

SUMMARY

Bacillus Calmette-Guérin

BCG MAJORELLE 100 mg

powder and solvent for intravesical suspension

Inclusion on list: First listing

Adopted by the Transparency Committee on 9 October 2024

Summary of opinion

Favourable opinion for reimbursement in:

“Treatment of non-invasive urothelial bladder carcinoma:

- Curative treatment of carcinoma in situ;
- Prophylactic treatment of recurrence of:
 - urothelial carcinoma limited to mucosa:
 - pTa G1-G2 if multifocal and/or recurrent tumour;
 - pTa G3.
 - urothelial carcinoma in lamina propria but not in muscularis propria of the bladder (pT1);
 - carcinoma in situ.”

No clinical added value of BCG MAJORELLE 100 mg powder and solvent for intravesical suspension compared to the other proprietary medicinal products containing BCG for intravesical instillation already available.

This document and its bibliographic reference are available to download at www.has-sante.fr

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Transparency Committee's conclusions

Clinical Benefit

- Bladder cancer is a life-threatening disease. It is the 7th most common cancer in France and primarily affects men (more than 80% of cases). Gross haematuria is the most common clinical sign. Signs of bladder irritation (pollakiuria, urgency of urination, burning on urination) are observed in 20% of cases.
- This is a curative and preventive medicinal product.
- Its efficacy/adverse effects ratio is high.
- These medicinal products are medicines used as an adjuvant to transurethral resection.
- There are medicinal therapeutic alternatives.

→ Public health benefit

BCG MAJORELLE is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of BCG MAJORELLE 100 mg powder and solvent for intravesical suspension is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indications and at the MA dosages.

- **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%**

Clinical Added Value

BCG MAJORELLE 100 mg powder and solvent for intravesical suspension medicinal products provide no clinical added value (CAV V) compared to the medicinal products already listed, i.e. IMMUCYST 81 mg powder for intravesical suspension and BCG-MEDAC powder and solvent for intravesical suspension.