

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

tislelizumab

TEVIMBRA 100 mg

concentrate for solution for infusion

First listing

Adopted by the Transparency Committee on 6 November 2024

Summary of opinion

Unfavourable opinion for reimbursement in the indication “TEVIMBRA as monotherapy is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma (OSCC) after prior platinum-based chemotherapy”

Transparency Committee's Conclusions

Clinical Benefit

- ➔ Oesophageal squamous cell carcinoma is a serious, life-threatening disease.
- ➔ This is a curative medicinal product.
- ➔ The efficacy/adverse effects ratio has not been adequately established given the absence of robust data in patients who could currently benefit from the treatment: patients having already received first-line immunotherapy, and patients with a CPS < 10 or a TPS < 1%.
- ➔ On the basis of currently available data, TEVIMBRA (tislelizumab) as monotherapy has no role in the current care pathway.

➔ Public health benefit

Considering:

- the seriousness of the disease, which is life-threatening in the short term, and its prevalence;
- the partially met medical need;
- the lack of response to the identified need considering:
 - evidence of an impact on mortality, but in a population not transposable to the population currently treated in France;
 - the lack of evidence of an impact on quality of life;
 - the lack of evidence of an impact on the organisation of care for patients or their families;

TEVIMBRA (tislelizumab) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of TEVIMBRA (tislelizumab) 100 mg concentrate for solution for infusion is insufficient in the MA indication to justify public funding.

The Committee issues an unfavourable opinion for inclusion of TEVIMBRA (tislelizumab) 100 mg concentrate for solution for infusion in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.