Wellmark Advantage Health Plan

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Effective Date: 1/1/2022

Tecentriq® (atezolizumab)

FDA approval: 5/18/2016
HCPCS: J9022
Benefit: Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage will be considered according to the following criteria
   a. Treatment must follow the FDA approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation
      i. Must be used with concomitant treatment according to FDA indication or NCCN category 1 or 2A recommendation
   b. Must be prescribed by, or in consultation with, an oncologist
   c. FDA approved age
   d. No prior use or failure with Tecentriq or another PD-L1 inhibitor
   e. Patient is not receiving therapy for a chronic condition, such as autoimmune disease, that requires treatment with a systemic immunosuppressant

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit align with FDA recommended dosing: 1200 mg every 21 days
   b. Initial Authorization Period: 6 months
   c. Renewal Criteria:
      i. Treatment may be continued until disease progression or until unacceptable toxicity occurs.
   d. Renewal Authorization Period: 1 year

C. Tecentriq is considered investigational when used for all other conditions, including but not limited to:
   a. Advanced renal cell carcinoma
   b. Unresectable or metastatic melanoma
   c. Classical hodgkins lymphoma
   d. Non FDA approved indications

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. FDA approved indication / Diagnosis

a. Treatment of patients with locally advanced or metastatic urothelial carcinoma who:
   i. Are not eligible for cisplatin containing chemotherapy and whose tumors express PD-L1 > 5% as determined by an FDA approved test
   OR
   ii. Are not eligible for any platinum containing chemotherapy regardless of PD-L1 status,
   OR
   iii. Have experienced disease progression during or following any platinum containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment
b. Treatment of patients who have metastatic non-small cell lung cancer 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
c. Treatment of patients who have metastatic non-squamour non-small cell lung cancer in combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment and have no EGFR or ALK genomic tumor aberrations
d. Treament of patients with metastatic non-squamous cell non-small cell lung cancer as first-line therapy in combination with paclitaxel protein-bound and carboplatin with no EGFR or ALK genomic tumor aberrations
e. Treatment of adult patients unresectable locally advanced or metastatic triple negative breast cancer in combination with paclitaxel protein-bound whose tumors express PD-L1 as determined by an FDA approved test.
f. For first-line treatment of adult patients with extensive-stage small cell lung cancer in combination with carboplatin and etoposide

**Please refer to most recent prescribing information.*
https://www.tecentriq.com/nsclc.html

B. Background Information

a. **Urothelial Carcinoma**
   i. In 2016, there were an estimated 76,960 new cases and 16,390 deaths from bladder cancer in the US. Bladder cancer is the sixth most common cancer in the US and is about three times more common in men than in women.
   ii. Urothelial (transitional cell) carcinomas are the most common histologic subtype in the US and may develop anywhere transitional epithelium is present, from the renal pelvis to the ureter, bladder, and proximal two-thirds of the urethra.
   iii. Greater than 90% of urothelial tumors originate in the bladder, 8% originate in the renal pelvis, and 2% originate in the ureter and urethra.
   iv. Systemic therapies for management of bladder cancer may include perioperative (neoadjuvant or adjuvant) chemotherapy, first- or second-line chemotherapy for metastatic disease, and radio sensitizing chemotherapy.
   v. The 5.2018 National Comprehensive Cancer Network (NCCN) guidelines list Tecentriq as first line therapy (category 2A) for patients whose tumors express PD-L1 or for patients who are not eligible

for platinum-containing chemotherapy regardless of PD-L1 expression for treatment of metastatic bladder cancer.

b. **Non-small cell lung cancer**
   i. The American Cancer Society estimates 234,030 new cases of lung cancer in the U.S. annually with approximately 199,000 of those cases representing NSCLC.
   ii. NSCLC is the second most common cause of cancer and is the leading cause of cancer death in the U.S.
   iii. The five year survival rate is less than 5% in patients with stage IV disease.

c. **Triple negative breast cancer**
   i. Triple-negative breast cancer is cancer that tests negative for estrogen receptors, progesterone receptors, and excess HER2 protein so they do not respond to hormonal therapy or medications that target HER2 protein receptors
   ii. About 10-20% of breast cancers are triple-negative breast cancers
   iii. Triple-negative breast cancer is considered to be more aggressive and have a poorer prognosis than other types of breast cancer, mainly because there are fewer targeted medicines that treat triple-negative breast cancer
   iv. Triple-negative breast cancer is more likely to be diagnosed in people younger than age 50, those of African-American or Hispanic decent, and those with a BRCA1 mutation

d. **Small cell lung cancer**
   i. Lung cancer is the second most common cancer and the leading cause of cancer death for men and women
   ii. It is estimated that 142,670 (76,650 men and 66,020 women) deaths from this disease will occur this year
   iii. About 13% of people diagnosed with lung cancer have small cell lung cancer
   iv. The general 5-year survival rate for people with small cell lung cancer is 6%

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

Black Box Warning: No

**Please refer to most recent prescribing information.*

E. Dosing and administration

a. Dosing: 1200 mg as an intravenous infusion over 60 minutes every 3 weeks

**Please refer to most recent prescribing information.*

F. How supplied

a. 1200 mg/20 mL single dose vial

References:

1. Tecentriq® injection for intravenous use [prescribing information]. South San Francisco, CA: Genentech, Inc (A member of the Roche Group); December 2018.
2. Rosenberg JE, Hoffman-Censits J, Powles T, et al. Atezolizumab in patients with locally advanced and metastatic urothelial carcinoma who have progressed following treatment with platinum-based chemotherapy: a single-arm, multicenter, phase 2 trial. *Lancet*. 2016; 387:1909-1920.
3. Highmark Therapeutic Drug Review: Antineoplastics: Biologic Response Modifiers. Locally advanced or metastatic urothelial cancer: atezolizumab (Tecentriq®). July 2016.
4. Express Scripts® Drug Evaluation - Tecentriq® (atezolizumab injection for intravenous use – Gentech [Roche]). Updated June 27, 2016.
5. National Comprehensive Cancer Network. NCCN Clinical practice guidelines in oncology. Bladder cancer Version 1.2016. http://www.nccn.org. Accessed on October 10, 2016.
6. F Barlesi, K Park, F Ciardiello, J von Pawel et al. Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicenter randomized controlled trial. Lancet January 2017: 21-27: pages 255–265.
7. Balar AV, Galsky MD, Rosenberg JE et al. Atezolizumab as first line treatment in cisplatin ineligible advanced and metastatic urothelial carcinoma: a single arm, multicenter, phase 2 trial. Lancet 2017; 389: 67 – 76.
8. ESI: Express Scripts Emerging Therapeutics Specialty Pipeline Report-Supplement List. November 2018.
9. National Comprehensive Cancer Network. NCCN Clinical practice guidelines in oncology. Non-Small Cell Lung Cancer Version 1.2019. https://www.nccn.org. Accessed on December 13, 2019.
10. Breastcancer.org. Triple negative breast cancer. Available at: https://www.breastcancer.org/symptoms/diagnosis/trip_neg. Accessed on December 17, 2019.
11. Cancer.net. Lung cancer – small cell statistics. July 2019. Available at : https://www.cancer.net/cancer-types/lung-cancer-small-cell/statistics. Accessed on December 17, 2019.

Policy History		
#	Date	Change Description
1.0	Effective Date: 1/1/2022	Effective date of policy.

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm*