HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
13 OCTOBER 2021

The legally binding text is the original French opinion version

atezolizumab
TECENTRIQ 1,200 mg concentrate for solution for infusion
TECENTRIQ 840 mg concentrate for solution for infusion

New indication

Key points

Favourable opinion for reimbursement, as monotherapy for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC.

What therapeutic improvement?

Therapeutic improvement compared to chemotherapy.

◗ Role in the care pathway?

The current management for metastatic non-small cell lung cancer (NSCLC) in first line-treatment, in the absence of molecular abnormalities (EGFR mutations, or ALK or ROS-1 rearrangements), in patients whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC), is based on immunotherapy, for eligible patients.

Pembrolizumab (anti-PD1 immunotherapy) is a first-line treatment:

- as monotherapy, in patients, and
- in combination with chemotherapy:
  - pemetrexed and platinum chemotherapy, in non-squamous NSCLC,
  - carboplatin and paclitaxel (or nab-paclitaxel) chemotherapy, in squamous NSCLC.

In the event of contraindication to immunotherapy, or to one of the chemotherapy drugs combined with pembrolizumab, chemotherapy is indicated. This involves dual therapy combining a platinum (cisplatin or carboplatin) with one of the following substances: vinorelbine, gemcitabine, docetaxel, paclitaxel or pemetrexed (only in non-squamous NSCLC for the latter). In non-squamous NSCLC, in the absence of contraindications, bevacizumab can be added to the dual chemotherapy regimen; and atezolizumab can be combined with bevacizumab + paclitaxel + carboplatin.

The OPDIVO/YERVOY (nivolumab/ipilimumab) combination, in combination with 2 cycles of platinum-based chemotherapy, is an alternative first-line treatment.

Role of the medicinal product in the care pathway

TECENTRIQ (atezolizumab) as monotherapy is an alternative as a first-line treatment in adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC.

The indirect comparison data provided does not enable TECENTRIQ (atezolizumab) to be positioned compared to the current standard of care. No significant difference in terms of overall survival has been demonstrated between TECENTRIQ (atezolizumab) and the other first-line treatment strategies (including pembrolizumab as monotherapy, the pembrolizumab + chemotherapy combination, and chemotherapy alone) via these indirect comparisons. The Committee points out that this absence of difference does not constitute demonstration of equivalence.

COMMITTEE'S CONCLUSIONS

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

Clinical benefit

◗ Metastatic non-small cell lung cancer (NSCLC) is a serious, life-threatening condition.

◗ The proprietary medicinal product TECENTRIQ (atezolizumab) is a curative medicinal product.

◗ Its efficacy/adverse effects ratio is high.

◗ There are therapeutic alternatives (see section 05 of the opinion), in particular pembrolizumab (as monotherapy or in combination with chemotherapy), which has demonstrated a superiority over chemotherapy alone in terms of overall survival, with an acceptable safety profile.

◗ TECENTRIQ (atezolizumab) is an alternative as a first-line treatment in adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC. Its role compared to pembrolizumab cannot be specified as the dossier currently stands, considering the absence of a formal conclusion that can be drawn from the results of indirect comparisons.

Public health impact

Considering:

- the seriousness of NSCLC, particularly at the metastatic stage,
- the incidence of the disease,
- the partially met medical need,
- the partial response provided by TECENTRIQ (atezolizumab) to the identified need,
- the lack of demonstrated impact on quality of life,
- the absence of data enabling assessment of the additional impact on the organisation of care,

TECENTRIQ (atezolizumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of TECENTRIQ (atezolizumab) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.

Clinical Added Value

Considering

- **demonstration of the superiority of TECENTRIQ (atezolizumab) as monotherapy compared to chemotherapy, in terms of overall survival: mean increase of 0.7 and 5.2 months respectively over the first 12 and 33.3 months of follow-up (RMST method), in a phase 3 randomised, open-label study, and**
- **the safety profile marked by a lower frequency of grade 3-4 adverse events, a similar frequency of serious adverse events and a higher frequency of adverse events of particular interest (identified as important risks in the RMP);**

and despite:

- **the follow-up analysis suggesting less benefit than that demonstrated in the primary analysis;**
- **the increased deaths in the atezolizumab group compared to chemotherapy, during the first 2 to 3 months of follow-up;**
- **the absence of any formal conclusion that can be drawn based on the quality-of-life results;**

the Transparency Committee considers that TECENTRIQ (atezolizumab) as monotherapy provides a minor clinical added value (CAV IV) compared to chemotherapy in the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC.