SUMMARY

cemiplimab

LIBTAYO 350 mg,

solution for dilution for infusion

Indication extension

Original French opinion adopted by the Transparency Committee on 10 January 2024

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Metastatic NSCLC is a serious life-threatening disease.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is poorly defined, and a loss of chance cannot be ruled out compared to the clinically relevant comparators with evidence of superiority versus chemotherapy in terms of overall survival, particularly in view of:
  - the lack of comparison to these available clinically relevant comparators at the start of part 2 of the EMPOWER-Lung 3 study (pembrolizumab monotherapy or in association), the manufacturer having chosen to retain chemotherapy alone in the control group even though a face-to-face trial was possible;
  - the major methodological limitations of the meta-analysis provided which do not allow any conclusions to be drawn as to the position compared to these comparators. This situation in no way constituting a recognition of equivalence;
  - the primary endpoint not reached (overall survival) in part 1 of the EMPOWER-Lung 3 study.
- There are therapeutic alternatives, in particular pembrolizumab (monotherapy or in association with a chemotherapy regimen).
- Hence, the Committee deems that LIBTAYO (cemiplimab) in association with a platinum salt-based chemotherapy regimen has no role in the therapeutic strategy.

➔ Public health benefit

In view of:

- the seriousness of NSCLC, in particular at the metastatic stage,
- the incidence of the condition,
- the partially met medical need,
- the lack of response to the identified need with lack of evidence of an additional impact on morbidity-mortality and quality of life,
- the lack of data allowing an assessment of the additional impact on delivery of care:

LIBTAYO (cemiplimab) in association with a platinum salt-based chemotherapy regimen is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LIBTAYO (cemiplimab) in association with a platinum salt-based chemotherapy regimen, is insufficient in the MA indication to justify public funding.

The Committee disapproves inclusion of LIBTAYO (cemiplimab) in association with a platinum salt-based chemotherapy regimen in the list of covered drugs for inpatients for the indication and at the MA dosages.

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