PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 12/14/2022

OVERVIEW

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

- **Hepatocellular carcinoma**, in combination with bevacizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy.
- **Melanoma**, in combination with Cotellic® (cobimetinib tablets) and Zelboraf® (vemurafenib tablets), for the treatment of patients with *BRAF V600* mutation-positive unresectable or metastatic disease.
- **Non-small cell lung cancer** (NSCLC), **metastatic**:
  - 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 adults whose tumors have 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 adults with 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 adults with non-squamous metastatic NSCLC with no *ALK* or *EGFR* genomic tumor aberrations.
  - As a single-agent, in adults 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 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 prescription benefit coverage of Tecentriq. 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 the medication to 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. **Hepatocellular Carcinoma.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, E, and F):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has unresectable or metastatic hepatocellular carcinoma; OR
     - **ii.** According to the prescriber, the patient is not a surgical candidate; AND
   - **C)** Patient has Child-Pugh Class A disease; AND
   - **D)** Patient has not received prior systemic therapy; AND
   - **E)** The medication will be used in combination with bevacizumab; AND
   - **F)** The medication is prescribed by or in consultation with an oncologist.

2. **Melanoma.** Approve for 1 year if the patient meets the following (A, B, C, D, and E):
   - **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 in combination with Cotellic (cobimetinib tablets) and Zelboraf (vemurafenib tablets); AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

3. **Non-Small Cell Lung Cancer.** Approve for the duration noted if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i, ii, iii, iv, or v):
     - **i.** Approve for 1 year if the patient has non-squamous 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*, *KRAS*, *BRAF V600E*, *NRTK1/2/3*, *MET* exon 14 skipping mutation, *RET* rearrangement.
       - **c)** Patient meets one of the following [(1), (2), or (3)]:
         - **(1)** Patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1% as determined by an approved test; OR
           Note: In this setting Tecentriq can be used either as a single agent or in combination with other agents.
         - **(2)** The medication will be used in combination with chemotherapy; OR
           Note: Examples of chemotherapy regimens may include bevacizumab, paclitaxel, and carboplatin; carboplatin and paclitaxel albumin-bound intravenous infusion).
         - **(3)** The medication is used as continuation maintenance therapy; OR
           Note: Tecentriq can be used in combination with bevacizumab or as single agent in this setting.
     - **ii.** Approve for 1 year if the patient has squamous cell NSCLC and meets all of the following (a, b, and c):
       - **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*, *KRAS*, *BRAF V600E*, *NRTK1/2/3*, *MET* exon 14 skipping mutation, *RET* rearrangement.

c) Patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 50% as determined by an approved test; OR

iii. Approve for 1 year if the patient has recurrent, advanced, or metastatic non-squamous cell NSCLC and meets one of the following (a, b, or c):

a) Patient meets all of the following [(1), (2), and (3)]:

(1) The tumor is epidermal growth factor receptor (*EGFR*) exon 20 mutation positive, *KRAS G12C* mutation positive, or *ERBB2* (*HER2*) mutation positive; AND

(2) The medication is used first-line; AND

(3) The medication is used in combination with chemotherapy; AND

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, *MET* exon 14 skipping mutation positive, or *RET* rearrangement 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 epidermal growth factor receptor (*EGFR*) exon 19 deletion or *L858R* positive, *EGFR S768I*, *L861Q*, and/or *G719X* mutation positive, *ALK* rearrangement positive, or *ROS1* rearrangement positive; AND

(2) The patient has received targeted drug therapy for the specific mutation; 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.

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 up to 1 year (total) if the patient meets both of the following (a and b):

a) Patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1% as determined by an approved test; AND

b) Patient has received previous adjuvant chemotherapy; AND

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

4. 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.

Other Uses with Supportive Evidence

5. Mesothelioma. Approve for 1 year if the patient meets the following criteria (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.

5. Urothelial Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient is currently receiving Tecentriq for the treatment of urothelial carcinoma; AND
C) According to the prescriber, the patient is deriving benefit from Tecentriq; AND
D) The medication is prescribed by or in consultation with an oncologist.

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; December 2022.
2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 9, 2022. Search term: atezolizumab.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 6.2022 – December 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 12, 2022.
4. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 9, 2022.
5. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – October 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 9, 2022.
6. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 3.2022 – October 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 9, 2022.
7. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 3.2032 – April 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: www.nccn.org. Accessed on December 9, 2022.
8. The NCCN Malignant Peritoneal Mesothelioma Clinical Practice Guidelines in Oncology (version 2.2022 – October 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 9, 2022.