

SPECIALTY GUIDELINE 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:
 - a. Are not eligible for cisplatin-containing chemotherapy, and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 5\%$ of the tumor area), as determined by an FDA-approved test, or
 - b. Are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, or
 - c. 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)
 - a. Indicated for the first line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
 - b. 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.
 - c. 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.
 - d. 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 $\geq 1\%$ 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 (HCC)

Reference number(s)
1766-A

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

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

B. Compendial Uses

1. Urothelial carcinoma
 - a. Bladder cancer
 - b. Primary carcinoma of the urethra
 - c. Upper genitourinary tract tumors
 - d. Urothelial carcinoma of the prostate
2. Non-small cell lung cancer (NSCLC)
3. Triple-negative breast cancer

All other indications are considered experimental/investigational and are not medically necessary.

II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- A. Test results confirming PD-L1 tumor expression (where applicable)
- B. Test results confirming tumor is positive for BRAF V600 mutation (where applicable)
- C. Test results confirming that the cancer cells are negative for the following receptors (where applicable):
 1. human epidermal growth factor receptor 2 (HER-2)
 2. estrogen
 3. progesterone

III. EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy

IV. CRITERIA FOR INITIAL APPROVAL

A. Urothelial Carcinoma - Bladder Cancer

Authorization of 6 months may be granted for treatment as a single agent for bladder cancer when any of the following criteria are met:

1. The requested medication is used as first line therapy in cisplatin ineligible persons whose tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area) or in persons who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression for any of the following:
 - a. Stage II or Stage IIIa disease if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent chemoradiotherapy
 - b. Locally advanced or metastatic disease
 - c. Metastatic or local recurrence post-cystectomy
 - d. Muscle invasive local recurrence or persistent disease in a preserved bladder

Reference number(s)
1766-A

2. The requested medication is used as subsequent systemic therapy following platinum containing chemotherapy for either of the following:
 - a. Locally advanced or metastatic disease
 - b. Metastatic or local recurrence post-cystectomy
 - c. Muscle invasive local recurrence or persistent disease in a preserved bladder

B. Urothelial Carcinoma - Primary Carcinoma of the Urethra

Authorization of 6 months may be granted for treatment as a single agent for primary carcinoma of the urethra when any of the following criteria are met:

1. The requested medication is used as first line therapy for recurrent, locally advanced or metastatic disease in cisplatin ineligible persons whose tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area) or in persons who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression.
2. The requested medication is used as subsequent therapy for recurrent, locally advanced or metastatic disease following platinum-containing chemotherapy.

C. Urothelial Carcinoma - Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate

Authorization of 6 months may be granted for treatment as a single agent for upper genitourinary tract tumors or urothelial carcinoma of the prostate when any of the following criteria are met:

1. The requested medication is used as first line therapy for locally advanced or metastatic disease in cisplatin ineligible persons whose tumors express PD-L1 (defined as PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area) or in persons who are not eligible for any platinum containing chemotherapy regardless of PD-L1 expression
2. The requested medication is used as subsequent therapy for locally advanced or metastatic disease following platinum-containing chemotherapy

D. Non-Small Cell Lung Cancer (NSCLC)

Authorization of 6 months may be granted for treatment of NSCLC when any of the following criteria are met:

1. The requested medication is used as a single agent for the first-line treatment of recurrent, advanced, or metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), with no EGFR or ALK genomic tumor aberrations
2. The requested medication is used as treatment for recurrent, advanced or metastatic nonsquamous NSCLC in combination with carboplatin, paclitaxel and bevacizumab (if EGFR or ALK positive, will be used following EGFR or ALK therapy)
3. The requested medication is used as treatment for recurrent, advanced or metastatic nonsquamous NSCLC in combination with paclitaxel protein-bound and carboplatin (if EGFR or ALK positive, will be used following EGFR or ALK therapy)
4. The requested medication is used as subsequent therapy as a single agent for recurrent, advanced, or metastatic disease

E. Breast Cancer

Authorization of 6 months may be granted for treatment of unresectable locally advanced, recurrent, or metastatic breast cancer when all of the following criteria are met:

1. The diagnosis of breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
 - a. human epidermal growth factor receptor 2 (HER-2)
 - b. estrogen
 - c. 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 greater than or equal to 1 percent of the tumor area).

Reference number(s)
1766-A

3. The requested medication will be used in combination with protein-bound paclitaxel (Abraxane).

F. Small Cell Lung Cancer (SCLC)

Authorization of 6 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.

G. Hepatocellular Carcinoma (HCC)

Authorization of 6 months may be granted for treatment of HCC when the requested medication will be used as initial treatment in combination with bevacizumab.

H. Melanoma

Authorization of 6 months may be granted for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma when the requested medication will be used in combination with cobimetinib (Cotellic) and vemurafenib (Zelboraf).

V. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

VI. 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. Available at: <https://www.nccn.org>. Accessed June 1, 2020.