HAUTE AUTORITÉ DE SANTÉ

# TRANSPARENCY COMMITTEE
## SUMMARY
## 3 MARCH 2021

*The legally binding text is the original French opinion version*

***avelumab***
**BAVENCIO 20 mg/ml concentrate for solution for infusion**

**New indication**

### Key points

Favourable opinion for reimbursement as monotherapy for the first-line maintenance treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy.

### What therapeutic improvement?

Therapeutic improvement compared to supportive care.

### Role in the care pathway?

The first-line treatment of urothelial carcinoma is founded on platinum-based polychemotherapy regimens. Cisplatin eligible patients may receive: gemcitabine + cisplatin, methotrexate + vinblastine + adriamycin + cisplatin, or paclitaxel + cisplatin + gemcitabine. For cisplatin ineligible patients, carboplatin-based chemotherapy is recommended.

For patients who are progression-free following their first-line platinum-based chemotherapy, there is no recommended maintenance treatment.

**Role of the medicinal product in the care pathway**

Considering the demonstration of a clinically relevant benefit in combination with supportive care compared to supportive care alone, in terms of overall survival, the Transparency Committee deems that BAVENCIO (avelumab), as monotherapy, is a first-line maintenance treatment in adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy. It should be noted that in the clinical study, patients had received cisplatin or carboplatin combined with gemcitabine. Uncertainty persists with respect to the level of efficacy in patients having received first-line MVAC (methotrexate, vinblastine, adriamycin, cisplatin) or paclitaxel + cisplatin + gemcitabine chemotherapy, since no patients included in the study had been treated with these protocols.

## COMMITTEE'S CONCLUSIONS

### Clinical benefit

◗ Urothelial carcinoma is a serious disease that is life-threatening.

◗ The proprietary medicinal product BAVENCIO (avelumab) is a curative medicinal product.

◗ Its efficacy/adverse effects ratio is high in adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy (cisplatin/carboplatin + gemcitabine). However, the transposability of the results to patients having received MVAC (methotrexate, vinblastine, adriamycin, cisplatin) chemotherapy cannot be confirmed.

◗ There is no alternative maintenance treatment in patients who are progression-free following their first-line platinum-based chemotherapy.

◗ BAVENCIO (avelumab), as monotherapy, is a first-line maintenance treatment in adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy (cisplatin/carboplatin + gemcitabine).

**Public health impact**

Considering:
- the seriousness of urothelial carcinoma,
- the unmet medical need,
- the partial response provided by BAVENCIO (avelumab) to the identified medical need, due to demonstration of its superiority compared to supportive care on overall survival,
- the lack of demonstrated impact on quality of life,
- the absence of data enabling assessment of the additional impact on the organisation of care,

BAVENCIO (avelumab) is unlikely to have an additional impact on public health.

**Given all these elements, the Committee deems that the clinical benefit of BAVENCIO (avelumab) is substantial in the MA indication.**

**The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the new indication and at the MA dosages.**

## Clinical Added Value

**Considering:**
- **demonstration of the superiority of BAVENCIO (avelumab), as monotherapy, compared to supportive care, in terms of overall survival (HR=0.69 [CI%: 0.54-0.92], with an individual estimate of an absolute improvement of 7.1 months, deemed clinically relevant), in an open-label, randomised phase 3 study and,**
- **the substantial medical need in the absence of alternatives in this indication,**

**and despite:**
- **the onset of grade ≥ 3 adverse events in one in two patients,**
- **a mainly immunological toxicity and infusion-related reactions (important identified risks according to the RMP),**
- **the lack of demonstrated impact on quality of life,**

**the Transparency Committee considers that BAVENCIO (avelumab), as monotherapy, provides moderate clinical added value (CAV III) compared to supportive care, in first-line maintenance treatment in adult patients with locally advanced or metastatic urothelial carcinoma (UC) who are progression-free following platinum-based chemotherapy.**