SUMMARY

pembrolizumab

KEYTRUDA 25 mg/ml

concentrate for solution for infusion

Indication extension

Original French opinion adopted by the Transparency Committee on 14 February 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement only in the indication: “KEYTRUDA, in combination with fluoropyrimidine and platinum-based chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 10”.

Unfavourable opinion for reimbursement in the other situations covered by the MA indication.

Transparency Committee’s conclusions

Clinical Benefit

- Advanced unresectable or metastatic gastric, gastro-oesophageal junction (GEJ) or oesophageal adenocarcinomas are serious, life-threatening diseases.
- The proprietary medicinal product KEYTRUDA (pembrolizumab) is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- Therapeutic alternatives are available.
- KEYTRUDA (pembrolizumab) in combination with fluoropyrimidine and platinum-containing chemotherapy is a first-line treatment for locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 10.

➔ Public health benefit

Considering:

- the seriousness of the condition and its prevalence,
- the partially met medical need,
- the partial response to the identified need, due to an impact on morbidity and mortality, with an improvement in overall survival and progression-free survival, but without evidence of an impact on quality of life,
- the absence of an expected additional impact on the care and/or life pathway,

KEYTRUDA (pembrolizumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of KEYTRUDA (pembrolizumab) 25 mg/ml, is:

- **substantial in combination with fluoropyrimidine and platinum-based chemotherapy in the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 10;**
- **insufficient to justify public funding in situations other than those retained for reimbursement.**

The Committee issues a favourable opinion for inclusion of KEYTRUDA (pembrolizumab) 25 mg/ml in the list of covered drugs for inpatients approved for use "in combination with fluoropyrimidine and platinum-based chemotherapy in the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 10" at the MA dosages, and an unfavourable opinion in situations other than those retained for reimbursement.

Clinical Added Value

Considering:

- demonstration in a phase 3, double-blind study of a superiority of KEYTRUDA (pembrolizumab) in combination with fluoropyrimidine and platinum-based chemotherapy compared with chemotherapy alone in patients whose tumours express PD-L1 with a CPS ≥ 10 in terms of:
  - overall survival: HR = 0.65 (95% CI [0.53; 0.79]; p< 0.0001);
  - progression-free survival: HR = 0.62 (95% CI [0.51; 0.76]; p< 0.0001)

and despite:

- a safety profile of KEYTRUDA (pembrolizumab) in combination with chemotherapy that is less favourable than that of chemotherapy alone, marked, in particular, by immune-mediated adverse effects (primarily dysthyroidism),
- the absence of robust data on quality of life,

the Transparency Committee deems that KEYTRUDA (pembrolizumab) in combination with fluoropyrimidine and platinum-based chemotherapy in the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 10 provides a moderate clinical added value (CAV III) compared to chemotherapy alone, in the same way as OPDIVO (nivolumab).