Tecentriq™ (atezolizumab)
(Intravenous)

Document Number: IC-0278

Last Review Date: 06/03/2019
Date of Origin: 06/28/2016
Dates Reviewed: 06/2016, 08/2016, 10/2016, 02/2017, 04/2017, 08/2017, 11/2017, 02/2018, 05/2018, 06/2018, 09/2018, 12/2018, 03/2019, 04/2019, 06/2019

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Tecentriq 1,200 mg single use vial: 1 vial per 21 days
- Tecentriq 840 mg single-use vial: 1 vials per 14 days

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

All Indications:

- 84 billable units every 14 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- 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 PS, renal insufficiency, etc.) may not be eligible for cisplatin. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.*

Breast Cancer †

- Used in combination with albumin-bound paclitaxel; **AND**
- Patient has triple-negative disease (TNBC) that is unresectable locally advanced, recurrent or metastatic; **AND**
- Patient has a PD-L1 expression of ≥ 1% **§**

Non-Small Cell Lung Cancer (NSCLC) †

- Patient has recurrent (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease), advanced, or metastatic disease; **AND**
    - Used in combination with carboplatin, paclitaxel, and bevacizumab for non-squamous disease; **AND**
        - Used as first-line therapy for genomic tumor aberration (i.e., EGFR, ALK) negative or unknown****** and/or PD-L1 expression-positive (≥1%) 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 <1% or unknown in patients with PS 0-1; **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 (≥ 1%) and EGFR, ALK negative or unknown****** with no prior platinum doublet therapy in patients with PS 0-1; **OR**
    - Used as continuation maintenance therapy as a single agent or in combination with bevacizumab in patients with non-squamous disease and a PS ≤ 2; **AND**
        - Patient is genomic tumor aberration (i.e., EGFR, ALK) negative or unknown**, and PD-L1 expression-positive (≥1%); **AND**
        - Patient achieved tumor response or stable disease following initial therapy in combination with carboplatin, paclitaxel, and bevacizumab; **OR**

- Used as subsequent therapy as a single-agent in patients with a PS ≤ 2; **AND**
  - Disease progressed during or following cytotoxic therapy (e.g., platinum-containing) that did not include priorPD-1/PD-L1 inhibitor therapy

******** *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

Genomic Aberration Targeted Therapies (*not all inclusive*) §§
Sensitizing EGFR mutation-positive tumors – Erlotinib – Afatinib – Gefitinib – Osimertinib – Dacomitinib
ALK rearrangement-positive tumors – Crizotinib – Ceritinib – Brigatinib – Alectinib – Lorlatinib
ROS1 rearrangement-positive tumors – Crizotinib – Ceritinib
BRAF V600E-mutation positive tumors – Dabrafenib/Trametinib
NTRK Gene Fusion positive tumors – Larotrectinib
PD-L1 expression-positive tumors (≥1%) – Pembrolizumab – Atezolizumab

§*As confirmed using an FDA approved assay* - http://www.fda.gov/companiondiagnostics † FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria identified in section III; **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 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.

Continuation Maintenance Therapy for NSCLC

- *Refer to Section III for criteria*

V. Dosage/Administration

Indication	Dose
Breast Cancer - Triple-Negative (TNBC)	840 mg intravenously on days 1 and 15 of a 28-day cycle until disease progression or unacceptable toxicity
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
NSCLC/SCLC	**Single Agent** 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 **Combination Therapy** The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: – 1200 mg every 3 weeks; then revert to single-agent therapy dosing after completion of 4-6 cycles of combination therapy

VI. Billing Code/Availability Information

HCPCS:

- J9022 – Injection, atezolizumab, 10 mg; 10 mg = 1 billable unit

NDC:

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

VII. References

1. Tecentriq [package insert]. South San Francisco, CA; Genentech, Inc; May 2019. Accessed May 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 cisplatin-ineligible 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 May 2019.
7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 3.2019. 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 May 2019.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 4.2019. 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 May 2019.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast

ICD-10	ICD-10 Description
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C61	Malignant neoplasm of prostate
C65.1	Malignant neoplasm of right renal pelvis

ICD-10	ICD-10 Description
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
Z85.3	Personal history of malignant neoplasm of breast
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-

coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC