Tecentriq™ (atezolizumab)
(Intravenous)

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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

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

- 120 billable units every 21 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._

§_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); **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 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 (≥ 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 PD-L1 expression-positive (≥50%); **AND**
- Patient has a performance status of 0-2; **AND**
- 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

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
PD-L1 expression-positive tumors (≥50%) – Pembrolizumab – Atezolizumab

† 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**
- Tumor response with 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
All indications	1200 mg intravenously every 21 days

VI. Billing Code/Availability Information

Jcode:

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

NDC:

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

VII. References

1. Tecentriq [package insert]. South San Francisco, CA; Genentech, Inc; December 2018. Accessed January 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 January 2019.

7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 1.2019. 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 January 2019.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 2.2019. 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 January 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
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

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
C65.1	Malignant neoplasm of right renal pelvis
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
Z85.51	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