

SPECIALTY GUIDELINE MANAGEMENT

TECENTRIQ (atezolizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Non-small cell lung cancer (NSCLC)
 - a. Tecentriq, as a single-agent, is indicated as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on $\geq 1\%$ of tumor cells, as determined by an FDA-approved test.
 - b. Tecentriq, as a single-agent, is indicated for the first line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
 - c. Tecentriq, in combination with bevacizumab, paclitaxel, and carboplatin, is indicated for the first-line treatment, of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
 - d. Tecentriq, in combination with paclitaxel protein-bound and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
 - e. Tecentriq as a single agent is indicated for the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq.
2. Small cell lung cancer (SCLC)

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).
3. Hepatocellular Carcinoma (HCC)

Tecentriq, in combination with bevacizumab, is indicated for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.
4. Melanoma
Tecentriq, in combination with cobimetinib and vemurafenib, is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.
5. Alveolar Soft Part Sarcoma (ASPS)
Tecentriq, as a single agent, is indicated for the treatment of adult and pediatric patients age 2 years and older with unresectable or metastatic ASPS.

Reference number(s)
1766-A

B. Compendial Uses

1. Non-small cell lung cancer (NSCLC)
2. Mesothelioma
3. Cervical Cancer

All other indications are considered experimental/investigational and not medically necessary.

II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Test results confirming PD-L1 tumor expression (where applicable)
- B. Test results confirming tumor is positive for BRAF V600 mutation (where applicable)
- C. Test results confirming the presence of EGFR exon 19 deletions or L858R mutations or ALK rearrangements (where applicable)

III. EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy

IV. CRITERIA FOR INITIAL APPROVAL

A. Non-Small Cell Lung Cancer (NSCLC)

1. Authorization of 6 months may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer when there are no EGFR exon 19 deletions or L858R mutations or ALK rearrangements (unless testing is not feasible due to insufficient tissue) and any of the following criteria are met:
 - a. The requested medication will be used as continued maintenance therapy as a single agent or in combination with bevacizumab.
 - b. The requested medication will be used as first line or subsequent therapy in combination with chemotherapy with or without bevacizumab.
 - c. The requested medication will be used as first line therapy for PD-L1 expression positive ($\geq 50\%$) tumors as a single agent.
2. Authorization of 6 months may be granted for treatment of stage II to III non-small cell lung cancer that is PD-L1 positive as single agent adjuvant therapy.
3. Authorization of 6 months may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer as single agent subsequent therapy.

B. Small Cell Lung Cancer (SCLC)

Authorization of 6 months may be granted for treatment of small cell lung cancer when the requested medication will be used as initial treatment in combination with etoposide and carboplatin (followed by single agent maintenance) for extensive-stage disease.

C. Hepatocellular Carcinoma (HCC)

Authorization of 6 months may be granted for treatment of unresectable, inoperable, metastatic, or disease with extensive liver tumor burden HCC when the requested medication will be used as initial treatment in combination with bevacizumab.

D. Melanoma

Reference number(s)
1766-A

Authorization of 6 months may be granted for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma when the requested medication will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf).

E. Mesothelioma

Authorization of 6 months may be granted for the subsequent treatment of peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when used in combination with bevacizumab.

F. Alveolar Soft Part Sarcoma (ASPS)

Authorization of 6 months may be granted for the treatment of unresectable or metastatic alveolar soft part sarcoma when used as a single agent.

G. Cervical Cancer

Authorization of 6 months may be granted for the treatment of persistent, recurrent or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) when used in combination with etoposide and either cisplatin or carboplatin.

V. CONTINUATION OF THERAPY

A. Adjuvant treatment of Non-Small Cell Lung Cancer (NSCLC)

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization of adjuvant therapy of non-small cell lung cancer who have not experienced disease recurrence or an unacceptable toxicity.

B. All other indications

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

VI. REFERENCES

1. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; May 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed December 13, 2023.