

Imfinzi® (durvalumab) (Intravenous)

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Document Number: IC-0490

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I. Length of Authorization ^{Δ 1}

- Non-Small Cell Lung Cancer: Coverage will be provided for 6 months and may be renewed up to a maximum of twelve (12) months of therapy.
- Small Cell Lung Cancer & Hepatobiliary Cancers: Coverage will be provided for (six) 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Imfinzi 120 mg/2.4 mL single-dose vial: 4 vials per 14 days
- Imfinzi 500 mg /10 mL single-dose vial: 2 vials per 14 days

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

- NSCLC: 112 billable units (1,120 mg) every 14 days
- SCLC : 150 billable units (1,500 mg) every 21 days x 6 doses, then 150 billable units (1,500) every 28 days
- Biliary Tract Cancer: 150 billable units (1,500 mg) every 21 days x 8 doses, then 150 billable units (1,500) every 28 days
- Hepatocellular Carcinoma: 150 billable units (1,500 mg) every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, cemiplimab, dostarlimab, etc.) unless otherwise specified ^Δ; **AND**

Non-Small Cell Lung Cancer (NSCLC) † 1,3-5

- Used as a single agent; **AND**
- Used as consolidation therapy; **AND**
- Patient has unresectable stage III disease; **AND**
- Disease has not progressed after definitive platinum-based chemoradiation; **AND**
- Patient has a performance status (PS) of 0-1

Small Cell Lung Cancer (SCLC) † Φ 1,3,7,8,10

- Patient has extensive stage disease (ES-SCLC); **AND**
 - Used as first-line therapy in combination with etoposide and either carboplatin or cisplatin; **OR**
 - Used as single-agent maintenance therapy after initial therapy with etoposide and either carboplatin or cisplatin

Hepatobiliary Cancers † ‡ 3,11,14

- Patient has hepatocellular carcinoma (HCC); **AND**
 - Used as first-line therapy as a single agent in patients with Child-Pugh class A hepatic impairment; **AND**
 - Patient has unresectable disease and is not a transplant candidate; **OR**
 - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
 - Patient has metastatic disease or extensive liver tumor burden; **OR**
- Patient has biliary tract cancer (e.g., gallbladder cancer or intra-/extra-hepatic cholangiocarcinoma); **AND**
 - Used in combination with cisplatin and gemcitabine; **AND**
 - Used as primary treatment for unresectable or metastatic disease; **OR**
 - Used for recurrent disease >6 months after surgery with curative intent and >6 months after completion of adjuvant 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 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.

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.

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

IV. Renewal Criteria ^{Δ 1,3}

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria 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: severe or life-threatening infusion-related reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatology reactions, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.; **AND**

NSCLC

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

Continuation Maintenance Therapy for SCLC

- *Refer to Section III for criteria*

V. Dosage/Administration ^{Δ 1,7,8,12}

Indication	Dose
Non-Small Cell Lung Cancer (NSCLC)	<p><u>Weight >30 kg:</u> Administer 10 mg/kg intravenously every 14 days OR 1,500 mg intravenously every 28 days until disease progression, unacceptable toxicity, or a maximum of 12 months of therapy</p> <p><u>Weight <30 kg:</u> Administer 10 mg/kg intravenously every 14 days until disease progression, unacceptable toxicity, or a maximum of 12 months of therapy</p>
Small Cell Lung Cancer (SCLC)	<p><u>Weight >30 kg:</u> Administer 1,500 mg intravenously in combination with chemotherapy every 21 days x 4 cycles*, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</p> <p><u>Weight <30 kg:</u></p>

	Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days x 4 cycles*, followed by a maintenance dose of 10 mg/kg as a single agent every 14 days thereafter, until disease progression or unacceptable toxicity * <u>Note</u> : patients may receive up to 2 additional cycles in combination with chemotherapy based on response and tolerability after the initial 4 cycles (6 cycles of combination therapy in total) ⁸
Hepatocellular Carcinoma	Administer 1,500 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Biliary Tract Cancer	<u>Weight >30 kg:</u> Administer 1,500 mg intravenously in combination with chemotherapy every 21 days for up to 8 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity <u>Weight <30 kg:</u> Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days for up to 8 cycles, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity
<u>Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:</u>	
<ul style="list-style-type: none"> • Patient weight > 30 kg and <75 kg: Use 20 mg/kg dosing <p><i>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.</i></p>	

VI. Billing Code/Availability Information

HCPCS Code:

- J9173 – Injection, durvalumab, 10 mg; 1 billable unit = 10 mg

NDC(s):

- Imfinzi 120 mg/2.4 mL single-dose vial: 00310-4500-xx
- Imfinzi 500 mg/10 mL single-dose vial: 00310-4611-xx

VII. References (STANDARD)

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3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) durvalumab. National Comprehensive Cancer Network, 2022. 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 September 2022.
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10. Goldman JW, Dvorkin M, Chen Y, et al. Durvalumab, with or without tremelimumab, plus platinum-etoposide versus platinum-etoposide alone in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): updated results from a randomised, controlled, open-label, phase 3 trial. *Lancet Oncol*. 2021 Jan;22(1):51-65. doi: 10.1016/S1470-2045(20)30539-8.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hepatobiliary Cancers. Version 2.2022. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®.

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VIII. References (ENHANCED)

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- 10e. Kudo M, Finn RS, Qin S, et al. Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomised phase 3 non-inferiority trial. *Lancet*. 2018 Mar 24;391(10126):1163-1173. doi: 10.1016/S0140-6736(18)30207-1.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of other and unspecified parts of biliary tract
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
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
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C78.00	Secondary malignant neoplasm of unspecified lung

ICD-10	ICD-10 Description
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
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

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

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC