Reference number(s)
2132-A

STANDARD MEDICARE PART B MANAGEMENT

Tecentriq (atezolizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Locally advanced or metastatic urothelial carcinoma
   Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:
   i. Are not eligible for cisplatin-containing chemotherapy, and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥5% of the tumor area), as determined by an FDA-approved test, or
   ii. Are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, or
   iii. Have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.

2. Metastatic non-small cell lung cancer (NSCLC)
   i. Indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
   ii. Indicated in combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment, of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
   iii. Indicated in combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
   iv. Indicated as a single agent for the treatment of adult patients with metastatic NSCLC 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 NSCLC harboring these aberrations prior to receiving the requested medication.

3. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC)
   Indicated in combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic 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.

4. Small cell lung cancer (SCLC)
   Indicated in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

5. Hepatocellular Carcinoma
   Indicated in combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

6. Melanoma
   Tecentriq, in combination with cobimetinib and vemurafenib, is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

B. Compendial Uses
   1. Subsequent therapy for urothelial carcinoma following platinum-containing chemotherapy
   2. Treatment of recurrent or advanced NSCLC whose tumors have high PD-L1 expression
   3. Treatment of metastatic, recurrent or advanced non-squamous non-small cell lung cancer (NSCLC) in combination with carboplatin, paclitaxel, and bevacizumab, or in combination with carboplatin and albumin-bound paclitaxel
   4. Continuation maintenance therapy for NSCLC when tumor response or stable disease is achieved following initial systemic therapy
   5. Subsequent therapy for recurrent, advanced or metastatic NSCLC
   6. Recurrent triple-negative breast cancer, PD-L1 positive
   7. Hepatocellular carcinoma, for patients who
      i. are inoperable by performance status or comorbidity, or have local disease or local disease with minimal extrahepatic disease only
      ii. have extensive tumor burden
   8. Advanced or metastatic renal cell cancer, first-line treatment in combination with bevacizumab

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

A. Urothelial carcinoma

Authorization of 12 months may be granted for treatment of urothelial carcinoma when any of the following criteria is met:

1. Member is not eligible for cisplatin-containing chemotherapy, and the member's tumor expresses PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥5% of the tumor area).
2. Member is not eligible for any platinum containing chemotherapy.
3. The requested medication will be used as subsequent therapy following platinum-containing chemotherapy.

B. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic NSCLC when any of the following criteria is met:

1. The requested medication is used as first-line treatment of tumors with high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]) and no EGFR or ALK genomic tumor aberrations.
2. The requested medication is used for nonsquamous NSCLC:
   i. in combination with carboplatin, paclitaxel, and bevacizumab, or
   ii. in combination with carboplatin and albumin-bound paclitaxel.
3. The requested medication will be used as subsequent therapy.

C. Breast cancer

Authorization of 12 months may be granted for treatment of unresectable locally advanced, recurrent, or metastatic triple-negative breast cancer when all of the following criteria are met:

1. The diagnosis of triple negative breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
   i. human epidermal growth factor receptor 2 (HER-2)
   ii. estrogen
   iii. progesterone
2. Tumors must express programmed death ligand 1 (PD-L1) (i.e., PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1 percent of the tumor area).
3. Tecentriq will be used in combination with protein-bound paclitaxel (Abraxane).

D. Small cell lung cancer (SCLC)

Authorization of 12 months may be granted for treatment of small cell lung cancer when the requested medication will be used as initial treatment in combination with etoposide and carboplatin (followed by single agent maintenance) for extensive-stage disease.

E. Hepatocellular carcinoma (HCC)

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma when the requested medication will be used as initial treatment in combination with bevacizumab.

F. Melanoma

Authorization of 12 months may be granted for treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma when the requested medication is used in combination with cobimetinib and vemurafenib.

G. Renal cell cancer

Authorization of 12 months may be granted for first-line treatment of advanced or metastatic renal cell cancer, in combination with bevacizumab.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section II.
C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; July 2020.
2. The NCCN Drugs & Biologics Compendium™ © 2020 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 27, 2020.
3. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2020- [cited July 27, 2020]. Available from: http://www.clinicalkey.com.