VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Oncology (Injectable) – Tecentriq Utilization Review Medical Policy
- Tecentriq® (atezolizumab injection for intravenous use – Genentech/Roche)

REVIEW DATE: 11/13/2019; selected revisions 06/24/2020

OVERVIEW

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

- **Breast cancer**, in combination with paclitaxel protein-bound (Abraxane) for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells of any intensity covering ≥ 1% of the tumor area), as determined by an FDA-approved test. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- **Hepatocellular carcinoma**, in combination with bevacizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy.
- **Metastatic non-small cell lung cancer** (NSCLC):
  - As a single-agent, for the first-line treatment of patients with metastatic NSCLC 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; OR
  - In combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic non-squamous NSCLC with no *ALK* or *EGFR* genomic tumor aberrations; OR
  - 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; OR
  - As a single-agent, in patients 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 adult patients with extensive-stage disease.
- **Urothelial carcinoma**, in patients with locally advanced or metastatic disease who:
  - Are not eligible for cisplatin-based chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor infiltrating immune cells covering ≥ 5% of the tumor area); OR
  - Are not eligible for any platinum-containing chemotherapy regardless of the PD-L1 status; OR
  - Have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.

  This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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 indication(s). 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.

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. Breast Cancer. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
- **A)** Patient has unresectable locally advanced or metastatic triple-negative breast cancer; AND
- **B)** The tumor is programmed death-ligand 1 (PD-L1)-positive; AND
- **C)** The medication will be used in combination with Abraxane (paclitaxel albumin-bound for injection); AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve Tecentriq dose of 840 mg administered as an intravenous infusion on Days 1 and 15 of each 28 day cycle.

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2. Hepatocellular Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
- **A)** Patient has unresectable or metastatic hepatocellular carcinoma; AND
- **B)** Patient has not received prior systemic 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 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. Non-Small Cell Lung Cancer. Approve for 1 year if the patient meets the following criteria (A, B, and C):
- **A)** Tecentriq is prescribed by or in consultation with an oncologist; AND
- **B)** Patient has advanced or metastatic disease; AND
- **C)** Patient meets one of the following (i, ii, or iii):
  - **i.** Patient has non-squamous NSCLC (i.e., adenocarcinoma, large cell, or NSCLC not otherwise specified) and the patient meets the following (a and b):
    - **a)** The tumor is negative for targetable mutations; AND

Note: Examples of targetable mutations include epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *ROS1*, *BRAF*, *MET exon 14* skipping mutation, *RET* rearrangement.

b) Patient meets one of the following [(1) or (2)]:

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

(2) Patient's tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1% to 49% as determined by an approved test and Tecentriq will be used in combination with chemotherapy; OR

Note: Examples of chemotherapy include bevacizumab, paclitaxel, and carboplatin, or carboplatin and Abraxane (paclitaxel, albumin-bound for injection).

ii. Patient has squamous cell NSCLC and meets both of the following (a and b):

a) The tumor is negative for targetable mutations; AND

Note: Examples of targetable mutations include epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *ROS1*, *BRAF*, *MET exon 14* skipping mutation, *RET* rearrangement.

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

iii. Patient's tumor is positive for targetable mutations and the patient meets both of the following (a and b):

Note: Examples of targetable mutations include epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *ROS1*, *BRAF*, *MET exon 14* skipping mutation, *RET* rearrangement:

a) Patient has tried at least one of the targeted therapy options; AND

b) Tecentriq will be used as subsequent therapy.

Dosing. Approve 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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4. Small Cell Lung Cancer. Approve for 1 year if Tecentriq is prescribed by or in consultation with an oncologist.

Dosing. Approve 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. Urothelial Carcinoma. Approve for 1 year if the patient meets the following criteria (A and B):

A) Patient meets ONE of the following conditions (i, ii, or iii):

i. According to the prescribing physician, the patient meets both of the following (a and b):

a) Patient is not eligible for cisplatin-based chemotherapy; AND

b) Patient's tumor expresses PD-L1 (i.e., PD-L1 stained tumor infiltrating immune cells covering ≥ 5% of the tumor area); OR

ii. According to the prescribing physician, the patient is not eligible for platinum-containing chemotherapy (i.e., cisplatin and carboplatin) [Note: this is regardless of the PD-L1 status]; OR

iii. Patient has tried at least one platinum- (cisplatin or carboplatin) containing chemotherapy; AND

B) Tecentriq is prescribed by or in consultation with an oncologist.

Dosing. Approve 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® injection for intravenous use [prescribing information]. South San Francisco, CA: Genentech, Inc (A member of the Roche Group); May 2020.
2. The NCCN Drugs & Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 8, 2020. Search term: atezolizumab.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 5.2020 – May 27, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 8, 2020.
4. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 4.2019 – July10, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 11, 2019.
5. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 1.2020 – October 10, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on November 11, 2019.
6. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – September 6, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: www.nccn.org. Accessed on November 11, 2019.
7. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (Version 3.2020 – June 1, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 8, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
Selected revision	Urothelial Carcinoma: added criteria for patients ineligible for cisplatin-based chemotherapy.	06/14/2017
Annual	• NSCLC: criteria were revised to add that Tecentriq is used as a single agent. Criteria were divided into non-squamous cell and squamous cell histologies. For non-squamous cell histologies, the list of targeted therapies used for each aberration was removed; testing for both EGFR and ALK is required; testing for ROS1 was removed; EGFR and ALK are negative was added as an option after testing; and criteria were added for testing for PD-L1 expression for Keytruda. For squamous cell carcinoma, criteria were added for testing for PD-L1 expression for Keytruda. See policy for details. Dosing is for single-agent Tecentriq. In Labs/Diagnostics, testing for PD-L1 expression for Keytruda was added. Testing for ROS1 rearrangements was removed. • Urothelial Carcinoma: criteria were revised to add that Tecentriq is single-agent therapy, and the dose is for single agent Tecentriq.	11/29/2017
Update	01/17/2018: No changes to criteria. Criteria for NSCLC were clarified. • NSCLC: criteria for PD-L1 expression testing for Keytruda were removed. Criteria require that Tecentriq be used as subsequent therapy after chemotherapy and that Keytruda and Opdivo have not been used. In Labs/Diagnostics, testing for PD-L1 expression for Keytruda was removed.	NA
Selected revision	• NSCLC: criteria for PD-L1 expression testing for Keytruda were removed. Criteria require that Tecentriq be used as subsequent therapy after chemotherapy and that Keytruda and Opdivo have not been used. In Labs/Diagnostics, testing for PD-L1 expression for Keytruda was removed.	1/24/2018
Annual revision	• **For all conditions:** updated approval duration to 1 year; response criteria were removed from the policy; criteria for the specific indication must be met for repeat authorization. Requirement that the patient have locally-advanced or metastatic disease was removed from the policy when chemotherapy is also required. Also, criteria stating that Tecentriq is used as a single agent is deleted since this is a Tecentriq is approved for combination use or trials are underway exploring combination therapies. • **NSCLC:** Updated criteria to accommodate new indication for Tecentriq in combination with Avastin and chemotherapy. Also updated to new MBM format with regards to dosing/duration. Deleted specific testing requirements for targetable mutations and instead re-worded criteria to state if targetable mutation is present, targeted therapies have been tried first. Due to change in disease course or interruption in therapy, criteria that other PD-1 inhibitors have not been tried before has been deleted. Deleted criteria "squamous cell carcinoma". Instead, the criteria for trial of previous systemic chemotherapy is written without specifying the type of NSCLC (so it applies to nonsquamous and squamous NSCLC). • **Urothelial carcinoma:** Reworded criteria to require a previous trial of at least one platinum-containing chemotherapy (previously required disease progression during or after trying one of these therapies). For patients that are not eligible for cisplatin, as per the prescriber, a requirement was added that the tumor expresses programmed death ligand-1 (PD-L1). Criteria were added to allow an exception for patients who, according to the prescriber, are not eligible for any platinum-based chemotherapy regardless of PD-L1 status. Modified dosing verbiage to approve for the FDA-approved dose of Tecentriq. • **Small cell lung cancer:** Added new approval condition based on NCCN guidelines and compendium.	12/19/2018
Annual Revision	• **Non-Small Cell Lung Cancer:** Deleted "unknown" in reference to targeted mutation status of tumor. Added *BRAF* and *ROS1* as targetable mutations. • **Dosing:** For all indications except breast cancer, modified Dosing to state "Approve one of the following doses". The approved Tecentriq doses and dosing intervals have been updated as per the prescribing information. • **Breast Cancer:** Added new approval condition based on new indication approval.	11/13/2019
Selected Revisions	• **NSCLC:** Updated criteria for non-squamous cell carcinoma to include additional targetable mutations and PD-L1 expression of ≥ 50% and ≥ 1% to 49%. Added criteria for squamous cell NSCLC and for patients that are targetable mutation positive. • **Hepatocellular carcinoma:** Added new approval condition and criteria.	06/24/2020

NSCLC – Non-small cell lung cancer; EGFR – Epidermal growth factor receptor; ALK – Anaplastic lymphoma kinase; PD-L1 – Programmed death-ligand 1.