VENTURA COUNTY
HEALTH CARE PLAN

# UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Oncology (Injectable – Programmed Death-Ligand 1) – Tecentriq Utilization Management Medical Policy
- Tecentriq® (atezolizumab intravenous infusion – Genentech/Roche)

**REVIEW DATE:** 01/22/2025

---

## OVERVIEW

Tecentriq, a programmed death-ligand 1 (PD-L1) blocking antibody, is indicated for the treatment of the following:[1]

- **Alveolar Soft Part Sarcoma**, in patients ≥ 2 years of age with unresectable or metastatic disease.
- **Hepatocellular carcinoma**, in combination with bevacizumab, for the treatment of unresectable or metastatic hepatocellular carcinoma in adults who have not received prior systemic therapy.
- **Melanoma**, in combination with Cotellic® (cobimetinib tablets) and Zelboraf® (vemurafenib tablets), for the treatment of *BRAF V600* mutation-positive unresectable or metastatic disease in adults.
- **Non-small cell lung cancer** (NSCLC), **metastatic** disease in adults:
  - As a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for adults with Stage II to IIIA disease whose tumors express PD-L1 on ≥ 1% of tumor cells.
  - As a single-agent, for the first-line treatment of tumors with high PD-L1 expression (PD-L1 staining ≥ 50% of tumor cells or PD-L1 staining of tumor infiltrating immune cells covering ≥ 10% of the tumor area), with no anaplastic lymphoma kinase (*ALK*) or epidermal growth factor receptor (*EGFR*) genomic tumor aberrations.
  - In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of metastatic non-squamous NSCLC with no *ALK* or *EGFR* genomic tumor aberrations.
  - In combination with paclitaxel protein-bound and carboplatin, for the first-line treatment of non-squamous metastatic NSCLC with no *ALK* or *EGFR* genomic tumor aberrations.
  - As a single-agent, for 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 these aberrations prior to receiving Tecentriq.
- **Small cell lung cancer**, in combination with carboplatin and etoposide, for the first-line treatment of adults with extensive-stage disease.

## POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tecentriq. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tecentriq as well as the monitoring required for adverse events and long-term efficacy, approval requires Tecentriq be prescribed by or in consultation with a prescriber who specializes in the condition being treated.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tecentriq is recommended in those who meet one of the following criteria:

**FDA-Approved Indications**

---

1. **Alveolar Soft Part Sarcoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 2 years of age; AND
   - **B)** Patient has unresectable or metastatic disease; AND
   - **C)** The medication is used as a single agent; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   **Dosing.** Approve ONE of the following dosing regimens (A or B):
   - **A)** Patient is ≥ 18 years of age: Approve ONE of the following (i, ii, or iii):
     - **i.** 840 mg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
     - **ii.** 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
     - **iii.** 1,680 mg administered as an intravenous infusion not more frequently than once every 4 weeks; OR
   - **B)** Patient is ≥ 2 to < 18 years of age: Approve 15 mg/kg (up to a maximum of 1,200) administered as an intravenous infusion not more frequently than once every 3 weeks.

---

2. **Hepatocellular Carcinoma.** Approve for the duration noted if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Approve for 1 year (total) if the patient meets ALL of the following (a, b, and c):
       - **a)** Patient has undergone resection or ablation therapy; AND
       - **b)** Patient is at high-risk of recurrence; AND
         Note: High-risk is defined as size > 5 cm, > 3 tumors, macovascular invasion, microvessel invasion on histology, or grade 3/4 histology.
       - **c)** Medication is used as adjuvant therapy; OR
     - **ii.** Approve for 1 year if the patient meets BOTH of the following (a and b):
       - **a)** Medication is used for first-line therapy; AND
       - **b)** According to the prescriber, the patient has ONE of the following [(1) or (2)]:
         - **(1)** Liver confined, unresectable disease and is deemed ineligible for transplant; OR
         - **(2)** Extrahepatic/metastatic disease and are deemed ineligible for resection, transplant or locoregional therapy; AND
   - **C)** The medication will be used in combination with bevacizumab; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   **Dosing.** Approve ONE of the following dosing regimens (A, B, or C):
   - **A)** 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
   - **B)** 840 mg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
   - **C)** 1,680 mg administered as an intravenous infusion not more frequently than once every 4 weeks.

---

3. **Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND

**B)** Patient has unresectable or metastatic melanoma; AND
**C)** Patient has *BRAF V600* mutation-positive disease; AND
**D)** The medication will be used as subsequent therapy; AND
**E)** The medication will be used in combination with Cotellic (cobimetinib tablets) and Zelboraf (vemurafenib tablets); AND
**F)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A, B, or C):
**A)** 840 mg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
**B)** 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
**C)** 1,680 mg administered as an intravenous infusion not more frequently than once every 4 weeks.

---

**4. Non-Small Cell Lung Cancer.** Approve for the duration noted if the patient meets ALL of the following (A, B, and C):
**A)** Patient is ≥ 18 years of age; AND
**B)** Patient meets ONE of the following (i, ii, iii, iv, v, or vi):
**i.** Approve for 1 year if the patient has non-squamous non-small cell lung cancer (NSCLC) and the patient meets ALL of the following (a, b, and c):
Note: Non-squamous NSCLC includes adenocarcinoma, large cell, or NSCLC not otherwise specified.
**a)** Patient has recurrent, advanced or metastatic disease; AND
**b)** The tumor is negative for actionable mutations; AND
Note: Examples of actionable mutations include epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *ROS1, BRAF V600E, NRTK1/2/3, MET* exon 14 skipping mutation, *RET* rearrangement, NRG1. May be *KRAS G12C* mutation positive.
**c)** The medication is used as first-line or continuation maintenance therapy; OR
**ii.** Approve for 1 year if the patient has squamous cell NSCLC and meets ALL of the following (a, b, c, and d):
**a)** Patient has recurrent, advanced, or metastatic disease; AND
**b)** The tumor is negative for actionable mutations; AND
Note: Examples of actionable mutations include epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *ROS1*, *BRAF V600E, NRTK1/2/3, MET* exon 14 skipping mutation, *RET* rearrangement. May be *KRAS G12C* mutation positive.
**c)** Patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 50% as determined by an approved test; AND
**d)** Medication is used as first-line or continuation maintenance therapy; OR
**iii.** Approve for 1 year if the patient has recurrent, advanced, or metastatic non-squamous cell NSCLC; is EGFR exon 19 deletion, exon 21 *L858R* mutation, *ALK* rearrangement, *RET* rearrangement, and *ROS1* rearrangement negative and meets ONE of the following (a, b, or c):
Note: Non-squamous NSCLC includes adenocarcinoma, large cell, or NSCLC not otherwise specified.
**a)** Patient meets ALL of the following [(1), (2), and (3)]:
**(1)** The tumor is *EGFR* exon 20 mutation positive, *NRG1* gene fusion positive, or *ERBB2* (*HER2*) mutation positive; AND
**(2)** The medication is used first-line; AND
**(3)** The medication is used in combination with chemotherapy; OR

Note: Examples of chemotherapy include carboplatin, paclitaxel, and bevacizumab; and carboplatin plus paclitaxel albumin-bound.

**b)** Patient meets ALL of the following [(1), (2), and (3)]:
- **(1)** The tumor is *BRAF V600E* mutation positive, *NTRK1/2/3* gene fusion positive, or *MET* exon 14 skipping mutation positive; AND
- **(2)** The medication is used for first-line or subsequent treatment; AND
- **(3)** The medication is used in combination with chemotherapy; OR
  Note: Examples of chemotherapy include carboplatin, paclitaxel, and bevacizumab; and carboplatin plus paclitaxel albumin-bound.

**c)** Patient meets ALL of the following [(1), (2), and (3)]:
- **(1)** The tumor is *EGFR S768I*, *L861Q*, and/or *G719X* mutation positive; AND
- **(2)** Patient has received targeted drug therapy for the specific mutation; AND
  Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), or Vizimpro (dacomitinib tablets).
- **(3)** The medication is used in combination with chemotherapy; OR
  Note: Examples of chemotherapy include carboplatin, paclitaxel, and bevacizumab; and carboplatin plus paclitaxel albumin-bound.

**iv.** Approve for 1 year if the patient meets ALL of the following (a, b, c, and d):
- **a)** Patient has recurrent, advanced, or metastatic disease; AND
- **b)** The medication is used as subsequent therapy; AND
- **c)** The medication is used as a single agent; AND
- **d)** The patient has not progressed on a programmed death receptor-1 (PD-1) or programmed death-ligand 1 inhibitor (PD-L1); OR
  Note: Examples of PD-1 or PD-L1 inhibitors include Tecentriq, Keytruda (pembrolizumab intravenous infusion), and Opdivo (nivolumab intravenous infusion).

**v.** Approve for 1 year if the patient meets ALL of the following (a, b, and c):
- **a)** Patient has squamous cell NSCLC; AND
- **b)** Patient is performance status 3; AND
- **c)** Medication is used as a single agent; OR

**vi.** Approve for up to 1 year (total) if the patient meets ALL of the following (a, b, c, and d):
- **a)** Patient has completely resected disease; AND
- **b)** Patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1% as determined by an approved test; AND
- **c)** Patient is negative for *EGFR* exon 19 deletion, exon 21 *L858R* mutations, and *ALK* rearrangements; AND
- **d)** Patient has received previous adjuvant chemotherapy; AND

**C)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A, B, or C):

**A)** 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR

**B)** 840 mg administered as an intravenous infusion not more frequently than once every 2 weeks; OR

**C)** 1,680 mg administered as an intravenous infusion not more frequently than once every 4 weeks.

---

**5. Small Cell Lung Cancer.** Approve for 1 year if the patient meets BOTH of the following (A and B):

**A)** Patient is ≥ 18 years of age; AND

**B)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A, B, or C):

**A)** 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
**B)** 840 mg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
**C)** 1,680 mg administered as an intravenous infusion not more frequently than once every 4 weeks.

**Other Uses with Supportive Evidence**

---

**6. Cervical Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
**A)** Patient is ≥ 18 years of age; AND
**B)** Patient has persistent, recurrent, or metastatic disease; AND
**C)** The medication is used in combination with chemotherapy; AND
Note: Examples of chemotherapy include cisplatin or carboplatin, with etoposide or paclitaxel.
**D)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

---

**7. Mesothelioma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
**A)** Patient is ≥ 18 years of age; AND
**B)** The medication is used as subsequent therapy; AND
**C)** The medication is used in combination with bevacizumab; AND
**D)** Patient has ONE of the following (i, ii, or iii):
**i.** Malignant peritoneal mesothelioma; OR
**ii.** Pericardial mesothelioma; OR
**iii.** Tunica vaginalis testis mesothelioma; AND
**E)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

---

**8. Urothelial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
**A)** Patient is ≥ 18 years of age; AND
**B)** Patient meets ONE of the following (i or ii):
**i.** Patient meets BOTH of the following (a and b):
**a)** Medication is used for first-line therapy; AND
**b)** Patient meets ONE of the following [(1) or (2)]:
**(1)** Patient is ineligible for cisplatin and tumor expresses programmed death-ligand 1 (PD-L1) tumor infiltrating immune cells covering ≥ 5% of tumor area; OR
**(2)** Patient is ineligible for any platinum-containing chemotherapy regardless of PD-L1 expression; OR
**ii.** Patient meets BOTH of the following (a and b):
**a)** Patient is currently receiving Tecentriq for the treatment of urothelial carcinoma; AND
**b)** According to the prescriber, the patient is deriving benefit from Tecentriq; AND
**C)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A, B, or C):

**A)** 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
**B)** 840 mg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
**C)** 1,680 mg administered as an intravenous infusion not more frequently than once every 4 weeks.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tecentriq is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Tecentriq® intravenous infusion [prescribing information]. South San Francisco, CA: Genentech; April 2024.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 13, 2025. Search term: atezolizumab.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 4.2024 – November 21, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 13, 2025.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – January 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 13, 2025.
5. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 5.2024 – October 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 13, 2025.
6. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – October 29, 2024). © 20243 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 13, 2025.
7. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 4.2024 – January 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 13, 2025.
8. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: www.nccn.org. Accessed on January 13, 2025.
9. The NCCN Mesothelioma: Peritoneal Clinical Practice Guidelines in Oncology (version 1.2025 – November 21, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 13, 2025.
10. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 13, 2025.
11. Raghav K, Liu S, Overman MJ, et al. Efficacy, safety, and biomarker analysis of combined PD-L1 (atezolizumab) and VEGF (bevacizumab) blockade in advanced malignant peritoneal mesothelioma. *Cancer Discov*. 2021;11:2738-2747.
12. Oaknin A, Gladieff L, Martinez-Garcia J, et al. Atezolizumab plus bevacizumab and chemotherapy for metastatic, persistent, or recurrent cervical cancer (BEATcc): a randomized, open-label, phase 3 trial. *Lancet*. 2023 Dec 1:S0140-6736(23)02405-4. doi: 10.1016/S0140-6736(23)02405-4.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **Hepatocellular Carcinoma:** Added B liver function to the requirement that the patient has Child-Pugh Class A or B liver function. Added requirement that the patient has unresectable disease and is not a transplant candidate, OR has liver-confined disease, inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease, OR has metastatic disease or extensive liver tumor burden.<br>**Melanoma:** Added requirement that the medication is used as subsequent therapy.<br>**Non-Small Cell Lung Cancer:** Added descriptor exon 21 to the requirement that the tumor is epidermal growth factor (*EGFR*) exon 19 deletion or exon 21 *L858R* positive, *EGFR S768I, L861Q*, and/or *G719X* mutation positive, *ALK* rearrangement positive, or *ROS1* rearrangement positive.<br>**Cervical Cancer:** Added new condition of approval. | 12/20/2023 |
| Annual Revision | **Hepatocellular Carcinoma:** Duration of approval was changed from 1 year to approve for the duration noted. Requirements that the patient has Child-Pugh Class A or B liver function and patient has not received prior systemic therapy were removed. Option for approval that the patient has unresectable or metastatic hepatocellular carcinoma and is | 01/22/2025 |

| | | |
|---|---|---|
| | not a surgical candidate; and patient has liver confined disease, inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease were removed. Added patient has undergone resection or ablation therapy, patient is at high-risk of recurrence, and medication is used for adjuvant therapy as new option for approval with duration of up to 1 year (total). Added medication is used first-line and patient has liver confined, unresectable disease and is deemed ineligible for transplant; or extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy, with a 1 year duration of approval.<br>**Non-Small Cell Lung Cancer:** Removed *KRAS* from list of actionable mutations and added may be *KRAS G12C* mutation positive to Note. Removed patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1% and medication will be used in combination with chemotherapy as options for approval. Added descriptor first-line to the medication will be used as first-line or continuation maintenance therapy. Added requirement that the medication is used as first-line or continuation maintenance therapy. Added *EGFR* exon 19 deletion, exon 21 *L858R* mutation, *ALK* rearrangement, *RET* rearrangement, and *ROS1* rearrangement negative to requirement that patient has recurrent, advanced, or metastatic non-squamous cell NSCLC, is *EGFR* exon 19 deletion, exon 21 *L858R* mutation, *ALK* rearrangement, *RET* rearrangement, and *ROS1* rearrangement negative and meets ONE of the following. Removed *KRAS G12C* mutation and added *NRG1* gene fusion to requirement that the tumor is *EGFR* exon 20 mutation positive, *NRG1* gene fusion positive or *ERBB2* (*HER2*) mutation positive. Removed *RET* rearrangement positive from requirement that the tumor is *BRAF V600E* mutation positive, *NTRK1/2/3* gene fusion positive, or *MET* exon 14 skipping mutation positive. Removed *EGFR* exon 19 deletion, exon 21 *L858R* positive, *ALK* rearrangement positive, or *ROS1* rearrangement positive from requirement that the tumor is *EGFR S768I, L861Q*, and/or *G719X* mutation positive. Removed examples of targeted drug therapy. Added option for approval for patients with squamous cell NSCLC, performance status of 3, and medication is used as a single agent. Added requirements for adjuvant therapy: patient has completed resected disease and patients is negative for *EGFR* exon 19 deletion, exon 21 *L858R* mutations and *ALK* rearrangements.<br>**Cervical Cancer:** Requirement that the patient has small neuroendocrine carcinoma of the cervix was removed.<br>**Urothelial Carcinoma:** Added option of approval for medication is used first-line and patient is ineligible for cisplatin and tumor expresses programmed death-ligand 1 (PD-L1) tumor infiltrating immune cells covering ≥ 5% of tumor area, or patient is ineligible for any platinum-containing chemotherapy regardless of PD-L1 expression. | |