Utilization Review Policy 185

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

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

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

a. **Alveolar Soft Part Sarcoma**, in patients ≥ 2 years of age with unresectable or metastatic disease.
b. **Hepatocellular carcinoma**, in combination with bevacizumab, for the treatment of unresectable or metastatic hepatocellular carcinoma in adults who have not received prior systemic therapy.
c. **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.

2) **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), for adults with no anaplastic lymphoma kinase (*ALK*) or epidermal growth factor receptor (*EGFR*) genomic tumor aberrations.
   - In combination with bevacizumab, paclitaxel, and carboplatin, in adults 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, in adults for the first-line treatment of 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 adults, 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

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1. **Alveolar Soft Part Sarcoma.** Approve for 1 year if the patient meets 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.

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2. **Hepatocellular Carcinoma.** Approve for 1 year if the patient meets the following (A, B, C, D, E, F, and G):

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 or B liver function; AND
D) According to the prescriber, the patient has ONE of the following (i, ii, or iii):
  i. Unresectable disease and is not a transplant candidate; OR
  ii. Liver-confined disease, inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; OR
  iii. Metastatic disease or extensive liver tumor burden; AND
E) Patient has not received prior systemic therapy; AND
F) The medication will be used in combination with bevacizumab; AND
G) 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 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.

A) Non-Small Cell Lung Cancer. Approve for the duration noted if the patient meets 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, or v):

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*, *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):
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 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; 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, *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 exon 21 *L858R* positive, *EGFR S768I*, *L861Q*, and/or *G719X* mutation positive, *ALK* rearrangement positive, or *ROS1* rearrangement 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), Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), Alecensa (alectinib capsules), Alunbrig (brigatinib tablets), Lorbrena (lorlatinib tablets), Rozlytrek (entrectinib capsules), 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 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.

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. 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 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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6. Cervical Cancer. 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 small cell neuroendocrine carcinoma of the cervix; AND
C) Patient has persistent, recurrent, or metastatic disease; AND
D) The medication is used in combination with chemotherapy; AND
Note: Examples of chemotherapy include cisplatin or carboplatin, with etoposide.
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.

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7. Mesothelioma. 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) 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):
a. Malignant peritoneal mesothelioma; OR

b. Pericardial mesothelioma; OR
c. 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.

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8. Urothelial Carcinoma. Approve for 1 year if the patient meets the following (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.

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

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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:** According to the prescriber, the patient is not a surgical candidate was added as another option for approval. Patient has Child-Pugh Class A disease was added as a requirement. **Non-Small Cell Lung Cancer:** Examples of non-squamous cell non-small cell lung cancer were moved to a Note. "Recurrent" was added as an additional descriptor to requirement that the patient has advanced or metastatic disease. Requirement that the tumor expresses programmed death-ligand 1 was changed	12/14/2022

	from ≥ 50% to ≥ 1%. Additional options for approval for recurrent, advanced, or metastatic non-squamous cell disease with specific genetic mutations were added. Another option of approval was added for patient with recurrent, advanced, or metastatic disease who has not progressed on a programmed death receptor-1 or programmed death-ligand 1 inhibitor therapy and medication will be used as a single agent. **Mesothelioma:** This condition was added as another condition of approval. **Urothelial Carcinoma:** Patient is currently receiving Tecentriq and deriving benefit from Tecentriq were added as requirements. Requirements that the patient is not eligible for cisplatin and the tumor expresses PD-L1; and patient is not eligible for platinum-containing chemotherapy were removed.	
Selected Revision	**Alveolar Soft Part Sarcoma:** Added new condition of approval.	03/08/2023
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
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024