OPINION ON MEDICINAL PRODUCTS

pembrolizumab

KEYTRUDA 25 mg/mL,

Dilutable solution for perfusion

New indication(s)

Adopted by the Transparency Committee on 14 September 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Positive opinion for the reimbursement of KEYTRUDA (pembrolizumab) in combination with chemotherapy with or without bevacizumab, in the treatment of adult patients with persistent, recurrent or metastatic cervical cancer, whose tumours express PD-L1 with a CPS ≥ 1.

Therapeutic improvement?

Therapeutic improvement in the care pathway.

Role in therapeutic strategy?

In persistent, recurrent or metastatic cervical cancer, management is based on palliative chemotherapy with the aim of relieving symptoms and improving quality of life. The recommended first-line treatment by the European Society for Medical Oncology (ESMO) (2017) and the National Comprehensive Cancer Network (NCCN) (2022) is cisplatin (or carboplatin in case of impaired renal function), paclitaxel and bevacizumab.

The use of topotecan (HYCAMTIN) instead of platinum salt is considered when the patient is not eligible for cisplatin or carboplatin (NCCN recommendation 2A).

In its opinion of 6 July 2016, the Committee listed the ACB of AVASTIN (bevacizumab) as substantial and assessed its CAV at level IV compared to paclitaxel and cisplatin chemotherapy (or topotecan in case of platinum salt ineligibility) based on a 4-arm randomised phase III study that showed an overall survival gain of 3.9 months (median of 16.8 months versus 12.9 months).

The 2022 NCCN guidelines included pembrolizumab as a first-line treatment for persistent, recurrent and metastatic cervical cancer when a CPS of 1 or more is found, in combination with dual or triple therapy with platinum salt, paclitaxel ± bevacizumab.

Role of the medicinal product:

KEYTRUDA (pembrolizumab) in combination with chemotherapy with or without bevacizumab, is a first-line treatment for persistent, recurrent or metastatic cervical cancer with tumours expressing PD-L1 with a CPS ≥ 1.

Committee's conclusions

Clinical Benefit

- Cervical cancer is a serious life-threatening condition.
- The proprietary medicinal product KEYTRUDA (pembrolizumab) is a curative medicinal product.
- The efficacy/adverse effect ratio is high.
- Therapeutic alternatives are available (see clinically relevant comparators)
- KEYTRUDA (pembrolizumab) is a first-line treatment for persistent, recurrent or metastatic cervical cancer whose tumours express PD-L1 with a CPS ≥ 1

Public health benefit

Considering:

- the severity of the disease and its prevalence,
- the partially met medical need,
- the additional partial response to the identified need due to improved progression-free survival and overall survival,
- the lack of data required to draw formal conclusions about quality of life,
- the lack of an expected additional impact on the care and/or life pathway,

KEYTRUDA (pembrolizumab) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of KEYTRUDA (pembrolizumab) is substantial in the marketing authorisation indication.

The Committee approves inclusion in the list of proprietary medicinal products approved for community use for the marketing authorisation indication(s) and at the marketing authorisation dosages.

Clinical Added Value

Considering:

- the demonstration in a phase III, randomised, double-blind study of the superiority of the combination of KEYTRUDA (pembrolizumab) and chemotherapy (platinum salt, paclitaxel) ± bevacizumab over chemotherapy alone, notably in terms of:
  - progression-free survival (gain of 2.2 months; HR = 0.62; 95% CI: [0.50; 0.77]),
  - overall survival with median not reached in the pembrolizumab group versus 16.3 months (HR = 0.64 ([0.50; 0.81]);
- the fact that the safety profile of KEYTRUDA (pembrolizumab) is already known, with similar AE incidences in the two treatment groups;

and despite the lack of formal conclusions that can be drawn from the quality-of-life results,

KEYTRUDA, in combination with chemotherapy, provides moderate clinical added value (CAV III) in the first-line treatment of adult patients with persistent, recurrent or metastatic cervical cancer whose tumours express PD-L1 with a CPS ≥ 1.