POLICY: Oncology – Tecentriq® (atezolizumab injection for intravenous use – Genentech [Roche])

DATE REVIEWED: 11/13/2019

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

1) Locally advanced or metastatic urothelial carcinoma who
   • Are not eligible for cisplatin-based chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor infiltrating immune cells [IC] 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.

2) Metastatic non-small cell lung cancer (NSCLC)
   • In combination with bevacizumab, paclitaxel, and carboplatin is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC with no anaplastic lymphoma kinase (ALK) or epidermal growth factor receptor (EGFR) genomic tumor aberrations; OR
   • As 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.

3) Advanced or metastatic triple-negative 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 (TNBC) whose tumors express PD-L1 (PD-L1 stained tumor infiltrating immune cells [IC] 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.

4) Small cell lung cancer (SCLC)
   • In combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage SCLC.

POLICY STATEMENT
This policy involves the use of Tecentriq. Prior authorization is recommended for medical benefit coverage of Tecentriq. Approval is recommended for those who meet the Criteria and Dosing for the diagnosis provided. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by an Express Scripts 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 AEs 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
1. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   
   A) For non-squamous NSCLC (i.e., adenocarcinoma, large cell, or NSCLC not otherwise specified) the patient meets ONE of the following criteria (i or ii):
   
   i. The tumor is negative for targetable mutations (i.e., epidermal growth factor receptor \([EGFR]\) mutation, anaplastic lymphoma kinase \([ALK]\) fusions, \(ROS1, BRAF\)); OR
   
   ii. If the NSCLC tumor is positive for a targetable mutation (i.e., epidermal growth factor receptor \([EGFR]\) mutation, anaplastic lymphoma kinase \([ALK]\) fusions), at least one of the targeted therapy options have been tried; AND
   
   B) Tecentriq will be used in ONE of the following therapy settings (i or ii):
   
   i. In combination with Avastin (bevacizumab for injection) and chemotherapy (e.g., paclitaxel, carboplatin) for non-squamous NSCLC; OR
   
   ii. The patient has tried at least one systemic chemotherapy regimen (e.g., carboplatin, cisplatin, Alimta [pemetrexed for injection], paclitaxel, gemcitabine, docetaxel); AND
   
   C) Tecentriq is prescribed by or in consultation with an oncologist.

**Dosing.** Approve one of the following doses:

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

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

A) The patient meets ONE of the following conditions (i, ii, or iii):
   
   i. According to the prescribing physician, the patient is not eligible for cisplatin-based chemotherapy AND the 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. The 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 one of the following doses:

A) Tecentriq dose of 1,200 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
B) Tecentriq dose of 840 mg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
C) Tecentriq dose of 1,680 mg administered as an intravenous infusion not more frequently than once every 4 weeks.
3. **Small Cell Lung Cancer.** Approve for 1 year if Tecentriq is prescribed by or in consultation with an oncologist.

**Dosing.** Approve one of the following Tecentriq doses:

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

4. **Breast Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):

- **A)** The 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 album-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 not more frequently than once every 28 days.

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**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Tecentriq has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

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**REFERENCES**

1. Tecentriq® injection for intravenous use [prescribing information]. South San Francisco, CA: Genentech, Inc (A member of the Roche Group); May 2019.


### HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Date Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy</td>
<td>NSCLC: new indication added.</td>
<td>06/29/2016</td>
</tr>
<tr>
<td>Annual</td>
<td>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.</td>
<td>11/16/2016</td>
</tr>
<tr>
<td>Selected</td>
<td>Urothelial Carcinoma: added criteria for patients ineligible for cisplatin-based chemotherapy.</td>
<td>06/14/2017</td>
</tr>
<tr>
<td>Annual</td>
<td>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.</td>
<td>11/29/2017</td>
</tr>
<tr>
<td>clarification</td>
<td>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.</td>
<td>01/17/2018</td>
</tr>
<tr>
<td>Selected</td>
<td>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.</td>
<td>1/24/2018</td>
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<tr>
<td>Annual revision</td>
<td>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). Small cell lung cancer: Added new approval condition based on NCCN guidelines and compendium.</td>
<td>12/19/2018</td>
</tr>
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<td>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.</td>
<td>11/3/2019</td>
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### History (Continued)

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Date Reviewed</th>
</tr>
</thead>
</table>
| 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 |