Approved Revision: Do Not Implement Until 8/31/21

Atezolizumab (Tecentriq®)

NDC CODE(S) 50242-0917-XX TECENTRIQ 60MG/ML Solution (GENENTECH)
50242-0918-XX TECENTRIQ 60MG/ML Solution (GENENTECH)

DESCRIPTION

Atezolizumab is a monoclonal antibody that binds to programmed death-ligand 1 (PD-L1), a transmembrane protein which may be expressed on tumor cells and/or tumor-infiltrating immune cells and are often increased. By binding to the receptors on PD-L1, atezolizumab prevents its binding to the PD-1 and B7.1 receptors found on T cells and antigen presenting cells. This releases the PD-L1/PD-1 mediated inhibition of the immune response and activates

POLICY

- Atezolizumab is considered ***medically necessary*** for the treatment of the following if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Urothelial Carcinoma (Bladder Cancer)
  - Breast Cancer [Triple Negative (TNBC)]
  - Hepatocellular Adenocarcinoma
  - Melanoma, cutaneous
  - Non-Small Cell Lung Cancer (NSCLC)
  - Small Cell Lung Cancer (SCLC)

- Atezolizumab for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, etc.) unless otherwise specified; **AND**

Urothelial Carcinoma (Bladder Cancer)

- Used as a single agent; **AND**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder; **OR**
  - Metastatic or local bladder cancer recurrence post-cystectomy; **OR**
  - Primary carcinoma of the urethra; **AND**
    - Used for recurrent *(excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes)* or metastatic disease; **OR**
    - Used for stage T3-4, cN1-2 disease or cN1-2 palpable inguinal lymph nodes; **OR**
  - Metastatic upper genitourinary (GU) tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **AND**

- Used as first-line therapy in cisplatin-ineligible patients*; **AND**
  - Patient is carboplatin-ineligible*; OR
  - Patient has a PD-L1 expression of ≥ 5% (PD-L1 stained tumor-infiltrating immune cells
  - [IC] covering ≥ 5% of the tumor area) as determined by an FDA-approved or CLIA-compliant test**

** Note:*
- *Cisplatin-ineligible comorbidities may include the following: GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.*
- *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3, etc.*

Breast Cancer

- Used in combination with albumin-bound paclitaxel; **AND**
- Patient has unresectable locally advanced, recurrent, unresectable (local or regional), or metastatic triple-negative disease (TNBC); **AND**
- Patient has a PD-L1 expression *(PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1% of the tumor area)* as determined by an FDA-approved or CLIA-compliant test**

Non-Small Cell Lung Cancer (NSCLC) §

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for EGFR, ALK, ROS1, BRAF, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, and RET rearrangement negative* tumors and PD-L1 ≥50% *(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 or CLIA-compliant test**; **AND**
      - Used as a single agent; **OR**
    - Used for non-squamous disease as one of the following:
      - Used in patients with PS 0-1 for EGFR, ALK, ROS1, BRAF, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, and RET rearrangement negative* tumors and PD-L1 <1%
      - Used in patients with PS 0-2 for EGFR, ALK, ROS1, BRAF, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, and RET rearrangement negative* tumors and PD-L1 ≥1%
      - Used in patients with PS 0-1 for BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon-14 skipping mutation; **AND**
      - Used in combination with carboplatin, paclitaxel, and bevacizumab; **OR**
      - Used in combination with carboplatin and albumin-bound paclitaxel; **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent; **OR**
    - Used for non-squamous disease as one of the following:
      - Used in patients with PS 0-1 for BRAF V600E-mutation, NTRK1/2/3 gene fusion or MET exon-14 skipping mutation
      - Used in patients with PS 0-1 and ROS1 positive tumors after prior targeted therapy§; **AND**
      - Used in combination with carboplatin, paclitaxel, and bevacizumab; **OR**
      - Used in combination with carboplatin and albumin-bound paclitaxel; **OR**
  - Used as continuation maintenance therapy in patients who have achieved a tumor response or stable disease following initial therapy; **AND**

- Used in combination with bevacizumab following a first-line regimen with atezolizumab, carboplatin, paclitaxel, and bevacizumab for non-squamous histology; **OR**
- Used as a single agent following a first-line regimen with atezolizumab, carboplatin, and albumin-bound paclitaxel for non-squamous histology; **OR**
- Used as a single agent following a first-line regimen with single agent atezolizumab

** Note: If there is insufficient issue to allow testing for all of EGFR, ALK, ROS1, ~~and~~ BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Small Cell Lung Cancer (SCLC)

- Patient has extensive stage disease (ES-SCLC) (excluding patients with poor PS 3-4 not due to SCLC); **AND**
  - Used as first-line therapy in combination with etoposide and carboplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with etoposide and carboplatin

Hepatocellular Carcinoma (HCC)

- Used as first-line therapy in combination with bevacizumab; **AND**
- Patient has Child-Pugh Class A disease; **AND**
- Patient has unresectable or inoperable (e.g., performance status, comorbidity or with minimal or uncertain extrahepatic-disease) disease, extensive liver tumor burden, or metastatic disease

Cutaneous Melanoma

- Patient has BRAF V600 mutation-positive disease; **AND**
- Patient has unresectable or metastatic disease*; **AND**
- Used as first-line therapy in combination with cobimetinib and vemurafenib

** Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

***If confirmed using an FDA approved assay - http://www.fda.gov/companiondiagnostics*

§Genomic Aberration/Mutational Driver Targeted Therapies (Note: not all inclusive, refer to guidelines for appropriate use)
Sensitizing *EGFR* mutation-positive tumors ▫ Afatinib ▫ Erlotinib ▫ Dacomitinib ▫ Gefitinib ▫ Osimertinib

ALK rearrangement-positive tumors ▫ Alectinib ▫ Brigatinib ▫ Ceritinib ▫ Crizotinib ▫ Lorlatinib
ROS1 rearrangement-positive tumors ▫ Ceritinib ▫ Crizotinib ▫ Entrectinib
BRAF V600E-mutation positive tumors ▫ Dabrafenib ± Trametinib ▫ Vemurafenib
NTRK Gene Fusion positive tumors ▫ Larotrectinib ▫ Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%) ▫ Pembrolizumab ▫ Atezolizumab ▫ Nivolumab ± ipilimumab
MET Exon-14 skipping mutations ▫ Capmatinib ▫ Crizotinib ▫ Teporinib
RET rearrangement-positive tumors ▫ Selpercatinib ▫ Cabozantinib ▫ Vandetanib ▫ Pralsetinib

RENEWAL CRITERIA

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Initial Approval Criteria; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis, etc.), severe infusion-related reactions, etc.

Continuation Maintenance Therapy for NSCLC or SCLC

- *Refer to Initial Approval Criteria*

DOSAGE/ADMINISTRATION

INDICATION	DOSE

NSCLC, TNBC, SCLC, HCC, UC	The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: ▫ 840 mg every 2 weeks or ▫ 1200 mg every 3 weeks or ▫ 1680 mg every 4 weeks
Cutaneous Melanoma	The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: ▫ 840 mg every 2 weeks or ▫ 1200 mg every 3 weeks or ▫ 1680 mg every 4 weeks **Prior to initiating TECENTRIQ, patients should receive a 28 day treatment cycle of cobimetinib 60 mg orally once daily (21 days on and 7 days off) and vemurafenib 960 mg orally twice daily from Days 1-21 and vemurafenib 720 mg orally twice daily from Days 22-28.*

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

168 billable units every 28 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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EFFECTIVE DATE 8/31/2021

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