Tecentriq® (atezolizumab)
(Intravenous)

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I. Length of Authorization Δ 1

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

- Adjuvant therapy in Non-Small Cell Lung Cancer (NSCLC) can be renewed up to a maximum of 12 months of therapy.*

Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.		
Dosing Frequency	**Maximum length of therapy**	**Maximum number of doses**
2 weeks	1 year	26 doses
3 weeks	1 year	18 doses
4 weeks	1 year	13 doses

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]:

- MPeM: 120 billable units every 21 days
- All other indications:
  - 168 billable units every 28 days
  - 120 billable units every 21 days
  - 84 billable units every 14 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **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, nivolumab/relatlimab-rmbw, retifanlimab, etc.) unless otherwise specified [Δ]; **AND**

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,5,6,8,11,12,17,23,9e-11e,14e]

- Used for 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 ≥50% (*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❖; **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 PD-L1 expression positive tumors (PD-L1 ≥ 1%) that are negative for actionable molecular biomarkers*
      - Patients with PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); **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 biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, or RET rearrangement

- Patients with PS 0-1 who are positive for one of the following molecular biomarkers and received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **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 regimen for non-squamous histology; **OR**
  - Used as a single agent following a first-line regimen with atezolizumab, carboplatin, and albumin-bound paclitaxel regimen for non-squamous histology; **OR**
  - Used as a single agent following a first-line regimen with single agent atezolizumab; **OR**

- Used as adjuvant therapy as a single agent; **AND**
  - Tumor expresses PD-L1 ≥1% as determined by an FDA-approved test or CLIA-compliant test❖; **AND**
  - Used following resection and previous adjuvant platinum-based chemotherapy; **AND**
  - Patient has stage II to IIIA disease †

> ** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). If there is insufficient issue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2) 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) † ‡ Φ [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 atezolizumab, etoposide, and carboplatin

Hepatocellular Carcinoma (HCC) † ‡ Φ [1,6,15,16,21]

- Used as first-line therapy in combination with bevacizumab; **AND**
- Patient has Child-Pugh Class A hepatic impairment; **AND**
- Patient has one of the following:
  - Unresectable or metastatic disease
  - Liver confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease
  - Extensive liver tumor burden

Malignant Peritoneal Mesothelioma (MPeM) ‡ [6,24,27,22e]

- Used as subsequent therapy in combination with bevacizumab

Cutaneous Melanoma † ‡ Φ [1,6,19,20]

- Patient has BRAF V600 mutation positive disease as detected by an FDA approved or CLIA compliant test❖; **AND**
- Used in combination with cobimetinib and vemurafenib; **AND**
- Patient has unresectable or metastatic disease; **AND**
- Used as first-line therapy

Alveolar Soft Part Sarcoma (ASPS) † ‡ Φ [1,6,26]

- Patient is at least 2 years of age; **AND**
- Used as a single agent; **AND**
- Patient has unresectable or metastatic disease that is not curable by surgery

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

❖*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	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK1/2/3* gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	– Dabrafenib ± trametinib – Vemurafenib – Encorafenib + binimetinib	– Larotrectinib – Entrectinib
PD-L1 tumor expression ≥ 1%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors	*ERBB2 (HER2)* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib – Adagrasib	– Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine

IV. Renewal Criteria [Δ 1,6]

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 [including Stevens-Johnson syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN)], myocarditis, pericarditis, vasculitis, solid organ transplant rejection, etc.), severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), 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

Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration) are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ [1,14,27]

Indication	Dose
NSCLC, SCLC, HCC	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 adjuvant treatment may continue up to a maximum of 12 months in patients without recurrent disease or unacceptable toxicity.*
Cutaneous Melanoma	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 **Prior to initiating atezolizumab, 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.*
MPeM	1200 mg every 3 weeks administered intravenously until disease progression or unacceptable toxicity
ASPS	The recommended dosage is administered intravenously until disease progression or unacceptable toxicity: <u>Adult patients:</u> – 840 mg every 2 weeks or – 1200 mg every 3 weeks or – 1680 mg every 4 weeks <u>Pediatric patients at least 2 years of age:</u> – 15 mg/kg (up to a maximum 1200 mg) every 3 weeks

VI. Billing Code/Availability Information

<u>HCPCS Code:</u>

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

<u>NDC(s):</u>

- 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

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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

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
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower 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

ICD-10	ICD-10 Description
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
C45.1	Mesothelioma of peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C7A.1	Malignant poorly differentiated neuroendocrine tumors
D19.1	Benign neoplasm of mesothelial tissue of peritoneum
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.820	Personal history of malignant melanoma of skin
Z85.831	Personal history of malignant neoplasm of soft tissue

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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