Tecentriq® (atezolizumab)
(Intravenous)

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I. Length of Authorization Δ [1,23,28]

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.*****
- Adjuvant therapy in Hepatocellular Carcinoma (HCC) 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

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

- Peritoneal Mesothelioma (*including pericardial and tunica vaginalis testis mesothelioma*): 120 billable units every 21 days
- All other indications: 504 billable units every 84 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, retifanlimab, toripalimab, tislelizumab etc.) unless otherwise specified [Δ]; **AND**

- Therapy will not be used concomitantly with subcutaneous atezolizumab *(Note: Not applicable when used as switch-therapy with subcutaneous atezolizumab)*; **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 as a single agent; **AND**
      - Patients with performance status (PS) 0-2 who have tumors that are negative for actionable molecular markers***** (may be KRAS G12C mutation positive) 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❖; **OR**
      - Patients with PS 3 **Ω** who have tumors that are negative for actionable molecular biomarkers***** (may be KRAS G12C mutation positive) regardless of PD-L1 status; **OR**
      - Patients with PS 3 **Ω** who have tumors positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, ERBB2 (HER2); **OR**
    - Used in combination with one of the following:
      - Carboplatin, paclitaxel, and bevacizumab
      - Carboplatin and albumin-bound paclitaxel; **AND**
      - Used for non-squamous disease; **AND**
      - Used for one of the following:
        - Patients with PS 0-1 who have tumors that are negative for actionable molecular markers***** (may be KRAS G12C mutation positive) and PD-L1 <1%
        - Patients with PS 0-2 who have tumors that are negative for actionable molecular biomarkers***** (may be KRAS G12C mutation positive) and PD-L1 expression positive tumors (PD-L1 ≥ 1%)
        - Patients with PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement, or ERBB2 (HER2); **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent; **AND**
      - Patients with PS 0-2; **OR**

- Patients with PS 3 **Ω** who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, RET rearrangement; **OR**
- Patients with PS 3 **Ω** who are positive for one of the following molecular biomarkers and received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R, EGFR S768I, L861Q and/or G719X, ALK rearrangement, or ROS1 rearrangement; **OR**

- Used in combination with one of the following:
  - Carboplatin, paclitaxel, and bevacizumab
  - Carboplatin and albumin-bound paclitaxel; **AND**
- Used for non-squamous disease; **AND**
- Used for 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; **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**

- 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 **†; OR**
    - Patient has stage IIIB (T3, N2) disease **Ω ‡**; **AND**
      - Disease is negative for EGFR exon 19 deletion or exon 21 L858R mutations, or ALK rearrangements

***Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. 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 [1,6,15,16,21,28,30e]

- Used in combination with bevacizumab; **AND**
  - Used as first-line therapy for unresectable or metastatic disease **†**; **OR**
  - Used as adjuvant therapy following resection or ablation; **AND**
    - Patient is at high risk of recurrence (defined as size > 5 cm, > 3 tumors, macrovascular invasion or microvessel invasion on histology or grade 3/4 histology)

Peritoneal Mesothelioma (PeM) ‡** [6,24,27,22e]

- Used as subsequent therapy in combination with bevacizumab; **AND**
- Patient previously received treatment with platinum and pemetrexed, unless contraindicated

*** Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma **Ω**.*

Cutaneous Melanoma † ‡ Φ [1,6,19,20,29]

- 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; **OR**
  - Used as subsequent therapy for disease progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition not previously used **Ω**; **OR**
  - Used as re-induction therapy in patients who experienced disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) from prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation **Ω**

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

Cervical Cancer ‡ Ω [6,14]

- Patient has small cell neuroendocrine carcinoma of the cervix (NECC); **AND**

- Used as first-line or subsequent therapy (if not used previously as first-line therapy) for persistent, recurrent, or metastatic disease; **AND**
  - Used in combination with etoposide AND either cisplatin or carboplatin; **OR**
- Used as single-agent maintenance therapy after initial therapy with atezolizumab, etoposide, AND either carboplatin or cisplatin

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*

Ω Please *note that the supporting data for this indication has been assessed and deemed to be of insufficient quality based on the review conducted for the Enhanced Oncology Value (EOV) program. However, due to the absence of viable alternative treatment options, this indication will be retained in our policy and evaluated on a case-by-case basis.*

† 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*)			
EGFR exon 19 deletion or exon 21 L858R tumors	*EGFR* S768I, L861Q, and/or G719X mutation positive tumors	*EGFR* exon 20 insertion mutation positive tumors	*NTRK1/2/3* gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab	– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab	– Amivantamab	– Larotrectinib – Entrectinib – Repotrectinib
ALK rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*ERBB2 (HER2)* mutation positive tumors
– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib – Repotrectinib	– Dabrafenib ± trametinib – Encorafenib + binimetinib – Vemurafenib	– Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine
PD-L1 tumor expression ≥ 1%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib – Adagrasib

IV. Renewal Criteria Δ [1,6]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I);* **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.

Cutaneous Melanoma (re-induction therapy)

- *Refer to Section III for criteria*

Continuation Maintenance Therapy for NSCLC or SCLC

- *Refer to Section III for criteria*

Continuation Maintenance Therapy for Cervical Cancer

- *Refer to Section III for criteria*

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 [1,14,27,28]

Indication	Dose

NSCLC, SCLC, Cervical Cancer	Administer 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.*
HCC	First-line therapy: – 840 mg every 2 weeks or – 1200 mg every 3 weeks or – 1680 mg every 4 weeks Administer intravenously until disease progression or unacceptable toxicity: Adjuvant therapy: – 1200 mg every 3 weeks Administer intravenously for 12 months or until disease progression or unacceptable toxicity.
Cutaneous Melanoma	Administer 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.*
Mesotheliomas *(peritoneal, pericardial, and tunica vaginalis testis)*	Administer 1200 mg every 3 weeks intravenously until disease progression or unacceptable toxicity
ASPS	Administer intravenously until disease progression or unacceptable toxicity: Adult patients: – 840 mg every 2 weeks or – 1200 mg every 3 weeks or – 1680 mg every 4 weeks Pediatric patients at least 2 years of age: – 15 mg/kg (up to a maximum 1200 mg) every 3 weeks

Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following: [30-34]

- 840 mg (15 mg/kg) in patients receiving therapy every 21 days who weigh ≤ 61 kg
- 1200 mg (20 mg/kg) in patient receiving therapy every 28 days who weigh ≤ 66 kg

Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- 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 (STANDARD)

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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
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

ICD-10	ICD-10 Description
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
C45.1	Mesothelioma of peritoneum
C45.2	Mesothelioma of pericardium
C45.7	Mesothelioma of other sites
C45.9	Mesothelioma, unspecified
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
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, 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

ICD-10	ICD-10 Description
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		
Jurisdictio	**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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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