**OPINION ON MEDICINAL PRODUCTS**

# pembrolizumab
# KEYTRUDA 25 mg/ml,

**solution for dilution for infusion**

New indication

**Adopted by the Transparency Committee on 4 January 2023**

**SUMMARY**

**The legally binding text is the original French opinion version**

## Key points

Disapproval of reimbursement of KEYTRUDA (pembrolizumab) as monotherapy for the treatment of adult patients with the following MSI-H or dMMR tumours:

- advanced or recurrent endometrial carcinoma, who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation;
- unresectable or metastatic gastric, small intestine, or biliary cancer, who have disease progression on or following at least one prior therapy.

## Therapeutic improvement?

No therapeutic improvement in the care pathway in all assessed indications.

## Role in therapeutic strategy?

Not applicable.

# Committee's conclusions

## Clinical Benefit

**Endometrial cancer**

- This is a serious life-threatening disease.
- The efficacy/adverse effect ratio is poorly defined.
- The proprietary medicinal product KEYTRUDA (pembrolizumab) is a curative medicinal product.
- There are some recommended drug treatments at this stage of the care pathway, but none specific to MSI status.
- KEYTRUDA (pembrolizumab) has no role in the therapeutic strategy (see Section 8).

**Gastric cancer:**

- This is a serious life-threatening disease.
- The efficacy/adverse effect ratio is poorly defined.
- The proprietary medicinal product KEYTRUDA (pembrolizumab) is a curative medicinal product.
- There are some recommended drug treatments at this stage of the care pathway, but none specific to MSI status.
- KEYTRUDA (pembrolizumab) has no role in the therapeutic strategy (see Section 8).

**Small intestine cancer:**

- This is a rare serious life-threatening disease.
- The efficacy/adverse effect ratio is poorly defined.
- The proprietary medicinal product KEYTRUDA (pembrolizumab) is a curative medicinal product.
- Alternative medications not specific to the small intestine are available; however, treatment is modelled on that of the treatments available for colorectal cancer.
- KEYTRUDA (pembrolizumab) has no role in the therapeutic strategy (see Section 8).

**Biliary cancer:**

- This is a serious life-threatening disease.
- The efficacy/adverse effect ratio is poorly defined.
- The proprietary medicinal product KEYTRUDA (pembrolizumab) is a curative medicinal product.
- There are some recommended drug treatments at this stage of the care pathway, but none specific to MSI status.
- KEYTRUDA (pembrolizumab) has no role in the therapeutic strategy (see Section 8).

- **Public health benefit (for all indications)**

Considering:

- the severity of the disease and its prevalence,
- the partially met medical need,
- the lack of response to the identified need, in the lack of evidence of an additional impact on morbidity-mortality or quality of life, due to the lack of robust comparative data in relation to clinically relevant comparators, though possible,

- the lack of data making it possible to assess the impact on quality of life and delivery of care.

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) as monotherapy is insufficient for all of the indications.**