HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
17 NOVEMBER 2021

The legally binding text is the original French opinion version

cemiplimab
LIBTAYO 350 mg concentrate for solution for infusion

Re-evaluation

Key points

Favourable opinion for reimbursement in the subgroup of patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation and who are not eligible for chemotherapy (situation of failure or contraindication to chemotherapy).

Unfavourable opinion for reimbursement in the rest of the MA population.

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

Role of the medicinal product in the care pathway

Considering the absence of direct comparative data and the absence of an indirect comparison of good methodological quality, the role of LIBTAYO (cemiplimab) in the care pathway cannot be specified compared to the chemotherapy protocols used as first or later-line treatments. Consequently, the Transparency Committee considers that, on the basis of currently available data, LIBTAYO (cemiplimab) is a treatment option only in patients who are not candidates for curative surgery or curative radiation and who are not eligible for chemotherapy (situation of failure or contraindication to chemotherapy).

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

◗ Cutaneous squamous cell carcinoma is a serious disease that is life-threatening.

◗ The proprietary medicinal product LIBTAYO (cemiplimab) is a curative medicinal product specific to cutaneous squamous cell carcinoma.

◗ The efficacy/adverse effects ratio is moderate.

◗ There are therapeutic alternatives as first-line treatment. In the event of non-eligibility for chemotherapy, in particular, or second-line treatment, there are no medicinal alternatives.

◗ Second-line treatment following the failure of chemotherapy and first-line treatment if chemotherapy is contraindicated.

Public health impact

Considering:

- the seriousness of metastatic or locally advanced cutaneous squamous cell carcinoma,
- the medical need inadequately met in first-line therapy and unmet in second-line therapy (non-eligibility for chemotherapy, in particular, or second-line treatment following the failure of chemotherapy),
- an annual incidence of around 1,000 cases for the indication assessed,
- the lack of demonstration of a response to the unmet medical need considering:
    - an impact on morbidity and mortality that is difficult to quantify in the absence of robust comparative data,
    - the non-demonstrated impact on quality of life due to a lack of demonstrative data,
    - the absence of assessment of an additional impact on the organisation of care.

LIBTAYO (cemiplimab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LIBTAYO (cemiplimab) is:

- **SUBSTANTIAL in the subgroup of patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation and who are not eligible for chemotherapy (situation of failure or contraindication to chemotherapy).**

- **INSUFFICIENT to justify public funding cover in view of the available alternatives in the rest of the MA population.**

The Committee issues a favourable opinion for maintenance of inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the subgroup of patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation and who are not eligible for chemotherapy (situation of failure or contraindication to chemotherapy).

The Committee issues an unfavourable opinion for maintenance of inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the rest of the MA population.

Clinical Added Value

- **Within the proposed reimbursement scope:**

Considering:

- **the available data based on three cohorts from a phase 2 non-comparative study and on compassionate use programme (ATU) data having suggested an efficacy of cemiplimab in terms of objective response rate in a heterogeneous population with locally advanced or metastatic cutaneous carcinoma,**
- **the substantial medical need for patients in whom all the other treatment options have been exhausted (patients who are not candidates for curative surgery or curative radiation and who are not eligible for chemotherapy),**

But taking into account:

- **uncertainties with respect to the specific effect size of this medicinal product, considering the absence of robust comparative data,**

The Transparency Committee considers that, as the dossier currently stands, LIBTAYO (cemiplimab) provides no clinical added value (CAV V) in the subgroup of patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation and who are not eligible for chemotherapy (situation of failure or contraindication to chemotherapy).