Reference number(s)
1766-A

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
   Tecentriq is 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 ≥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. Tecentriq is 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.
   b. Tecentriq is indicated 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 these aberrations prior to receiving Tecentriq.

3. Unresectable locally advanced or metastatic triple-negative breast cancer (TNBC)
   Tecentriq is 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)
   Tecentriq is indicated in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

B. Compendial Uses

1. Non-small cell lung cancer after progression on or after cytotoxic chemotherapy
2. Negative epidermal growth factor receptor (EGFR), negative anaplastic lymphoma kinase (ALK), negative c-ros oncogene 1 (ROS1) non-squamous non-small cell lung cancer
3. Positive epidermal growth factor receptor (EGFR), positive anaplastic lymphoma kinase (ALK), positive c-ros oncogene 1 (ROS1) non-small cell lung cancer after failure of targeted therapy

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Urothelial carcinoma

Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial carcinoma when any of the following criteria are 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), as determined by an FDA-approved test, or
2. Member is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, or
3. The disease has progressed during or following platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.

B. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of metastatic NSCLC when any of the following criteria are met:

1. The disease has progressed during or following cytotoxic chemotherapy.
2. Member has positive epidermal growth factor receptor (EGFR) mutation, positive anaplastic lymphoma kinase (ALK), or positive c-ros oncogene 1 (ROS1) gene rearrangement who have had disease progression on targeted FDA-approved therapy (e.g., erlotinib, afatinib, gefitinib, crizotinib, ceritinib) prior to receiving Tecentriq.
3. Member has non-squamous histology and is negative for epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or c-ros oncogene 1 (ROS1) mutation.

C. Breast cancer

Authorization of 12 months may be granted for treatment of breast cancer when any 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 ≥ 1 percent of the tumor area), as determined by an FDA approved test.
3. Tecentriq will be used in combination with protein-bound paclitaxel.

D. Small cell lung cancer (SCLC)

Authorization of 12 months may be granted for treatment of small cell lung cancer when both of the following criteria are met:

1. Patient has extensive-stage disease.
2. Tecentriq will be used in combination with etoposide and carboplatin.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCE

1. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; March 2019.
2. The NCCN Drugs & Biologics Compendium™ © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 18, 2019.