SUMMARY

midazolam

MIDAZOLAM VIATRIS 1 mg/ml and 5 mg/ml

solution for injection or rectal use

Reassessment at the request of the CT

Original French opinion adopted by the Transparency Committee on 12 June 2024

The legally binding text is the original French opinion version

Summary of opinion

Unfavourable opinion for reimbursement in premedication before induction of anaesthesia in adults and children over the age of 6 months.

Transparency Committee's conclusions

Clinical Benefit

- Premedication, **the indication in the present reassessment**, is defined as the administration of medicinal products in order to prepare a patient for care, painful investigations or anaesthesia. The primary objective is to relieve perioperative anxiety.
- This is a preventive medicinal product.
- The efficacy/adverse effects ratio has not been adequately established in view of the data supplied, which have a low level of evidence.
- In view of the data with a low level of evidence supplied, in a context of a marked reduction in the use of IV premedication in routine practice and the absence of any recommendation, according to expert opinion, MIDAZOLAM VIATRIS (midazolam) 1 mg/ml and 5 mg/ml solutions for injection or rectal use have no role in the care pathway in the premedication indication.

Public health benefit

Considering:

- the seriousness of the condition and its prevalence,
- the currently met medical need,
- the lack of additional response to the identified need due to:
  - the lack of evidence of an additional impact on morbidity,

- the lack of evidence of an additional impact on quality of life,
- the lack of evidence of an additional impact on the organisation of care in the absence of data,

MIDAZOLAM VIATRIS (midazolam) 1 mg/ml and 5 mg/ml solutions for injection or rectal use are unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of MIDAZOLAM VIATRIS (midazolam) 1 mg/ml and 5 mg/ml solutions for injection or rectal use are insufficient to justify public funding cover in premedication before induction of anaesthesia in adults and children over the age of 6 months in view of the available alternatives.

The Committee issues an unfavourable opinion for maintenance of inclusion of MIDAZOLAM VIATRIS (midazolam) 1 mg/ml and 5 mg/ml solutions for injection or rectal use in the list of covered drugs for inpatients approved for use in the indication for premedication before induction of anaesthesia in adults and children over the age of 6 months.

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