

SUMMARY

clorazepate dipotassium

TRANXENE 20 mg/2 ml

solution for injection

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 certain functional investigations in adults.

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, TRANXENE (clorazepate dipotassium) 20 mg/2 mL solution for injection has 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,

TRANXENE (clorazepate dipotassium) 20 mg/2 mL is unlikely to have an additional impact on public health.

The Committee deems that the clinical benefit of TRANXENE (clorazepate dipotassium) 20 mg/2 mL solution for injection is insufficient to justify public funding cover in premedication before certain functional investigations in adults in view of the available alternatives.

The Committee issues an unfavourable opinion for maintenance of inclusion of TRANXENE (clorazepate dipotassium) 20 mg/2 mL solution for injection in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication in premedication before certain functional investigations.