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).