I. PURPOSE
To define and describe the accepted indications for Tecentriq (atezolizumab) usage in the treatment of cancer.

II. DEFINITIONS

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.

Tecentriq (atezolizumab) is FDA approved (1) for the treatment of patients 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. (2) It is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. (3) Triple-Negative Breast Cancer (TNBC): 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) SCLCL: in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer.

Tecentriq (atezolizumab) is available in 840 mg and 1200 mg (60 mg/mL) single use vials for injection.

III. POLICY
New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Tecentriq (atezolizumab) 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 or who are not eligible for ANY platinum containing chemotherapy regardless of PD-L1 expression OR
ii. As subsequent therapy post platinum 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 patients with performance status 0-2 for **ONE** of the following:
      i. As a single agent following:
         1. Progression on a first-line cytotoxic regimen OR
         2. Further progression on other systemic therapy OR
      ii. In combination with carboplatin, paclitaxel, and bevacizumab for members with performance status (PS) 0-1 and tumors of nonsquamous cell histology as the following:
         1. As initial therapy for EGFR, ALK, ROS1, BRAF negative or unknown, and PD-L1 <50% or unknown OR
         2. As subsequent therapy for EGFR, ALK, ROS1, BRAF positive and prior EGFR inhibitor OR
         3. As subsequent therapy for PD-L1 ≥ 50% and prior pembrolizumab therapy.
      iii. Continuation maintenance (if previously received first-line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen) for recurrent or metastatic disease in members with performance status 0-2, tumors of nonsquamous cell histology, who achieve tumor response or stable disease following initial cytotoxic therapy.

3. **Small Cell Lung Cancer (SCLC)**
   a. Tecentriq (atezolizumab) is being used as initial treatment in combination with etoposide and carboplatin for extensive stage disease.

4. **Breast Cancer**
   a. Tecentriq (atezolizumab) is being used in combination with albumin-bound paclitaxel for PD-L1 positive triple negative recurrent or stage IV (M1) disease.

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

1. Tecentriq (atezolizumab) is being used after disease progression with the same regimen.
2. Concurrent use with other chemotherapy or prior use of immune checkpoint blockade therapies, including anti-CTLA-4, anti-PD-1, and anti-PD-L1 therapeutic antibodies.
3. Concurrent active infections, autoimmune diseases, or central nervous system metastases requiring therapy.
4. Concurrent use with systemic immunosuppressive therapy or systemic steroid therapy.
5. Dosing exceeds single dose limit of Tecentriq (atezolizumab) 840 mg IV every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks.

6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Tecentriq (atezolizumab) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. Dosage and Administration: The preferred dosing is 1200 mg every 3 weeks where applicable in bladder, NSCLC, and SCLC.
   a. Bladder, NSCLC, and SCLC: 840 mg IV every 2 weeks, 1,200 mg every 3 weeks, or 1,680 mg every 4 weeks via infusion over 60 minutes until disease progression or unacceptable toxicity; if first infusion is tolerated, may infuse all subsequent doses over 30 minutes.
   b. Breast cancer: 840 mg IV infusion over 60 minutes for the first infusion and if tolerated over 30 minutes thereafter on days 1 and 15, followed by paclitaxel protein-bound 100 mg/m(2) on days 1, 8, and 15 of each 28-day cycle until disease progression or unacceptable toxicity.

2. Dosage Adjustments:
   a. Colitis or diarrhea, grade 2 or 3: Withhold dose and manage toxicity; may resume when recovery to grade 0 or 1. Permanently discontinue for grade 4 toxicity. Atezolizumab dose reductions are not recommended.
   b. Symptomatic hypophysitis, adrenal insufficiency, hypothyroidism, hyperthyroidism: Withhold dose and manage toxicity; may resume when recovery to grade 0 or 1. Permanently discontinue for grade 4 hypophysitis. Atezolizumab dose reductions are not recommended.
   c. Hyperglycemia, grade 3 or 4: Withhold dose and manage toxicity; may resume when recovery to grade 0 or 1. Atezolizumab dose reductions are not recommended.
   d. Infection, grade 3 or 4: Withhold dose and manage toxicity; may resume when recovery to grade 0 or 1. Atezolizumab dose reductions are not recommended.
   e. Infusion-related reaction (Grade 1 or 2): Interrupt or slow the rate of infusion
   f. Infusion-related reaction (Grade 3 or 4): Permanently discontinue use
   g. Hepatitis (AST or ALT greater than 3 and up to 8 times ULN or total bilirubin greater than 1.5 and up to 3 times ULN): Withhold dose until resolved or Grade 1 and corticosteroid dose is prednisONE 10 mg/day or less (or equivalent); permanently discontinue if not able to reduce prednisONE dose to 10 mg/day or less (or equivalent) within 12 weeks after last dose
   h. Hepatitis (AST or ALT greater than 8 times the ULN or total bilirubin greater than 3 times the ULN): Permanently discontinue therapy.
   i. Immune-related reactions involving a major organ (Grade 3): Withhold dose until Grade 1 or resolved and corticosteroid dose is prednisONE 10 mg/day or less (or equivalent); permanently discontinue if not recovered to Grade 0 or 1 or not able to reduce prednisONE
dose to 10 mg/day or less (or equivalent) within 12 weeks after last dose, or if Grade 3 event recurs
j. Immune-related reactions involving a major organ (Grade 4): Permanently discontinue.
k. Pneumonitis, grade 2: Withhold dose and manage toxicity; may resume when recovery to grade 0 or 1. Permanently discontinue for grade 3 or 4 toxicity. Atezolizumab dose reductions are not recommended.

3. Monitoring
   a. Tumor response may be indicative of efficacy.
   b. Changes in liver function, AST, ALT, and bilirubin, and symptoms of hepatitis; prior to and periodically during treatment.
   c. Changes in thyroid function; prior to and periodically during treatment.
   d. Signs and symptoms of hypophysitis.
   e. Signs and symptoms of acute pancreatitis.
   f. Signs and symptoms of diarrhea or colitis.
   g. Signs and symptoms of endocrinopathies.
   h. Signs and symptoms of infection.
   i. Signs and symptoms of meningitis or encephalitis.
   j. Signs (radiographic imaging) and symptoms of pneumonitis.
   k. Symptoms of motor or sensory neuropathy.

V. APPROVAL AUTHORITY
   1. Review – UM Department
   2. Final Approval – UM Committee

VI. ATTACHMENTS
   None

VII. REFERENCES