

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., cemiplimab, nivolumab, pembrolizumab, durvalumab, avelumab, 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
 - Disease recurrence post-cystectomy
 - Primary Carcinoma of the Urethra; **AND**
 - Used for recurrent or metastatic disease and the patient does not have recurrent stage T3-4 disease or palpable inguinal lymph nodes; **OR**
 - Used as primary treatment as a single agent for clinical stage T3-4, cN1-2 disease or cN1-2 palpable inguinal lymph nodes
 - Metastatic Upper GU Tract Tumors

- Metastatic Urothelial Carcinoma of the Prostate; **AND**
- Used as first-line therapy in cisplatin-ineligible patients; **AND**
 - Patient is carboplatin-ineligible; **OR**
 - Patient has a PD-L1 expression of $\geq 5\%$; **OR**
- Used as subsequent therapy after previous platinum treatment*

**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.*

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 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 (e.g., EGFR, ALK, etc.); **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**
 - Patient has a performance status of 0-1; **AND**
 - Used as first-line therapy for genomic tumor aberration (e.g., EGFR, ALK, ROS1, BRAF) negative or unknown** and PD-L1 <50% or unknown OR BRAF V600E-mutation positive OR PD-L1 $\geq 50\%$ and EGFR, ALK negative or unknown; **OR**
 - Used as subsequent therapy for genomic tumor aberration (e.g., EGFR, ALK, ROS1) positive and prior targeted therapy OR BRAF V600E-mutation positive OR PD-L1 $\geq 50\%$ and EGFR, ALK negative or unknown** with no prior platinum doublets; **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 has genomic tumor aberration (e.g., EGFR, ALK, etc) negative or unknown**, and PD-L1 expression $\geq 50\%$; **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**
- May be used as a single agent or in combination with bevacizumab

Small Cell Lung Cancer (SCLC) †

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

****** 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.

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

Genomic Aberration Targeted Therapies (not all inclusive) §§
Sensitizing EGFR mutation-positive tumors <ul style="list-style-type: none"> - Erlotinib - Afatinib - Gefitinib - Osimertinib - Dacomitinib
ALK rearrangement-positive tumors <ul style="list-style-type: none"> - Crizotinib - Ceritinib - Brigatinib - Alectinib
ROS1 rearrangement-positive tumors <ul style="list-style-type: none"> - Crizotinib - Ceritinib
BRAF V600E-mutation positive tumors <ul style="list-style-type: none"> - Dabrafenib/Trametinib
PD-L1 expression-positive tumors (≥50%) <ul style="list-style-type: none"> - 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.

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; July 2018. Accessed November 2018.
2. Ventana Product Library, Roche Pharmaceuticals. VENTANA PD-L1 [SP142] Assay. <http://www.ventana.com/ventana-pd-l1-sp142-assay-2/> and produc 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, 2018. 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 November 2018.
7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 5.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are

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8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 5.2018. National Comprehensive Cancer Network, 2018. 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 November 2018.

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
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

ICD-10	ICD-10 Description
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

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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