

Tecentriq® (atezolizumab) (Intravenous)

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I. Length of Authorization $\Delta^{,1}$

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

• Adjuvant therapy in NSCLC can be authorized up to a maximum of 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]:

- MPeM and Cervical Cancer: 120 billable units every 21 days
- All other indications: 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 (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, etc.) unless otherwise specified Δ; AND

Non-Small Cell Lung Cancer (NSCLC) † ± 1,5,6,8,11,12,17,23



- 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
 - o 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 mutations: 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 mutations: 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 mutations 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 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 CLIAcompliant test*; AND
 - o Used following resection and previous adjuvant chemotherapy; AND
 - Patient has stage II to IIIA disease †; OR
 - Patient has stage IIIB (T3, N2) disease ‡; 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 exon 14 skipping mutation, RET rearrangement, 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
 - o 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
 - o Patient has unresectable or metastatic disease; **OR**
 - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease; OR
 - o Patient has extensive liver tumor burden

Malignant Peritoneal** Mesothelioma (MPeM) ‡ 6,24

- Used as subsequent therapy in combination with bevacizumab
- ** Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.

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



- o 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; 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

Alveolar Soft Part Sarcoma (ASPS) † Φ 1,26

- 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 ‡ 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
- ♦ 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) Mobocertinib (exon-20 insertion) 	 Alectinib Brigatinib Ceritinib Crizotinib Lorlatinib 	CeritinibCrizotinibEntrectinibLorlatinib	Dabrafenib ± trametinibVemurafenib	LarotrectinibEntrectinib
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 	CapmatinibCrizotinibTepotinib	SelpercatinibCabozantinibPralsetinib	SotorasibAdagrasib	 Fam-trastuzumab deruxtecan-nxki Ado-trastuzumab emtansine



IV. Renewal Criteria ^{\(\Delta \)} 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, 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

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 (i.e., receipt of 24 months of therapy) 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 beyond the 24-month limit 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 PDdirected therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ 1,14,25

Indication Dose



NSCLC, SCLC, HCC	The recommended dosage is administered intravenously until disease progression or unacceptable toxicity:
Solo, nec	- 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:
Ivielanoma	 840 mg every 2 weeks or 1200 mg every 3 weeks or 1680 mg every 4 weeks *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.
MPeM, Cervical Cancer	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: 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

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

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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



ICD-10	ICD-10 Description
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
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



ICD-10	ICD-10 Description	
C45.9	Mesothelioma, 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	
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	
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	

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	



Medicare Part B Administrative Contractor (MAC) Jurisdictions			
Jurisdiction	Applicable State/US Territory	Contractor	
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	КҮ, ОН	CGS Administrators, LLC	



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customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

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PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- · Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist PreferredOne Insurance Company PO Box 59212 Minneapolis, MN 55459-0212 Phone: 1.800.940.5049 (TTY: 763.847.4013) Fax: 763.847.4010 customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

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