HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
13 MAY 2020

The legally binding text is the original French opinion version

atezolizumab
TECENTRIQ 1200 mg concentrate for solution for infusion

New indication

Key points

Favourable opinion for reimbursement in the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC), in combination with carboplatin and etoposide.

What therapeutic improvement?

Therapeutic improvement compared to carboplatin + etoposide chemotherapy.

Role in the care pathway?

The treatment of extensive-stage small cell lung cancer (ES-SCLC) is based on a combination of chemotherapies, with several protocols having demonstrated similar efficacy.

The first-line treatment is the cisplatin + etoposide protocol for 4 to 6 cycles. For elderly, frail patients (ECOG ≥ 2) or in whom the use of cisplatin is contraindicated, the use of carboplatin is recommended.

Other protocols may also be used, particularly in the event of a contraindication to etoposide (cisplatin or carboplatin + irinotecan, gemcitabine + carboplatin, cisplatin + topotecan etc.).

Prophylactic cranial irradiation is recommended for patients in good general condition (ECOG 0 to 2) who have responded to a first treatment line and in whom brain imaging is negative.

Role of the medicinal product in the care pathway

TECENTRIQ (atezolizumab), used in combination with carboplatin + etoposide chemotherapy, then alone as a maintenance therapy, is a first-line treatment in adult patients with extensive-stage small cell lung cancer (ES-SCLC).

The Committee nevertheless highlights that:
- a subpopulation of “good responder” patients appears to benefit from long-term treatment, without it being possible to identify these patients,
- no data are available in patients with an ECOG performance score > 1,
- and that data are limited in patients with brain metastases.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Extensive-stage small cell lung cancer (ES-SCLC) is a serious, life-threatening disease.
◗ This is a curative treatment.
◗ Considering the effect size, deemed to be modest but clinically relevant in view of the disease and the toxicity profile of combination of atezolizumab with chemotherapy, the Committee considers that the efficacy/adverse effects ratio is high.
◗ There are first-line medicinal alternatives, in particular chemotherapy protocols combining etoposide with a platinum salt.
◗ TECENTRIQ (atezolizumab), used in combination with carboplatin + etoposide chemotherapy, then alone as a maintenance therapy, is a first-line treatment in adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Public health impact

Considering:

- the seriousness of SCLC, particularly at extensive stages, with a life expectancy of 3 to 6 months without treatment and a median survival of 10 to 12 months for treated patients,
- the incidence of the disease,
- the medical need, considered to be partially met in first-line therapy by existing chemotherapies,
- demonstration of an additional impact deemed to be modest in terms of morbidity and mortality of combining atezolizumab with carboplatin + etoposide chemotherapy followed by maintenance monotherapy with atezolizumab, compared to chemotherapy alone,
- the lack of elements supporting the absence of a deterioration in the care and/or life pathway in the absence of robust quality of life data,
- the lack of any demonstrated impact on the organisation of care (hospitalisation, AE, etc.),
- the partial response to the identified medical need,

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

Given all these elements, the Committee deems that the clinical benefit of TECENTRIQ 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 atezolizumab combined with carboplatin + etoposide chemotherapy compared to chemotherapy alone, in a randomised, double-blind study, in terms of progression-free survival and overall survival (primary endpoints),**
- **the effect size, deemed to be modest but clinically relevant in view of the disease (increases of 0.9 months in PFS; HR = 0.77; $CI_{95\%}$ [0.62; 0.96] and 2 months in OS; HR = 0.70; $CI_{95\%}$ [0.54; 0.91]),**

and despite:

- **the exploratory nature of the quality of life data,**
- **the safety profile of the atezolizumab + carboplatin/etoposide combination, marked by a comparable frequency of grade ≥ 3 AEs and SAEs but a higher frequency of immunological AEs (32.3% vs 18.4%) and treatment discontinuations due to an AE (11.1% vs 3.1%),**

- **uncertainty concerning the effect of atezolizumab given the difficulty in differentiating between the proportion attributable to the induction therapy in combination with chemotherapy and that attributable to maintenance therapy with atezolizumab alone,**
- **and the impossibility of identifying "good responder" patients who appear to benefit from long-term treatment,**

the Committee considers that TECENTRIQ (atezolizumab), in combination with carboplatin and etoposide, provides a minor clinical added value (CAV IV) compared to chemotherapy alone, in the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).