**SUMMARY**

atezolizumab

# TECENTRIQ 1,875 mg

**solution for injection**

## Inclusion on list: First listing

**Range supplement**

**Original French opinion adopted by the Transparency Committee on 10 April 2024**

## Summary of opinion

Favourable opinion for reimbursement, only in the currently reimbursable indications of TECENTRIQ 840 mg, 1,200 mg (atezolizumab) concentrate for solution for infusion (I.V.):

- TECENTRIQ, in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC. In patients with EGFR-mutant or ALK-positive NSCLC, TECENTRIQ, in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies;
- TECENTRIQ as monotherapy is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumours have a PD-L1 expression ≥ 50% TC or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR-mutant or ALK-positive NSCLC;
- TECENTRIQ as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy. Patients with EGFR-mutant or ALK-positive NSCLC should also have received targeted therapies before receiving TECENTRIQ;
- TECENTRIQ, in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC);
- TECENTRIQ, in combination with bevacizumab, is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

No clinical added value of the new TECENTRIQ 1,875 mg (atezolizumab) solution for injection form compared to the solution for injection (IV) forms already available.

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# Transparency Committee's conclusions

## Clinical Benefit

### Non-small cell lung cancer

**As first-line treatment of non-squamous NSCLC in combination with bevacizumab, paclitaxel and carboplatin**

- Metastatic non-squamous non-small cell lung cancer (NSCLC) is a serious and life-threatening disease.
- The proprietary medicinal product TECENTRIQ 1,875 mg (atezolizumab) in combination with bevacizumab and paclitaxel and carboplatin-based chemotherapy is a curative medicinal product.
- The efficacy/adverse effects ratio of TECENTRIQ (atezolizumab) in combination with bevacizumab and paclitaxel and carboplatin-based chemotherapy is:
  - moderate in patients who do not have EGFR mutations or ALK gene rearrangements;
  - cannot be established in patients whose tumours have an EGFR mutation or ALK gene re-arrangement, in the absence of data in these patients, excluded from the primary analysis of the study examined for TECENTRIQ 1,200 mg.
- There are medicinal alternatives.
- As for the proprietary medicinal products TECENTRIQ 840 mg, 1,200 mg (atezolizumab):
  - In patients whose tumours do not have EGFR mutations or ALK gene rearrangements, TECENTRIQ (atezolizumab), in combination with bevacizumab and paclitaxel and carboplatin-based chemotherapy, is a therapeutic alternative in patients with metastatic non-squamous non-small cell lung carcinoma (NSCLC).
  - In patients whose tumours have an EGFR mutation or ALK gene rearrangement: TECENTRIQ (atezolizumab) in combination with bevacizumab and paclitaxel and carboplatin-based chemotherapy, has no role in the care pathway in the absence of available clinical data in the patients concerned.

### Public health benefit

TECENTRIQ 1,875 mg (atezolizumab) is unlikely to have an additional impact on public health compared to the forms already listed.

**The Committee deems that the clinical benefit of TECENTRIQ 1,875 mg (atezolizumab), in combination with bevacizumab, paclitaxel and carboplatin, is:**

- **moderate as first-line treatment in adult patients with metastatic non-squamous NSCLC whose tumours do not have EGFR mutations or ALK gene rearrangements;**
- **insufficient to justify public funding cover in patients with EGFR-mutant or ALK gene arrangement-positive (ALK-positive) metastatic non-squamous NSCLC, after failure of appropriate targeted therapies.**

**The Committee issues a favourable opinion for inclusion in the list of covered drugs for inpatients approved for use in the indication as first-line treatment in adult patients with metastatic non-squamous NSCLC whose tumours do not have EGFR mutations or ALK gene rearrangements, and at the MA dosages.**

**The Committee issues an unfavourable opinion for inclusion in the list of covered drugs for inpatients approved for use in the indication as first-line treatment in adult patients with EGFR-mutant or ALK-positive metastatic non-squamous NSCLC, after failure of appropriate targeted therapies, and at the MA dosages.**

**As first-line treatment of NSCLC as monotherapy**

- Metastatic non-small cell lung cancer (NSCLC) is a serious and life-threatening disease.
- The proprietary medicinal product TECENTRIQ (atezolizumab) is a curative medicinal product.
- Its efficacy/adverse effects ratio is high.
- There are therapeutic alternatives.
- 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 benefit**

TECENTRIQ 1,875 mg (atezolizumab) is unlikely to have an additional impact on public health compared to the forms already listed.

**The Committee deems that the clinical benefit of TECENTRIQ 1,875 mg (atezolizumab) as monotherapy is substantial in the first-line treatment of patients with NSCLC whose tumours have a PD-L1 expression ≥ 50% TC or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR-mutant or ALK-positive NSCLC.**

**The Committee issues a favourable opinion for inclusion in the list of covered drugs for inpatients approved for use in the indication as monotherapy for the first-line treatment of patients with NSCLC whose tumours have a PD-L1 expression ≥ 50% TC or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR-mutant or ALK-positive NSCLC.**

**As second-line treatment of NSCLC as monotherapy**

- Advanced non-small cell lung cancer (NSCLC) is a serious, life-threatening disease.
- This is a specific curative treatment for advanced NSCLC.
- The efficacy/adverse effects ratio is high in the MA indication, with the exception of advanced NSCLC with ALK gene rearrangement (ALK-positive) for which the efficacy/adverse effects ratio has not been established in the absence of clinical data.
- There are medicinal alternatives.
- This is a second or later-line treatment, following the failure of prior chemotherapy. As the dossier currently stands, and in the absence of available clinical data, atezolizumab has not demonstrated a role in the care pathway for advanced NSCLC with ALK gene rearrangement (ALK-positive), after failure of appropriate targeted therapies and prior chemotherapy.

- **Public health benefit**

TECENTRIQ 1,875 mg (atezolizumab) is unlikely to have an additional impact on public health compared to the forms already listed.

**The Committee deems that the clinical benefit of TECENTRIQ 1,875 mg (atezolizumab), as monotherapy, is:**

- **substantial in the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy, with patients with activating EGFR mutation also having to have received a prior targeted therapy;**
- **insufficient in the treatment of adult patients with ALK-positive locally advanced or metastatic NSCLC after prior chemotherapy.**

**The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in the indication as monotherapy in the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy, with patients with activating EGFR mutation also having to have received a prior targeted therapy.**

**The Committee issues an unfavourable opinion for inclusion in the list of covered drugs for inpatients approved for use in the indication as monotherapy in the treatment in adult patients with ALK-positive locally advanced or metastatic NSCLC after prior chemotherapy.**

### Small cell lung cancer

- Extensive-stage small cell lung cancer (ES-SCLC) is a serious, life-threatening disease.
- The proprietary medicinal product TECENTRIQ 1,875 mg (atezolizumab) is a curative medicinal product.
- As for the proprietary medicinal products TECENTRIQ 840 mg, 1,200 mg (atezolizumab), the efficacy/adverse effects ratio is high.
- There are medicinal alternatives, as first-line treatment.
- 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 benefit

TECENTRIQ 1,875 mg (atezolizumab) is unlikely to have an additional impact on public health compared to the forms already listed.

**The Committee considers that the clinical benefit of TECENTRIQ 1,875 mg (atezolizumab) is substantial in the MA indication.**

**The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in the indication and at the MA dosages.**

## Hepatocellular carcinoma

- ➔ Hepatocellular carcinoma is a serious, life-threatening disease in the short term.
- ➔ The proprietary medicinal product TECENTRIQ 1,875 mg (atezolizumab) in combination with bevacizumab, is a curative medicinal product.
- ➔ As for the proprietary medicinal products TECENTRIQ 840 mg, 1,200 mg (atezolizumab), its efficacy/adverse effects ratio is high in patients who have not received prior systemic therapy, with preserved hepatic function (Child-Pugh A), an ECOG score of 0 or 1, and not eligible for locoregional therapies or in the event of failure of one of these therapies. The transposability of the results to the French population (different aetiology profile) cannot be confirmed, however.
- ➔ There are medicinal alternatives.
- ➔ TECENTRIQ (atezolizumab), in combination with bevacizumab, is a first-line treatment in patients with advanced or unresectable hepatocellular carcinoma, who have not received prior systemic therapy, with preserved hepatic function (Child-Pugh A), an ECOG score of 0 or 1, and not eligible for locoregional therapies or in the event of failure of one of these therapies. It has no role in the other situations in the absence of clinical data.

### ➔ Public health benefit

TECENTRIQ 1,875 mg (atezolizumab), in combination with bevacizumab, is unlikely to have an additional impact on public health compared to the forms already listed.

**The Committee deems that the clinical benefit of TECENTRIQ 1,875 mg (atezolizumab) is:**

- **substantial in the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC), who have not received prior systemic therapy only in patients with preserved hepatic function (Child-Pugh A), an ECOG score of 0 or 1, and not eligible for locoregional therapies or in the event of failure of one of these therapies;**
- **insufficient in other situations to justify public funding cover.**

**The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in the indication "treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC), who have not received prior systemic therapy, with preserved hepatic function (Child-Pugh A), an ECOG score of 0 or 1, and not eligible for locoregional therapies or in the event of failure of one of these therapies" and at the MA dosages.**

**The Committee issues an unfavourable opinion for inclusion in the list of covered drugs for inpatients approved for use in the other situations.**

## Clinical Added Value

**This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the solution for infusion (IV) forms already listed**.