Tecentriq® (atezolizumab)

Last Review Date: August 5, 2020	Number: MG.MM.PH.169

Definition

Tecentriq (atezolizumab) is FDA approved for the treatment of members with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy, 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 are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status,. It is indicated for the treatment of members with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. It is also indicated in combination with paclitaxel protein-bound for the treatment of adult members with unresectable locally advanced or metastatic triple-negative breast cancer 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.

Tecentriq (atezolizumab) is a monoclonal antibody which binds to PD-L1 expressed on tumor cells or tumor infiltrating immune cells and blocks its interaction with PD-1 and B7.1 receptors present on T cells and antigen presenting cells, which releases the inhibition of the immune response and activates the antitumor response.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 120 billable units per 21 days

I. INITIAL APPROVAL CRITERIA

Tecentriq *may be considered medically necessary when any of the following selection criteria is met:*

1. **Bladder Cancer**
    a. The member has transitional cell carcinoma of the urothelium (including renal pelvis, ureters, urinary bladder, urethra) and Tecentriq (atezolizumab) is being used as a single agent for *ONE* of the following:
        i. First line in cisplatin ineligible members whose tumors express PD-L1 as determined by an FDA-approved test: **OR**
        ii. Member is not eligible for ANY platinum containing chemotherapy regardless of PD-L1 expression; **OR**
        iii. As subsequent therapy post platinum chemotherapy , or within 12 months of neoadjuvant or adjuvant chemotherapy

2. **Non-Small Cell Lung Cancer (NSCLC)**
    a. The member has NSCLC and Tecentriq (atezolizumab) is being used (if pembrolizumab/nivolumab not previously given) as subsequent therapy for metastatic disease in members with performance status 0-2 for **ONE** of the following:
        i. For the first-line treatment of adult members 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; **OR**
        ii. In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult members with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations; **OR**
        iii. In combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult memberss with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations; **OR**
        iv. For the treatment of adult members with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Members with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to

receiving Tecentriq (atezolizumab).

3. **Small Cell Lung Cancer (SCLC)**
    a. Member is taking in combination with carboplatin and etoposide, for the first-line treatment of adult members with extensive-stage small cell lung cancer (ES-SCLC).

4. **Triple-Negative Breast Cancer (TNBC)**
    a. Member has a documented diagnosis of locally advanced or metastatic TNBC; **AND**
    b. 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; **AND**
    c. Tecentriq will be used in combination with paclitaxel protein-bound.

5. **Hepatocellular Carcinoma (HCC)**
    a. In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

6. **Melanoma**
    a. Member has a documented diagnosis of BRAF V600 mutation-positive unresectable or metastatic melanoma; **AND**
    b. Tecentriq (atezolizumab) will be used in combination with cobimetinib and vemurafenib.

Limitations/Exclusions

Tecentriq (atezolizumab) is not considered medically necessary when any of the following selection criteria is met:

1. Member must be 18 years of age or older
2. Tecentriq (atezolizumab) is being used after disease progression with the same regimen.
3. Prior use of immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies.
4. Concurrent active infections, autoimmune diseases, or central nervous system metastases requiring therapy.
5. Concurrent use with systemic immunosuppressive therapy or systemic steroid therapy.
6. Dosing exceeds single dose limit of Tecentriq (atezolizumab) 1200 mg.
7. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

- Member continues to meet the criteria in INITIAL APPROVAL CRITERIA; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug including severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, skin, etc.), severe infection, ocular inflammatory toxicity, myasthenic syndrome, Guillain-Barre syndrome, meningoencephalitis, pancreatitis, etc.

Dosage/Administration

TECENTRIQ® (atezolizumab) Prescribing Information

Indication	Dose
Triple-Negative Breast Cancer, Metastatic	– 840 mg IV infusion over 60 minutes followed by 100 mg/m2 paclitaxel protein-bound. For each 28-day cycle, Tecentriq is administered on days 1 and 15, and paclitaxel protein-bound is administered on days 1, 8, and 15. If first infusion is tolerated, may infuse all subsequent doses over 30 minutes.
Melanoma	– Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer TECENTRIQ 840 mg every 2 weeks with cobimetinib 60 mg orally once daily (21 days on /7 days off) and vemurafenib 720 mg orally twice daily.
All Other Indications	– 1,200 mg IV infusion over 60 minutes every 3 weeks until disease progression or unacceptable toxicity occurs; if first infusion is tolerated, may infuse all subsequent doses over 30 minutes

Applicable Procedure Codes

J9022	Injection, atezolizumab, 10 mg, 1 billable unit = 10 mg

Applicable NDCs

50242-0917-xx	Tecentriq 1200mg/20mL single use vial
50242-0918-xx	Tecentriq 840mg/14mL single use vial

Applicable Diagnosis Codes

ICD-10	ICD-10 Description
C22.0	Liver cell carcinoma, hepatocellular carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus

C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C50.011—C50.019, C50.111—C50.119, C50.211—C50.219, C50.311—C50.319, C50.411—C50.419, C50.511—C50.519, C50.611—C50.619, C50.811—C50.819, C50.911—C50.919	Malignant neoplasm of the female breast
C50.021—C50.029, C50.121—C50.129, C50.221—C50.229, C50.321—C50.329, C50.421—C50.429, C50.521—C50.529, C50.621—C50.629, C50.821—C50.829, C50.921—C50.929	Malignant neoplasm of the female breast
C61	Malignant neoplasm of prostate
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder

C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C79.31	Secondary malignant neoplasm of brain
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
D09.0	Carcinoma in situ of bladder
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
C43.0-C43.9	Malignant melanoma of skin, by site

Revision History

<table>
<tr><td>8/5/2020</td><td>Updated the following Indications/criteria and dosing per FDA Label:
1. BRAF V600 mutation-positive unresectable or metastatic melanoma.
2. Added the following ICD-10 codes:
<table><tr><th>ICD-10</th><th>ICD-10 Description</th></tr><tr><td>C43.0-C43.9</td><td>Malignant melanoma of skin, by site</td></tr></table></td></tr>
<tr><td>06/05/2020</td><td>Updated the following Indications/criteria per FDA Label:
1. Under Initial Criteria: Bladder Cancer – added bolded text to the criteria: As subsequent therapy post platinum chemotherapy , or within 12 months of neoadjuvant or adjuvant chemotherapy.

2. Non-Small Cell Lung Cancer - For the first-line treatment of adult members 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.

3. Hepatocellular Carcinoma (HCC) newly approved indication - In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.

Under Limitations and Exclusions (added): Member must be 18 years of age or older

Added the following ICD-10 codes:</td></tr>
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12/16/2019	<table><tr><th>ICD-10</th><th>ICD-10 Description</th></tr><tr><td>C22.0</td><td>Liver cell carcinoma, hepatocellular carcinoma</td></tr><tr><td>C22.8</td><td>Malignant neoplasm of liver, primary, unspecified as to type</td></tr></table> Updated indications to match FDA label: added Small Cell Lung Cancer (SCLC) and criteria: Member is taking in combination with carboplatin and etoposide, for the first-line treatment of adult members with extensive-stage small cell lung cancer (ES-SCLC).

References

1) Tecentriq prescribing information. Genentech, Inc. South San Francisco, CA. 2019.
2) Clinical Pharmacology Elsevier Gold Standard. 2018.
3) Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
4) National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2018.
5) AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018.