**SUMMARY**

pembrolizumab

KEYTRUDA 25 mg/ml, concentrate for solution for infusion

New indication

Adopted by the Transparency Committee on 18 January 2023

The legally binding text is the original French opinion version

**Key points**

Favourable opinion for reimbursement of KEYTRUDA (pembrolizumab) in the adjuvant treatment of adults with clear cell renal cell carcinoma only, at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

Unfavourable opinion for reimbursement of KEYTRUDA (pembrolizumab) in the adjuvant treatment of adults with renal cell carcinoma with a histological type other than clear cell.

**What therapeutic improvement?**

Therapeutic improvement in the care pathway for clear cell renal cell carcinoma.

No therapeutic improvement in the care pathway for renal cell carcinoma with a histological type other than clear cell.

**Role in the care pathway?**

KEYTRUDA (pembrolizumab) is an adjuvant treatment in adults with clear cell renal cell carcinoma, at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.
Committee’s conclusions

Clinical Benefit

In clear cell renal cell carcinoma:

- Renal cell carcinoma is a severe, life-threatening disease.
- The proprietary medicinal product KEYTRUDA (pembrolizumab) is a medicinal product intended to prevent recurrence.
- The efficacy/adverse effects ratio is high.
- There is no recommended drug treatment at this stage of treatment.
- This product is a first-line treatment in the context of adjuvant therapy to surgery.

- Public health benefit

Considering:
- the seriousness of the disease and its incidence;
- the unmet medical need;
- the response to the identified need;
- a demonstrated additional impact on recurrence-free survival;
- an additional impact on the organisation of care;
- the additional impact on the care and/or life pathway which has not been studied,

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

Considering all these elements, the Committee deems that the clinical benefit of KEYTRUDA (pembrolizumab) is substantial.

In non-clear cell renal cell carcinoma (chromophobe and papillary):

Considering the absence of data in these histological subtypes, the Committee deems that the clinical benefit of KEYTRUDA (pembrolizumab) is insufficient.

Clinical Added Value

In clear cell renal cell carcinoma:

Considering:
- evidence of superiority of pembrolizumab versus placebo on the primary endpoint, investigator-assessed recurrence-free survival, with HR=0.68 (CI95%: [0.53 - 0.87]), p= 0.0010;
- the lack of evidence of superiority of the pembrolizumab group versus the placebo group in terms of overall survival (p=NS) and the currently immature data;
- an increased toxicity in the pembrolizumab group, marked in particular by adverse events of grade 3 or more (32.2% versus 17.7%) and serious adverse events (20.7% versus 11.5%);
- the absence of a demonstrated impact on quality of life (exploratory endpoint);

the Committee considers that as the dossier currently stands, KEYTRUDA (pembrolizumab) provides a minor clinical added value (CAV IV) as monotherapy in the adjuvant treatment of adults with clear cell renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.