

Original French opinion adopted by the Transparency Committee.

The legally binding text is the original French opinion version.

SUMMARY

midazolam

BUCCOLAM 10 mg

oromucosal solution

Modification of the listing conditions

Adopted by the Transparency Committee on 2 September 2025

Summary of opinion

Favourable opinion for reimbursement in the treatment of prolonged, acute, convulsive seizures in adults.

Transparency Committee's conclusions

Clinical Benefit

- Epileptic seizures are symptoms of very heterogeneous conditions. Prolonged seizures, and particularly status epilepticus, are emergency situations and can be life- and/or function-threatening.
- This is a curative medicinal product for prolonged, acute, convulsive seizures.
- The efficacy/adverse effects ratio is high.
- It is a first-line alternative to the other benzodiazepines available in the treatment of prolonged, acute, convulsive seizures in adults.

→ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the partial response to the identified need given:
 - the lack of evidence of an additional impact on morbidity and mortality,
 - the lack of evidence of an additional impact on quality of life,
 - a potential impact on the organisation of care given its route of administration compared to the available alternatives, but with no formal evidence of this,

BUCCOLAM (midazolam) 10 mg oromucosal solution is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of BUCCOLAM (midazolam) 10 mg oromucosal solution is substantial in the treatment of prolonged, acute, convulsive seizures in adults.

The Committee issues a favourable opinion for inclusion of BUCCOLAM (midazolam) 10 mg oromucosal solution in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the treatment of prolonged, acute, convulsive seizures in adults, and at the MA dosages.

→ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

- the efficacy of midazolam oromucosal solution having been established in the treatment of prolonged, acute, convulsive seizures in the paediatric population, primarily as an alternative to rectal diazepam,
- the efficacy in adults based on extrapolation of the efficacy results observed in the paediatric population and pharmacokinetic data,
- the lack of comparative efficacy data in adults versus the other benzodiazepines available,
- the oromucosal administration method, which is more appropriate for outpatient treatment than the routes of administration of the other benzodiazepines available, but without any formal evidence of an improvement in care conditions,
- the known safety profile of midazolam, with the profile in adults having been considered to be identical to that observed in children,

the Committee deems that BUCCOLAM (midazolam) 10 mg oromucosal solution provides no clinical added value (CAV V) in the current care pathway, which includes relevant comparators in the treatment of prolonged, acute, convulsive seizures in adults.