Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

enfortumab vedotin

PADCEV 20 mg and 30 mg

powder for concentrate for solution for infusion

Inclusion on list

Adopted by the Transparency Committee on 18 December 2024

Summary of opinion

Favourable opinion for reimbursement "in combination with pembrolizumab, in the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma who are eligible for platinum-based chemotherapy".

Transparency Committee's Conclusions

Clinical Benefit

- Unresectable or metastatic urothelial carcinoma is a serious, life-threatening disease.
- The proprietary medicinal product PADCEV (enfortumab vedotin) in combination with pembrolizumab is a curative medicinal product.
- The efficacy/adverse effects ratio of PADCEV (enfortumab vedotin) is high in the MA indication, considering:
  - evidence of superiority versus platinum-based chemotherapy, particularly in terms of overall survival and progression-free survival, with, however,
  - a toxicity profile marked by the frequent occurrence of skin disorders, peripheral sensory neuropathy, and treatment discontinuations due to adverse events (39.8% versus 21.5%),
- There are medicinal alternatives in the first-line treatment of advanced or metastatic urothelial carcinoma.
- This is a first-line treatment in view of the therapies available, in the first-line treatment of unresectable or metastatic urothelial carcinoma.

Public health benefit

Considering:

- the seriousness and prevalence of urothelial carcinoma,
- the partially met medical need,
- the partial response to the identified need given:

- the partial response to the identified need and, in particular, evidence of an additional impact on mortality in the pivotal study. However, concerns remain, primarily regarding skin and neurological toxicities;
- the lack of evidence of an impact on quality of life;
- the absence of data enabling assessment of the additional impact on the organisation of care;

PADCEV (enfortumab vedotin) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of PADCEV (enfortumab vedotin) 20 mg and 30 mg powder for concentrate for solution for infusion is substantial "in combination with pembrolizumab, for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma who are eligible for platinum-based chemotherapy".

The Committee issues a favourable opinion for inclusion of PADCEV (enfortumab vedotin) 20 mg and 30 mg powder for concentrate for solution for infusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- evidence of the superiority of PADCEV (enfortumab vedotin) in combination with pembrolizumab compared to platinum-based chemotherapy (gemcitabine + cisplatin or carboplatin), in a randomised, open-label phase 3 study in terms of overall survival (HR = 0.468; $CI_{95\%}$[0.376; 0.582]), and in progression-free survival (HR = 0.450; $CI_{95\%}$ [0.3777; 0.538]);

and despite:

- the absence of improvement in terms of time to pain progression;
- a toxicity profile marked by the frequent occurrence of skin disorders, peripheral sensory neuropathy, and treatment discontinuations due to adverse events (39.8% versus 21.5%);
- the lack of evidence of an improvement in quality of life (exploratory endpoint);

the Committee deems that PADCEV (enfortumab vedotin) 20 mg and 30 mg powder for concentrate for solution for infusion provides a moderate clinical added value (CAV III) compared to platinum-based chemotherapy.