OPINION ON MEDICINAL PRODUCTS

atezolizumab

TECENTRIQ 840 mg and 1200 mg,

solution for dilution for infusion

New indication(s)

Adopted by the Transparency Committee on 14 December 2022

SUMMARY

The legally binding text is the original French opinion version

Key points

Disapproval of reimbursement as monotherapy for adjuvant treatment, after complete resection and platinum-based chemotherapy, of adult patients with non-small cell lung cancer (NSCLC) with a high risk of recurrence, presenting with PD-L1 tumour expression ≥ 50% on tumour cells (TC) and not presenting with EGFR-mutated or ALK-gene rearranged (ALK-positive) NSCLC.

Role in therapeutic strategy?

The therapeutic management of NSCLC particularly depends on the stage of the disease at the time of diagnosis. At localised stages (stages I and II), immediate surgical treatment may be proposed for patients deemed eligible (complete excision deemed possible, no contraindication to excision surgery). At the locally advanced stage IIIA, a number of therapeutic strategies may be proposed, depending on tumour resectability and patient operability: immediate surgery, neoadjuvant chemotherapy followed by surgery, or radio-chemotherapy followed by immunotherapy.

At stages II or III, platinum-based adjuvant chemotherapy is recommended for cases of immediate surgery with complete resection, particularly the cisplatin-vinorelbine or cisplatin-pemetrexed association (only for non-epidermoid NSCLC) Adjuvant chemotherapy is not recommended for stage I cases.

In the absence of EGFR mutation, the follow-up treatment consists of monitoring.

Role of the medicinal product

Considering:

- **the major methodological limitations associated with the efficacy analyses conducted in the cohort finally selected for the marketing authorisation (particularly sub-group, post-hoc analyses, not adjusted for multiplicity, with no tested interaction, using a different stratification criterion from those used for randomisation), meaning that no formal conclusion can be drawn;**
- **the adjuvant context, in which an estimated proportion of between 37% and 63% will not relapse (almost equivalent to recovery), without additional treatment;**
- **the increased toxicity associated with the use of TECENTRIQ (atezolizumab), versus monitoring, in the adjuvant context mentioned above;**

the Committee deems that TECENTRIQ (atezolizumab) has no role in the current therapeutic strategy.

Committee's conclusions

Actual Clinical Benefit

- Non-small cell lung cancer is a serious life-threatening disease.
- The proprietary medicinal product TECENTRIQ (atezolizumab) is a curative medicinal product.
- Considering the major methodological limitations of the data from the IMpower010 study, with marketing authorisation cohort findings from sub-group, post-hoc analyses, not adjusted for multiplicity, with no tested interaction, and using different stratification criteria from those used for randomisation, meaning that no formal conclusion can be drawn; the increased toxicity associated with the use of TECENTRIQ (atezolizumab); the adjuvant context, in which an estimated proportion of between 37% and 63% will not relapse (practically equivalent to recovery), without additional treatment; the Committee deems that the efficacy/adverse effect ratio of TECENTRIQ (atezolizumab) is poorly defined.
- No therapeutic alternative is available (see Clinically relevant comparators). However, the Committee notes that approximately one out of every two patients will not relapse (practically equivalent to recovery), managed with monitoring alone.
- TECENTRIQ (atezolizumab) has no role in the current therapeutic strategy (see Role in therapeutic strategy).

➔ Public health benefit

Considering:

- the severity of non-small cell lung cancer,
- the unmet medical need,
- the lack of response to the identified medical need,
- the lack of data making it possible to assess a potential additional impact on quality of life, delivery of care, the care and/or life pathway.

TECENTRIQ (atezolizumab) is not likely to have a public health benefit.

Considering all of these elements, the Committee deems that the actual clinical benefit of TECENTRIQ (atezolizumab) is insufficient to justify public funding in view in the marketing authorisation indication.

The Committee disapproves inclusion in the list of proprietary medicinal products approved for community use for the marketing authorisation indication and at the marketing authorisation dosages.