| Policy Title: | Tecentriq ( atezolizumab)<br>Intravenous | | |
|---|---|---|---|
| | | **Department:** | PHA |
| **Effective Date:** | 01/01/2020 | | |
| **Review Date:** | 9/1/2019, 12/13/2019 | | |
| **Revision Date:** | 9/1/2019, 12/13/2019 | | |

**Purpose:** To support safe, effective and appropriate use of Tecentriq (atezolizumab).

**Scope:** Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

**Policy Statement:** Tecentriq (atezolizumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:** Coverage of Tecentriq (atezolizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

***Initial Criteria:***

- Patient must be at least 18 years old; AND
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, etc.) unless otherwise specified; AND

**Bladder Cancer/Urothelial Carcinoma**

- Must be used as a single agent; AND
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic Urothelial Carcinoma; OR
  - Disease recurrence post-cystectomy; OR
  - Primary Carcinoma of the Urethra; AND
    - Used for recurrent or metastatic disease and the patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; OR
    - Used as primary treatment for clinical stage T3-4, cN1-2 disease or cN1-2 palpable inguinal lymph nodes; OR
  - Metastatic Upper GU Tract Tumors; OR
  - Metastatic Urothelial Carcinoma of the Prostate; AND
- Used as subsequent therapy after previous platinum treatment*; OR
- Used as first-line therapy in cisplatin-ineligible patients; AND
- Patient is carboplatin-ineligible; OR
- Patient has a PD-L1 expression of ≥5%

*If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy. Patients with comorbidities (e.g., hearing loss, neuropathy, poor performance status [PS], renal insufficiency, etc.) may not be eligible for cisplatin. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60mL/min or a PS of 2.

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

**Non-Small Cell Lung Cancer (NSCLC)**

- Must be used as a single agent; AND
    - Used as subsequent therapy in patients with recurrent (excluding locoregional recurrent without evidence of disseminated disease), advanced, or metastatic disease; AND
    - Disease must have progressed during or following cytotoxic (e.g., platinum-containing) therapy; AND
    - Patient has a performance status score of 0-2; AND
    - Patients with genomic tumor aberrations must have progressed following systemic therapy for those aberrations (i.e., EGFR, ALK) See chart below; OR

- Used in combination with carboplatin, paclitaxel, and bevacizumab; AND
    - Patient has nonsquamous recurrent (excluding locoregional recurrent without evidence of disseminated disease), advanced, or metastatic disease; AND
        - Used as first-line therapy for genomic tumor aberration (i.e., EGFR, ALK) negative or unknown** and PD-L1 expression-positive (≥50%) in patients with PS 0-2; OR
        - Used as first-line therapy for genomic tumor aberration (i.e., EGFR, ALK, ROS1, BRAF) negative or unknown** and PD-L1 < 50% or unknown in patients with PS0-1; OR
        - Used for BRAF V600E-mutation positive tumors in patients with PS 0-1; OR
        - Used as subsequent therapy for genomic tumor aberration (i.e., EGFR, ALK, ROS1 ) positive and prior targeted therapy in patients with PS 0-1; OR
        - Used as subsequent therapy for PD-L1 expression-positive (≥ 50%) and EGFR, ALK negative or unknown** with no prior platinum doublet therapy in patients with PS 0-1; OR

- Used as continuation maintenance therapy; AND
    - Patient has nonsquamous recurrent (excluding locoregional recurrent without evidence of disseminated disease), advanced, or metastatic disease ; AND
    - Patient is genomic tumor aberration (i.e., EGFR, ALK) negative or unknown**, and PDL1 expression-positive (≥50%); AND
    - Patient has a performance status of 0-2; AND
    - Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include 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.;
    - Patient achieved tumor response or stable disease following initial therapy in combination with carboplatin, paclitaxel, and bevacizumab; AND
    - Must be used as a single agent or in combination with bevacizumab.

**Every effort needs to be made to establish the genetic alteration status. A blood assay may be used if a tissue assay is not feasible.

**Small Cell Lung Cancer (SCLC)**

- Used in combination with etoposide and carboplatin; AND
- Used as initial treatment for extensive stage disease.

**Triple-negative Breast Cancer (TNBC):**

- Used in combination with paclitaxel protein-bound (Abraxane) for the treatment of adults with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC**) whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering greater than or equal to 1% of the tumor area), as determined by an FDA approved companion diagnostic test (e.g., VENTANA PD-L1 [SP142] Assay).

** TNBC = estrogen receptor (ER) negative, progesterone receptor (PR) negative, human epidermal growth factor receptor 2 (HER2) negative.

| Genomic Aberration Targeted Therapies (not all inclusive) |
|---|
| Sensitizing EGFR mutation-positive tumors<br>• Erlotinib<br>• Afatinib<br>• Gefitinib<br>• Osimertinib<br>• Dacomitinib |
| ALK rearrangement-positive tumors:<br>• Crizotinib<br>• Ceritinib<br>• Brigatinib<br>• Alectinib<br>• Lorlatinib |
| ROS1 rearrangement-positive tumors:<br>• Crizotinib<br>• Ceritinib |
| BRAF V600E-mutation positive tumors:<br>• Dabrafenib/Trametinib |
| PD-L1 expression-positive tumors (≥50%):<br>• Pembrolizumab<br>• Atezolizumab |

***Continuation of Therapy Criteria*:**

- Patient continues to meet initial criteria; AND
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; AND
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include 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.; OR
- Continuation Maintenance Therapy for NSCLC, must meet initial criteria.

**Coverage durations:**

- Initial & Renewal coverage = 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

**Dosage/Administration:**

| Indication | Dose (1 billable unit = 10mg) |
|---|---|
| All indications, except TNBC | 1200 mg intravenously every 21 days |
| TNBC | 840 mg IV infusion for the first infusion and if tolerated thereafter on days 1 and 15 every 28 days |

**Dosing Limits:**

Maximum Units (per dose and over time): 120 billable units every 21 days or for TNBC 84 units for initial dose, then 168 units every month.

**Investigational Use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:** Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

| HCPCS/CPT Code | Description |
|---|---|
| J9022 | Injection, atezolizumab, 10 mg |

References:

1. Tecentriq [package insert]. South San Francisco, CA; Genentech, Inc; April 2019.

2. Ventana Product Library, Roche Pharmaceuticals. VENTANA PD-L1 [SP142] Assay. http://www.ventana.com/ventana-pd-l1-sp142-assay-2/ and product label https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160006C.pdf . Accessed May 2018
3. U.S. Food and Drug Administrations (FDA). Division of Drug Information. Health Alert. http://s2027422842.t.en25.com/e/es?s=2027422842&e=88882&elqTrackId=B1F0B909CCF90C71B9C490C37BFE6647&elq=3f0714083e82421a8af346a664bedbfb&elqaid=3588&elqat=1. Accessed May 2018
4. Balar AV, Galsky MD, Rosenberg JE, et al. Atezolizumab as first-line therapy in cisplatinineligible patients with locally advanced and metastatic urothelial carcinoma: a single-arm, multicentre, phase 2 trial. Lancet. 2017 January 07; 389(10064): 67–76. doi:10.1016/S0140- 6736(16)32455-2.
5. Socinski MA, Jotte RM, Cappuzzo F, et. al. Atezolizumab for First-Line Treatment of Metastatic Nonsquamous NSCLC. N Engl J Med 2018; 378:2288-2301. DOI: 10.1056/NEJMoa1716948.
6. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) atezolizumab. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2019.

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