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) [NDC Unit]:

- 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) [HCPCS Unit]:

- Hepatocellular Adenocarcinoma: 120 billable units every 21 days
- All other indications: 84 billable units every 14 days

III. Initial Approval Criteria[1]

Coverage is provided in the following conditions:

- Patient must be at least 18 years old; **AND**

Universal Criteria

- 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 † [1,4,6,7,10]

- Used as a single agent; **AND**
- Patient has one of the following diagnoses:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Local bladder cancer recurrence or persistent disease in a preserved bladder; **OR**
  - Local or metastatic bladder cancer recurrence post-cystectomy; **OR**
  - Recurrent or metastatic primary carcinoma of the urethra; **AND**

- Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes; **OR**
- Patient has recurrent or metastatic clinical stage T3-4, cN1-2 disease or cN1-2 palpable inguinal lymph nodes (primary treatment only); **OR**

  - Metastatic upper genitourinary (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% as determined by an FDA-approved or CLIA-compliant test §

Note:

– *If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).*

- *Cisplatin-ineligible comorbidities may include the following: GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.*
- *Carboplatin-ineligible comorbidities may include the following: CrCl < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3, etc.*

Breast Cancer † [1,6,13]

- Used in combination with albumin-bound paclitaxel; **AND**
- Patient has unresectable locally advanced, recurrent, or metastatic triple-negative disease (TNBC); **AND**
- Patient has a PD-L1 expression (PD-L1 stained tumor-infiltrating immune cells [IC] of any intensity covering ≥ 1% of the tumor area) as determined by an FDA-approved or CLIA-compliant test §

Non-Small Cell Lung Cancer (NSCLC) † § [1,5,6,8,11,12,17]

- Patient has metastatic disease; **AND**
  - Used as single-agent treatment; **AND**
  - Used as first-line therapy who are EGFR and ALK genomic tumor aberration negative; **AND**
  - Patient tumors have high PD-L1 expression (*PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]*), as determined by an FDA-approved test or CLIA-compliant test; **OR**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**

- Used for non-squamous disease in combination with carboplatin, paclitaxel, and bevacizumab OR in combination with carboplatin and nab-paclitaxel in patients with PS 0-1; **AND**
  - Used as first-line therapy for EGFR, ALK, ROS1, BRAF, MET exon 14 skipping mutation, and RET rearrangement negative tumors and PD-L1 <1%; **OR**
  - Used as first-line or subsequent therapy for BRAF V600E-mutation, NTRK gene fusion, MET exon-14 skipping mutation, or RET rearrangement positive tumors; **OR**
  - Used as subsequent therapy for EGFR, ALK, or ROS1 tumors positive and prior targeted therapy§§; **OR**
- Used as continuation maintenance therapy in patients with non-squamous disease and a PS ≤ 2; **AND**
  - Used in combination with bevacizumab in patients with a tumor response or stable disease following first-line therapy with atezolizumab, carboplatin, paclitaxel, and bevacizumab regimen; **OR**
  - Used as a single agent in patients with a tumor response or stable disease following first-line therapy with atezolizumab, carboplatin, and albumin-bound paclitaxel regimen; **OR**
- Used as subsequent therapy as a single-agent in patients with a PS ≤ 2

Small Cell Lung Cancer (SCLC) † Φ [1,6,14,18]

- Patient has extensive stage disease (ES-SCLC) (excluding patients with poor PS 3-4 not due to SCLC); **AND**
  - Used as first-line therapy in combination with etoposide and carboplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with etoposide and carboplatin; **AND**
- Must not be used for relapsed disease in patients on maintenance therapy with atezolizumab or durvalumab at the time relapse (**NOTE:** If relapse occurred >6 months after atezolizumab or durvalumab maintenance therapy, patient should be re-treated with carboplatin + etoposide alone or cisplatin + etoposide alone)

Hepatocellular Adenocarcinoma ‡ [6,15,16]

- Used as first-line therapy in combination with bevacizumab; **AND**
- Patient is Child-Pugh Class A; **AND**
  - Patient has unresectable disease and is not a transplant candidate; **OR**
  - Patient is inoperable due to performance status or comorbidity; **OR**
  - Patient has local disease or local disease with minimal extrahepatic disease only; **OR**
  - Patient has metastatic disease or extensive liver tumor burden

§*If confirmed using an FDA approved assay - http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §
Sensitizing *EGFR* mutation-positive tumors – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib
ALK rearrangement-positive tumors – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib
ROS1 rearrangement-positive tumors – Ceritinib – Crizotinib – Entrectinib
BRAF V600E-mutation positive tumors – Dabrafenib ± Trametinib – Vemurafenib
NTRK Gene Fusion positive tumors – Larotrectinib – Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%) – Pembrolizumab – Atezolizumab – Nivolumab ± ipilimumab
MET Exon-14 skipping mutations – Capmatinib – Crizotinib
RET rearrangement-positive tumors – Selpercatinib – Cabozantinib – Vandetanib

IV. Renewal Criteria[1,4-8,10-16]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. 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, etc.), severe infection, etc.

Continuation Maintenance Therapy for NSCLC or SCLC

- *Refer to Section III for criteria*

V. Dosage/Administration[1,16]

Indication	Dose
Triple Negative Breast Cancer (TNBC)	Administer 840 mg intravenously on days 1 and 15 of a 28-day cycle until disease progression or unacceptable toxicity
Urothelial Carcinoma (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
Non-Small Cell Lung Cancer (NSCLC)	**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
Small-Cell Lung Cancer (SCLC)	**Combination Therapy with carboplatin and etoposide** 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 cycles of carboplatin and etoposide **Single Agent Maintenance Therapy** 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
Hepatocellular Adenocarcinoma	**Combination Therapy with bevacizumab** The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: – 1200 mg every 3 weeks

VI. Billing Code/Availability Information

HCPCS code:

- 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

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.0	Liver cell carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA):

Jurisdiction(s): 15	**NCD/LCD/Article Document (s):** A56830
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56830&bc=gAAAAAAAAAAAAA	

Jurisdiction(s): J&M	**NCD/LCD/Article Document (s):** A56141
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56141&bc=gAAAAAAAAAAA	

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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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