CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 09/03/2025

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 adults:
  - In combination with carboplatin and etoposide, for the first-line treatment of extensive-stage disease.
  - In combination with Zepzelca® (lurbinectedin intravenous infusion) for maintenance treatment of extensive-stage disease that has not progressed after first-line induction therapy with Tecentriq Hybreza or Tecentriq® (atezolizumab intravenous infusion), carboplatin and etoposide.

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

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1. Alveolar Soft Part Sarcoma. Approve for 1 year if the patient meets Both of the following (A and B):
- **A)** Patient is ≥ 2 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 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.

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2. Hepatocellular Carcinoma. 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 meets ONE of the following (i or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** The 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 is deemed ineligible for resection, transplant or locoregional therapy; OR
  - **ii.** The medication is used as subsequent-line 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.

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3. Melanoma. 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 *BRAF V600* mutation-positive disease; AND
C) The medication will be used in combination with Cotellic (cobimetinib tablets) and Zelboraf (vemurafenib tablets); 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) 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.

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4. Non-Small Cell Lung Cancer – Adjuvant. 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) The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor *(EGFR)* exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase *(ALK)*, *RET*, or *ROS1; AND*
C) Patient meets ALL of the following (i, ii, and iii):
  i. Patient has completely resected or node positive disease; AND
  ii. The tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1%; AND
  iii. Patient has received previous adjuvant chemotherapy; 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.

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5. Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic. 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. The tumor is positive for epidermal growth factor receptor *(EGRF)* exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase *(ALK)*, *RET*, or *ROS1*; OR
  ii. The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor *(EGFR)* exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase *(ALK)*, *RET*, or *ROS1* and meets ONE of the following (a, b, c, or d):
    a) The medication is used as first-line therapy and the tumor is positive for ONE of the following [(1), (2), or (3)]:
      (1) *EGFR* exon 20 mutation; OR
      (2) *ERBB2* (*HER2*) mutation; OR
      (3) *NRG1* gene fusion; OR
    b) The medication is used for first-line or subsequent treatment and the tumor is positive for ONE of the following [(1), (2), or (3)]:
      (1) *BRAF V600E* mutation; OR
      (2) *NTRK1/2/3* gene fusion; OR

(3) *MET* exon 14 skipping mutation; OR

c) The medication is used as subsequent therapy and the tumor is *EGFR* S768I, L861Q, and/or G719X mutation positive; OR

d) The medication is used as first-line or continuation maintenance therapy and the tumor has no actionable mutations; AND
Note: The tumor does NOT have the following mutations: *EGFR* exon 19 deletion, *EGFR* exon 21 L857R. *EGFR* S768I, *EGFR* L861Q, *EGFR* G719X, *EGFR* exon 20 insertion, , *ALK* rearrangement, *ROS1* rearrangement, *BRAF* V600E, *NTRK* 1/2/3 gene fusion, *METex14* skipping, *RET* rearrangement, *ERBB2* (HER2), and *NRG1* gene fusion.

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

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

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

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

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

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6. 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

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7. 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.

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8. Colon Cancer: Approve for 1 year if the patient meets ALL of the following (A, B, and C)

A) The patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. The disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); OR

ii. The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase); AND

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

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

9. 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.

10. 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 BOTH of the following (i and ii):
i. The medication is used for first-line therapy; AND
ii. Patient meets ONE of the following (a or b):
a) Patient is ineligible for cisplatin and tumor expresses programmed death-ligand 1 (PD-L1) tumor infiltrating immune cells covering ≥ 5% of tumor area; OR
b) Patient is ineligible for any platinum-containing chemotherapy regardless of PD-L1 expression; 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 August14, 2025. Search term: atezolizumab.
3. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 – May 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 14, 2025.

4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 8.2025 – August 15, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 29, 2025.
5. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – March 25, 2025). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 14, 2025.
6. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – July 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 25, 2025.
7. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – March 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 14, 2025.
8. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 2.2025 – January 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: www.nccn.org. Accessed on August 14, 2025.
9. The NCCN Mesothelioma: Peritoneal Clinical Practice Guidelines in Oncology (version 2.2025 – January 14, 2025). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 14, 2025.
10. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – March 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 14, 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.
13. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 4.2025 – June 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 14, 2025.

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. **Melanoma:** Added requirement that the medication is used as subsequent therapy. **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. **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 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. **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	01/22/2025

	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. **Cervical Cancer:** Requirement that the patient has small neuroendocrine carcinoma of the cervix was removed. **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.	
Early Annual Revision	**Alveolar Soft Part Sarcoma:** The requirements the patient has unresectable or metastatic disease and the medication is used as a single agent were removed. **Hepatocellular Carcinoma:** The approval duration was modified to approve for 1 year for all approval options. The options for approval that the patient has undergone resection or ablation therapy, has high-risk of recurrence, and the medication is used as adjuvant therapy has been removed. The medication will be used as subsequent-line therapy was added as an approval option. **Melanoma:** The requirements that the patient has unresectable or metastatic melanoma and that the medication will be used as subsequent therapy have been removed. **Non-Small Cell Lung Cancer – Adjuvant:** The condition of approval was changed to as listed. Previously, all non-small cell lung cancer (NSCLC) was addressed more generally under NSCLC. The approval duration was modified to approve for 1 year. A requirement was added that the tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGRF) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1. **Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease**: The indication was changed to as listed. Previously, all non-small cell lung cancer (NSCLC) was addressed more generally under NSCLC. The approval duration was modified to approve for 1 year for all approval options. A requirement was added that the tumor is positive for epidermal growth factor receptor (EGRF) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, or ROS1. The differentiation of the different types of NSCLC (non-squamous cell NSCLC and squamous cell NSCLC) were removed as options for approval. For all lines of therapy, removed the medication will be used in combination with chemotherapy as an option for approval. For subsequent therapy, the patient has received targeted drug therapy for the specific mutation and that the patient has not progressed on programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) were removed as options of approval. The patient has squamous cell NSCLC, is performance status 3, and the medication is used as a single-agent have been removed as approval options. The patient has completely resected disease and the tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1% as determined by an approved test were removed as approval options. For first-line therapy or as continuation maintenance therapy, a requirement was added that the tumor has no actionable mutations; a Note was added listing the following actionable mutations: EFGR exon 19 deletion, EFGR exon 21 L858R, EFGR S768I, EGFR L861Q, EGFR G719X, EGFR exon 20 insertion, ALK rearrangement, ROS1 rearrangement, BRAF V600E, NTRK 1/2/3 gene fusion, METex14 skipping, RET rearrangement, ERBB2 (HER2), and NRG1 gene fusion. For first-line and continuation maintenance therapy; the patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 50% as determined by an approved test was removed as an approval option. **Colon Cancer:** This was added as a new condition of approval. **Urothelial Carcinoma:** The options that the patient is currently receiving Tecentriq for the treatment of urothelial carcinoma and according to the prescriber, the patient is deriving benefit from Tecentriq were removed.	09/03/2025

Update	**Overview:** Updated the overview to reflect changes in the Small-Cell Lung Cancer indication. No criteria changes.	10/08/2025