SUMMARY

avelumab

BAVENCIO 20 mg/mL

concentrate for solution for infusion

Reassessment at the request of the TC / following ministerial referral

Original French opinion adopted by the Transparency Committee on 4 October 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Metastatic Merkel cell carcinoma (MCC) is a serious, life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse reaction ratio is moderate in patients previously treated with chemotherapy in view of the efficacy results from the phase 2 non comparative study and the safety profile.
- Despite the absence of standard treatment, therapeutic alternatives are used in clinical practice in France as second and later-line treatment.

- **Public health benefit**

Considering:

- the seriousness of the disease and its low incidence,
- the inadequately met medical need in patients previously treated with chemotherapy,
- the partial response to the identified partially met need:
  - An additional impact on morbidity and mortality that is difficult to quantify in the absence of a phase 3 comparative study on mortality and quality of life, or, at the very least, a robust indirect comparison with the usual treatment;
  - the lack of evidence of any additional impact on the organisation of care;
  - the absence of a demonstrated impact on the care and/or life pathway;

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

Considering all these elements, the Committee deems that the clinical benefit of BAVENCIO 20 mg/mL (avelumab) concentrate for solution for infusion remains substantial in the treatment as monotherapy of adult patients with metastatic Merkel cell carcinoma (MCC) previously treated with chemotherapy.

The Committee issues a favourable opinion for maintenance of BAVENCIO 20 mg/mL (avelumab) concentrate for solution in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the treatment of patients with metastatic Merkel cell carcinoma (MCC) previously treated with chemotherapy and at the MA dosages.

Clinical Added Value

Considering:

- the medical need inadequately met by chemotherapies due to their poor safety in elderly patients with comorbidities, or in the event of current contraindication to chemotherapy,
- the updated results of the JAVELIN study, showing a relative stability in survival at between 24 and 60 months, with an overall survival at 60 months of 26%,
- descriptive results for overall survival at 24 months in the post-registration study consistent with those observed in the JAVELIN study but which do not enable quantification of the potential therapeutic benefit of avelumab compared to initial management before the introduction of avelumab,
- the safety of avelumab deemed to be acceptable in this elderly population,
- international guidelines positioning immunotherapies, including avelumab, as a first-line treatment for metastatic Merkel cell carcinoma (MCC),

And despite:

- the methodological limits of the follow-up data in the JAVELIN study, which is a non-comparative study, and the retrospective and observational data from the CARADERM database,

the Committee deems that BAVENCIO 20 mg/mL (avelumab) concentrate for solution for infusion provides a minor clinical added value (CAV IV) in the current care pathway (see chapter 2.2).