

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: 2 vials per 28 days

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

- Peritoneal Mesothelioma: 120 billable units every 21 days
- All other indications: 504 billable units every 84 days

III. Initial Approval Criteria¹

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 ^A; **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 $\geq 50\%$ (*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**
 - Use of atezolizumab will be restricted to patients with a contraindication or intolerance to single-agent cemiplimab; **OR**
 - Used in combination with one of the following:
 - Carboplatin, paclitaxel, and bevacizumab
 - Carboplatin and albumin-bound paclitaxel; **AND**
- Use of atezolizumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **AND**
- Used for non-squamous disease; **AND**
 - Patients with PS 0-1 who have tumors that are negative for actionable molecular markers* (may be KRAS G12C mutation positive) and PD-L1 $< 1\%$; **OR**
 - 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 $\geq 1\%$); **OR**
 - 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**
 - Used in combination with one of the following:

- Carboplatin, paclitaxel, and bevacizumab
- Carboplatin and albumin-bound paclitaxel; **AND**

➤ Use of atezolizumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **AND**

- Used for non-squamous disease; **AND**
 - 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; **OR**
 - 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 $\geq 1\%$ 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). 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) † ‡ Ⓢ 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 †; **AND**
 - Patient has Child-Pugh Class A hepatic impairment; **AND**

Patient has Barcelona Clinic Liver Cancer (BCLC) stage B that is ineligible for locoregional therapy OR BCLC stage C:

 - Use of atezolizumab will be restricted to patients with a contraindication or intolerance to durvalumab in combination with tremelimumab-actl; **OR**
 - Used as adjuvant therapy following resection or ablation; **AND**
 - Patient has Child-Pugh Class A hepatic impairment; **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

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

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)**

<i>EGFR</i> exon 19 deletion or exon 21 L858R tumors	<i>EGFR</i> S768I, L861Q, and/or G719X mutation positive tumors	<i>EGFR</i> exon 20 insertion mutation positive tumors	<i>NTRK1/2/3</i> gene fusion positive tumors
<ul style="list-style-type: none"> – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab 	<ul style="list-style-type: none"> – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab 	<ul style="list-style-type: none"> – Amivantamab 	<ul style="list-style-type: none"> – Larotrectinib – Entrectinib
ALK rearrangement-positive tumors	<i>ROS1</i> rearrangement-positive tumors	<i>BRAF</i> V600E-mutation positive tumors	<i>ERBB2 (HER2)</i> mutation positive tumors
<ul style="list-style-type: none"> – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib 	<ul style="list-style-type: none"> – Ceritinib – Crizotinib – Entrectinib – Lorlatinib – Repotrectinib 	<ul style="list-style-type: none"> – Dabrafenib ± trametinib – Encorafenib + binimetinib – Vemurafenib 	<ul style="list-style-type: none"> – Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine
PD-L1 tumor expression ≥ 1%	<i>MET</i> exon-14 skipping mutations	<i>RET</i> rearrangement-positive tumors	<i>KRAS G12C</i> mutation positive tumors
<ul style="list-style-type: none"> – Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab 	<ul style="list-style-type: none"> – Capmatinib – Crizotinib – Tepotinib 	<ul style="list-style-type: none"> – Selpercatinib – Cabozantinib – Pralsetinib 	<ul style="list-style-type: none"> – Sotorasib – Adagrasib

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 1,14,27,28}

Indication	Dose
NSCLC, SCLC	Administer 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>
HCC	Administer intravenously until disease progression or unacceptable toxicity: First-line therapy: <ul style="list-style-type: none"> – 840 mg every 2 weeks or – 1200 mg every 3 weeks or – 1680 mg every 4 weeks Adjuvant therapy: <ul style="list-style-type: none"> – 1200 mg every 3 weeks
Cutaneous Melanoma	Administer 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 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.</i>
PeM	Administer 1200mg every 3 weeks intravenously until disease progression or unacceptable toxicity
ASPS	Administer intravenously until disease progression or unacceptable toxicity: <u>Adult patients:</u> <ul style="list-style-type: none"> – 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> <ul style="list-style-type: none"> – 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 (STANDARD)

1. Tecentriq [package insert]. South San Francisco, CA; Genentech, Inc; April 2024. Accessed June 2024.
2. Ventana Product Library, Roche Pharmaceuticals. VENTANA PD-L1 [SP142] Assay. <http://www.ventana.com/ventana-pd-l1-sp142-assay-2/> and product label https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160006C.pdf. Accessed July 2023.
3. U.S. Food and Drug Administrations (FDA). Division of Drug Information. Health Alert. <http://s2027422842.t.en25.com/e/es?s=2027422842&e=88882&elqTrackId=B1F0B909CCF90C71B9C490C37BFE6647&elq=3f0714083e82421a8af346a664bedbfb&elqaid=3588&elqat=1>. Accessed May 2018.
4. Balar AV, Galsky MD, Rosenberg JE, et al. Atezolizumab as first-line therapy in cisplatin-ineligible patients with locally advanced and metastatic urothelial carcinoma: a single-arm, multicentre, phase 2 trial. *Lancet*. 2017 January 07; 389(10064): 67–76. doi:10.1016/S0140-6736(16)32455-2.
5. Socinski MA, Jotte RM, Cappuzzo F, et. al. Atezolizumab for First-Line Treatment of Metastatic Nonsquamous NSCLC. *N Engl J Med* 2018; 378:2288-2301. DOI: 10.1056/NEJMoa1716948.
6. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) atezolizumab. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 4.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.

8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 7.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
9. Gupta S, Sonpavde G, Grivas P, et al. Defining “platinum-ineligible” patients with metastatic urothelial cancer (mUC). *J Clin Oncol*. 2019 Mar 1;37(7_suppl):451.
10. Rosenberg JE, Hoffman-Censits J, Powles T, et al. Atezolizumab in patients with locally advanced and metastatic urothelial carcinoma who have progressed following treatment with platinum-based chemotherapy: a single-arm, multicentre, phase 2 trial. *Lancet*. 2016 May 7;387(10031):1909-20. doi: 10.1016/S0140-6736(16)00561-4. Epub 2016 Mar 4.
11. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. *Lancet Oncol*. 2019 Jul;20(7):924-937. doi: 10.1016/S1470-2045(19)30167-6. Epub 2019 May 20.
12. Rittmeyer A, Barlesi F, Waterkamp D, et al. Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicentre randomised controlled trial. *Lancet*. 2017 Jan 21;389(10066):255-265. doi: 10.1016/S0140-6736(16)32517-X. Epub 2016 Dec 13.
13. Schmid P, Adams S, Rugo HS, et al. Atezolizumab and Nab-Paclitaxel in Advanced Triple-Negative Breast Cancer. *N Engl J Med*. 2018 Nov 29;379(22):2108-2121. doi: 10.1056/NEJMoa1809615. Epub 2018 Oct 20.
14. Horn L, Mansfield AS, Szczesna A, et al. First-Line Atezolizumab plus Chemotherapy in Extensive-Stage Small-Cell Lung Cancer. *N Engl J Med*. 2018 Dec 6;379(23):2220-2229. doi: 10.1056/NEJMoa1809064. Epub 2018 Sep 25.
15. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hepatocellular Carcinoma. Version 1.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
16. Pishvaian MJ, Lee MS, Ryoo B, et al. Updated safety and clinical activity results from a Phase Ib study of atezolizumab + bevacizumab in hepatocellular carcinoma (HCC). ESMO 2018 Congress. Munich, Germany; 2018.
17. De Marinis F, Jassem J, Spigel DR, et al. 480TiP IMpower110: Phase III study on 1L atezolizumab (atezo) in PD-L1–selected chemotherapy (chemo)-naive NSCLC patients (pts). *Annals of Oncology*. 2016 Dec 1;27(suppl_9).

18. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Cell Lung Cancer. Version 3.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
19. Gutzmer R, Stroyakovskiy D, Gogas H, et al. Atezolizumab, vemurafenib, and cobimetinib as first-line treatment for unresectable advanced BRAFV600 mutation-positive melanoma (IMspire150): primary analysis of the randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2020;395(10240):1835-1844. doi:10.1016/S0140-6736(20)30934-X.
20. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Melanoma: Cutaneous. Version 2.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
21. Finn RS, Qin S, Ikeda M, et al; IMbrave150 Investigators. Atezolizumab plus Bevacizumab in Unresectable Hepatocellular Carcinoma. *N Engl J Med*. 2020 May 14;382(20):1894-1905.
22. Bellmunt, J. (2023). Treatment of metastatic urothelial cancer of the bladder and urinary tract. In Lerner SP, Shah S (Eds.), *UptoDate*. Accessed December 13, 2023. Available from https://www.uptodate.com/contents/treatment-of-metastatic-urothelial-cancer-of-the-bladder-and-urinary-tract?search=cisplatin%20ineligible&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
23. Felip E, Altorki N, Zhou C, et al. Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB-IIIa non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial. *Lancet*. 2021 Oct 9;398(10308):1344-1357. doi: 10.1016/S0140-6736(21)02098-5. Epub 2021 Sep 20.
24. Raghav KPS, Overman MJ, Liu S, et al. A phase II trial of atezolizumab and bevacizumab in patients with relapsed/refractory and unresectable malignant peritoneal mesothelioma. *Journal of Clinical Oncology* 2020 38:15_suppl, 9013-9013.
25. De Santis M, Bellmunt J, Mead G, et al. Randomized phase II/III trial assessing gemcitabine/ carboplatin and methotrexate/carboplatin/vinblastine in patients with advanced urothelial cancer "unfit" for cisplatin-based chemotherapy: phase II--results of EORTC study 30986. *J Clin Oncol*. 2009 Nov 20;27(33):5634-9. doi: 10.1200/JCO.2008.21.4924. Epub 2009 Sep 28.
26. Naqash AR, O'Sullivan Coyne GH, Moore N, et al. Phase II study of atezolizumab in advanced alveolar soft part sarcoma (ASPS). *Journal of Clinical Oncology* 2021 39:15_suppl, 11519-11519.

27. Raghav K, Liu S, Overman MJ, et al. Efficacy, Safety, and Biomarker Analysis of Combined PD-L1 (Atezolizumab) and VEGF (Bevacizumab) Blockade in Advanced Malignant Peritoneal Mesothelioma. *Cancer Discov.* 2021 Nov;11(11):2738-2747. doi: 10.1158/2159-8290.CD-21-0331.
28. Qin S, Chen M, Cheng AL, Kaseb AO, et al. Atezolizumab plus bevacizumab versus active surveillance in patients with resected or ablated high-risk hepatocellular carcinoma (IMbrave050): a randomised, open-label, multicentre, phase 3 trial. *Lancet.* 2023 Nov 18;402(10415):1835-1847. doi: 10.1016/S0140-6736(23)01796-8.
29. Ascierto PA, Stroyakovskiy D, Gogas H, et al. Overall survival with first-line atezolizumab in combination with vemurafenib and cobimetinib in BRAFV600 mutation-positive advanced melanoma (IMspire150): second interim analysis of a multicentre, randomised, phase 3 study. *Lancet Oncol* 2023;24:33-44.

VIII. References (ENHANCED)

- 1e. Balar AV, Castellano D, O'Donnell PH, et al. Pembrolizumab as first-line therapy in cisplatin-ineligible advanced urothelial cancer: Results from the total KEYNOTE-052 study population. *J Clin Oncol* 2017 Feb;35(6_suppl):284.
- 2e. De Santis M, Bellmunt J, Mead G, et al. Randomized phase II/III trial assessing gemcitabine/carboplatin and methotrexate/carboplatin/vinblastine in patients with advanced urothelial cancer who are unfit for cisplatin-based chemotherapy: EORTC study 30986. *J Clin Oncol.* 2012;30(2):191–199. doi:10.1200/JCO.2011.37.3571.
- 3e. Powles T, Durán I, van der Heijden MS, et al. Atezolizumab versus chemotherapy in patients with platinum-treated locally advanced or metastatic urothelial carcinoma (IMvigor211): a multicentre, open-label, phase 3 randomised controlled trial. *Lancet.* 2018 Feb 24;391(10122):748-757. doi: 10.1016/S0140-6736(17)33297-X.
- 4e. Bellmunt J, de Wit R, Vaughn DJ, et al. Pembrolizumab as Second-Line Therapy for Advanced Urothelial Carcinoma. *N Engl J Med.* 2017;376(11):1015–1026. doi:10.1056/NEJMoa1613683.
- 5e. Sharma P, Retz M, Siefker-Radtke A, et al. Nivolumab in metastatic urothelial carcinoma after platinum therapy (CheckMate 275): a multicentre, single-arm, phase 2 trial. *Lancet Oncol.* 2017 Mar;18(3):312-322. doi: 10.1016/S1470-2045(17)30065-7.
- 6e. Massard C, Gordon MS, Sharma S, et al. Safety and Efficacy of Durvalumab (MEDI4736), an Anti-Programmed Cell Death Ligand-1 Immune Checkpoint Inhibitor, in Patients With Advanced Urothelial Bladder Cancer. *J Clin Oncol.* 2016;34(26):3119–3125. doi:10.1200/JCO.2016.67.9761.
- 7e. Patel MR, Ellerton J, Infante JR, et al. Avelumab in metastatic urothelial carcinoma after platinum failure (JAVELIN Solid Tumor): pooled results from two expansion cohorts of an open-label, phase 1 trial. *Lancet Oncol.* 2018 Jan;19(1):51-64. doi: 10.1016/S1470-2045(17)30900-2.

- 8e. Siefker-Radtke AO, Necchi A, Park SH, et al. First results from the primary analysis population of the phase 2 study of erdafitinib (ERDA; JNJ-42756493) in patients (pts) with metastatic or unresectable urothelial carcinoma (mUC) and FGFR alterations (FGFRalt). *J Clin Oncol* 2018;36(15_suppl):4503.
- 9e. Reck M, Rodríguez-Abreu D, Robinson AG, et al. Pembrolizumab versus Chemotherapy for PD-L1–Positive Non–Small-Cell Lung Cancer. *N Engl J Med* 2016; 375:1823–1833.
- 10e. Gandhi L, Rodríguez-Abreu D, Gadgeel S, et al. Pembrolizumab plus Chemotherapy in Metastatic Non–Small-Cell Lung Cancer. *N Engl J Med* 2018; 378:2078–2092.
- 11e. Barlesi F, Park K, Ciardiello F, et al. Primary analysis from OAK, a randomized phase III study comparing atezolizumab with docetaxel in 2L/3L NSCLC. *Ann of Oncol* 2016 Oct;27(suppl_6):LBA44_PR.
- 12e. Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus Docetaxel in Advanced Nonsquamous Non-Small-Cell Lung Cancer. *N Engl J Med*. 2015;373(17):1627–1639. doi:10.1056/NEJMoa1507643.
- 13e. Herbst RS, Baas P, Kim DW, et al. Pembrolizumab versus docetaxel for previously treated, PD-L1-positive, advanced non-small-cell lung cancer (KEYNOTE-010): a randomised controlled trial. *Lancet*. 2016 Apr 9;387(10027):1540–50. doi: 10.1016/S0140-6736(15)01281-7.
- 14e. Spigel D et al. IMpower110: Interim OS Analysis of a Phase III Study of Atezolizumab (atezo) vs Platinum-Based Chemotherapy (chemo) as 1L Treatment (tx) in PD-L1–selected NSCLC [ESMO 2019 Abstract LBA78].
- 15e. Paz-Ares L, Dvorkin M, Chen Y, et al. Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomised, controlled, open-label, phase 3 trial. *Lancet*. 2019;394(10212):1929–1939. doi:10.1016/S0140-6736(19)32222-6.
- 16e. Zalcman G, Peters S, Mansfield AS, et al. Checkmate 743: A phase 3, randomized, open-label trial of nivolumab (nivo) plus ipilimumab (ipi) vs pemetrexed plus cisplatin or carboplatin as first-line therapy in unresectable pleural mesothelioma. *Journal of Clinical Oncology* 2017 35:15_suppl, TPS8581-TPS8581.
- 17e. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. *Lancet Oncol*. 2019 Jul;20(7):924–937. doi: 10.1016/S1470-2045(19)30167-6. Epub 2019 May 20.
- 18e. Powles T, Park SH, Voog E, et al. Maintenance avelumab + best supportive care (BSC) versus BSC alone after platinum-based first-line (1L) chemotherapy in advanced urothelial carcinoma (UC): JAVELIN Bladder 100 phase III interim analysis. *J Clin Oncol*. 2020;38(18_suppl):LBA1-LBA1.
- 19e. Cortes J, Cescon DW, Rugo HS, et al. KEYNOTE-355: Randomized, double-blind, phase III study of pembrolizumab + chemotherapy versus placebo + chemotherapy for previously

- untreated locally recurrent inoperable or metastatic triple-negative breast cancer. *Journal of Clinical Oncology* 38, no. 15_suppl (May 20, 2020):1000-1000.
- 20e. Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. *Lancet*. 2021 Feb 13;397(10274):592-604.
 - 21e. Miles D, Gligorov J, André F, et al. Primary results from IMpassion131, a double-blind, placebo-controlled, randomised phase III trial of first-line paclitaxel with or without atezolizumab for unresectable locally advanced/metastatic triple-negative breast cancer. *Ann Oncol*. 2021 Aug;32(8):994-1004. doi: 10.1016/j.annonc.2021.05.801. Epub 2021 Jul 1.
 - 22e. Fennell DA, Ewings S, Ottensmeier C, et al. Nivolumab versus placebo in patients with relapsed malignant mesothelioma (CONFIRM): a multicentre, double-blind, randomised, phase 3 trial. *Lancet Oncol* 2021; 22:1530.
 - 23e. Galsky MD, Arija JÁA, Bamias A, et al; IMvigor130 Study Group. Atezolizumab with or without chemotherapy in metastatic urothelial cancer (IMvigor130): a multicentre, randomised, placebo-controlled phase 3 trial. *Lancet*. 2020 May 16;395(10236):1547-1557. doi: 10.1016/S0140-6736(20)30230-0. PMID: 32416780.
 - 24e. Johnson ML, Cho BC, Luft A, et al; POSEIDON investigators. Durvalumab With or Without Tremelimumab in Combination With Chemotherapy as First-Line Therapy for Metastatic Non-Small-Cell Lung Cancer: The Phase III POSEIDON Study. *J Clin Oncol*. 2022 Nov 3;JCO2200975. doi: 10.1200/JCO.22.00975.
 - 25e. Gogishvili M, Melkadze T, Makharadze T, et al. LBA51 EMPOWER-Lung 3: Cemiplimab in combination with platinum doublet chemotherapy for first-line (1L) treatment of advanced non-small cell lung cancer (NSCLC). *Annals of Oncology*, ISSN: 0923-7534, Vol: 32, SUPPLEMENT 5, S1328, SEPTEMBER 01, 2021. DOI10.1016/j.annonc.2021.08.2130.
 - 26e. Wilky BA, Trucco MM, Subhawong TK, et al. Axitinib plus pembrolizumab in patients with advanced sarcomas including alveolar soft-part sarcoma: a single-centre, single-arm, phase 2 trial. *Lancet Oncol*. 2019 Jun;20(6):837-848. doi: 10.1016/S1470-2045(19)30153-6. Epub 2019 May 8.
 - 27e. D'Alessio A, Fulgenzi CAM, Nishida N, et al. Preliminary evidence of safety and tolerability of atezolizumab plus bevacizumab in patients with hepatocellular carcinoma and Child-Pugh A and B cirrhosis: A real-world study. *Hepatology*. 2022 Oct;76(4):1000-1012. doi: 10.1002/hep.32468.
 - 28e. Stacchiotti S, Negri T, Zaffaroni N, et al. Sunitinib in advanced alveolar soft part sarcoma: evidence of a direct antitumor effect. *Ann Oncol*. 2011 Jul;22(7):1682-1690. doi: 10.1093/annonc/mdq644. Epub 2011 Jan 17.
 - 29e. Stacchiotti S, Mir O, Le Cesne A, et al. Activity of Pazopanib and Trabectedin in Advanced Alveolar Soft Part Sarcoma. *Oncologist*. 2018 Jan;23(1):62-70. doi: 10.1634/theoncologist.2017-0161. Epub 2017 Jul 28.

- 30e. Kudo M. Durvalumab plus tremelimumab in unresectable hepatocellular carcinoma. *Hepatobiliary Surgery and Nutrition*. 2022;11(4):592-596. doi:<https://doi.org/10.21037/hbsn-22-143>
- 31e. Ascierto PA, Dréno B, Larkin J, et al. 5-Year Outcomes with Cobimetinib plus Vemurafenib in BRAFV600 Mutation–Positive Advanced Melanoma: Extended Follow-up of the coBRIM Study. *Clinical Cancer Research*. 2021;27(19):5225-5235. doi:<https://doi.org/10.1158/1078-0432.ccr-21-0809>
- 32e. Robert C, Karaszewska B, Schachter J, et al. Improved Overall Survival in Melanoma with Combined Dabrafenib and Trametinib. *New England Journal of Medicine*. 2015;372(1):30-39. doi:<https://doi.org/10.1056/nejmoa1412690>
- 33e. Dummer R, Ascierto PA, Gogas HJ, et al. Encorafenib plus binimetinib versus vemurafenib or encorafenib in patients with BRAF-mutant melanoma (COLUMBUS): a multicentre, open-label, randomised phase 3 trial. *The Lancet Oncology*. 2018;19(5):603-615. doi:[https://doi.org/10.1016/S1470-2045\(18\)30142-6](https://doi.org/10.1016/S1470-2045(18)30142-6)
- 34e. Ferrucci PF, Giacomo AMD, Vecchio MD, et al. KEYNOTE-022 part 3: a randomized, double-blind, phase 2 study of pembrolizumab, dabrafenib, and trametinib in BRAF-mutant melanoma. *Journal for ImmunoTherapy of Cancer*. 2020;8(2):e001806. doi:<https://doi.org/10.1136/jitc-2020-001806>
- 35e. Magellan Rx Management. Tecentriq Clinical Literature Review Analysis. Last updated June 2024. Accessed June 2024.

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

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ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
Z85.831	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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

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	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC