

Tecentriq[®] (atezolizumab) (Intravenous)

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I. Length of Authorization

Coverage will be provided for six (6) months and may be renewed (unless otherwise specified).

- Adjuvant therapy in NSCLC can be authorized up to a maximum of twelve (12) months of therapy.

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 vial per 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 168 billable units every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **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, dostarlimab, etc.) unless otherwise specified; **AND**

Urothelial Carcinoma (Bladder Cancer) † ‡ ^{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**

- Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder ‡; **OR**
- Metastatic or local bladder cancer recurrence post-cystectomy ‡; **OR**
- Primary carcinoma of the urethra ‡; **AND**
 - Used for recurrent (*excluding recurrence of stage T3-4 disease or palpable inguinal lymph nodes*) or metastatic disease; **OR**
 - Used for stage T3-4, cN1-2 disease or cN1-2 palpable inguinal lymph nodes; **OR**
- Metastatic upper genitourinary (GU) tract tumors ‡; **OR**
- 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 $\geq 5\%$ (*PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 5\%$ of the tumor area*) as determined by an FDA-approved or CLIA-compliant test❖

*** Note:**^{7,9,23}

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

Non-Small Cell Lung Cancer (NSCLC) † ‡ § ^{1,5,6,8,11,12,17,24}

- 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 as first-line therapy; **AND**
 - Used for tumors that are negative for actionable molecular markers* and PD-L1 $\geq 50\%$ (*PD-L1 stained $\geq 50\%$ of tumor cells [TC $\geq 50\%$] or PD-L1 stained tumor-infiltrating immune cells [IC] covering $\geq 10\%$ of the tumor area [IC $\geq 10\%$]), as determined by an FDA-approved test or CLIA-compliant test❖; **AND**
 - Used as a single agent; **OR***
 - Used for non-squamous disease in one of the following:
 - Patients with PS 0-1 who have tumors that are negative for actionable molecular markers* and PD-L1 $< 1\%$
 - Patients with tumors that are negative for actionable molecular markers* and PD-L1 $\geq 1\%$
 - Patients with PS 0-1 who are positive for one of the following molecular markers: BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon-14 skipping mutation; **AND**

- Used in combination with carboplatin, paclitaxel, and bevacizumab; **OR**
- Used in combination with carboplatin and albumin-bound paclitaxel; **OR**
- Used as subsequent therapy; **AND**
 - Used as a single agent; **OR**
 - Used for non-squamous disease in one of the following:
 - Patients with PS 0-1 who are positive for one of the following molecular markers: BRAF V600E-mutation, NTRK1/2/3 gene fusion, or MET exon-14 skipping mutation
 - Patients with PS 0-1 who have ROS1 positive tumors and have received prior targeted therapy; **AND**
 - Used in combination with carboplatin, paclitaxel, and bevacizumab; **OR**
 - Used in combination with carboplatin and albumin-bound paclitaxel; **OR**
- Used as continuation maintenance therapy in patients who have achieved a tumor response or stable disease following initial therapy; **AND**
 - Used in combination with bevacizumab following a first-line regimen with atezolizumab, carboplatin, paclitaxel, and bevacizumab for non-squamous histology; **OR**
 - Used as a single agent following a first-line regimen with atezolizumab, carboplatin, and albumin-bound paclitaxel for non-squamous histology; **OR**
 - Used as a single agent following a first-line regimen with single agent atezolizumab; **OR**
- Patient has stage II to IIIA disease; **AND**
 - Used as a single agent; **AND**
 - Used as adjuvant treatment following resection and platinum-based chemotherapy; **AND**
 - Tumor expresses PD-L1 $\geq 1\%$ as determined by an FDA-approved test or CLIA-compliant test❖

** Note: Actionable molecular genomic biomarkers include EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient issue to allow testing for all of EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Small Cell Lung Cancer (SCLC) † ‡ Ⓢ 1,6,14,18

- Patient has extensive stage disease (ES-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

Hepatocellular Carcinoma (HCC) † ‡ Ⓢ 1,6,15,16,22

- Used as first-line therapy in combination with bevacizumab; **AND**
- Patient has Child-Pugh Class A disease; **AND**
- Patient has unresectable or metastatic disease, inoperable (*e.g., performance status, comorbidity or with minimal or uncertain extrahepatic-disease*) liver-confined disease, or extensive liver tumor burden

Cutaneous Melanoma † ⊕ 1,6,19,21

- Patient has BRAF V600 mutation-positive disease; **AND**
- Patient has unresectable or metastatic disease*; **AND**
- Used as first-line therapy in combination with cobimetinib and vemurafenib

* *Metastatic disease includes stage III clinical satellite/in transit metastases or local satellite/in-transit recurrence in patients with limited resectable and unresectable disease, unresectable nodal recurrence, and disseminated (unresectable) distant metastatic disease*

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

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

Genomic Aberration/Mutational Driver Targeted Therapies (Note: not all inclusive, refer to guidelines for appropriate use) §				
Sensitizing <i>EGFR</i> mutation-positive tumors	<i>ALK</i> rearrangement-positive tumors	<i>ROS1</i> rearrangement-positive tumors	<i>BRAF</i> V600E-mutation positive tumors	<i>NTRK</i> Gene Fusion positive tumors
<ul style="list-style-type: none"> – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab (<i>exon-20 insertion</i>) 	<ul style="list-style-type: none"> – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib 	<ul style="list-style-type: none"> – Ceritinib – Crizotinib – Entrectinib 	<ul style="list-style-type: none"> – Dabrafenib ± Trametinib – Vemurafenib 	<ul style="list-style-type: none"> – Larotrectinib – Entrectinib
PD-1/PD-L1 expression-positive tumors (≥1%)	<i>MET</i> Exon-14 skipping mutations	<i>RET</i> rearrangement-positive tumors	<i>KRAS</i> G12C mutations	
<ul style="list-style-type: none"> – Pembrolizumab – Atezolizumab – Nivolumab ± ipilimumab 	<ul style="list-style-type: none"> – Capmatinib – Crizotinib – Tepotinib 	<ul style="list-style-type: none"> – Selpercatinib – Cabozantinib – Vandetanib – Pralsetinib 	<ul style="list-style-type: none"> – Sotorasib 	

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: immune-mediated adverse reactions (*e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis, etc.*), severe infusion-related reactions, etc.

Continuation Maintenance Therapy for NSCLC or SCLC

- Refer to Section III for criteria

NSCLC (adjuvant treatment)

- Patient has not exceeded a maximum of twelve (12) months of therapy

V. Dosage/Administration ^{1,16}

Indication	Dose
NSCLC, SCLC, HCC, UC	The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: <ul style="list-style-type: none">– 840 mg every 2 weeks or– 1200 mg every 3 weeks or– 1680 mg every 4 weeks <i>*NSCLC adjuvant treatment may continue up to a maximum of 12 months in patients without recurrent disease or unacceptable toxicity.</i>
Cutaneous Melanoma	The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: <ul style="list-style-type: none">– 840 mg every 2 weeks or– 1200 mg every 3 weeks or– 1680 mg every 4 weeks <i>*Prior to initiating Tecentriq, patients should receive a 28 day treatment cycle of cobimetinib 60 mg orally once daily (21 days on and 7 days off) and vemurafenib 960 mg orally twice daily from Days 1-21 and vemurafenib 720 mg orally twice daily from Days 22-28.</i>

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

ICD-10	ICD-10 Description
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
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

ICD-10	ICD-10 Description
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), 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: <https://www.cms.gov/medicare-coverage-database/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): 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