children similar to that observed in adults,

but:

- the absence of comparison in the paediatric study and robust efficacy and safety data,
- the limited safety data in terms of follow-up duration, limiting monitoring of the occurrence of adverse events (AE) such as retention of gadolinium in the brain or nephrogenic systemic fibrosis (NSF), an AE associated with the administration of a gadolinium-based contrast agent, the symptoms of which can develop several weeks to several months after its administration,

the Committee deems that VUEWAY (gadopiclenol) 0.5 mmol/mL solution for injection provides no clinical added value (CAV V) compared with gadobutrol.