Imfinzi® (durvalumab)
(Intravenous)

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I. Length of Authorization Δ [1]

- Non-Small Cell Lung Cancer (single agent use): Coverage will be provided for 6 months and may be renewed up to a maximum of 12 months of therapy.
- Non-Small Cell Lung Cancer (use in combination with tremelimumab-actl and platinum-based chemotherapy), Small Cell Lung Cancer & Hepatobiliary Cancers: Coverage will be provided for 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 mg) every 28 days
- Biliary Tract Cancer: 150 billable units (1,500 mg) every 21 days x 8 doses, then 150 billable units (1,500 mg) 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, nivolumab/relatlimab-rmbw, etc.) unless otherwise specified Δ; **AND**

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

- Patient has a performance status (PS) of 0-1; **AND**
  - Used as a single agent; **AND**
    - Used as consolidation therapy; **AND**
    - Patient has unresectable stage II-III disease; **AND**
    - Disease has not progressed after definitive chemoradiation; **OR**
  - Used in combination with tremelimumab-actl and platinum-based chemotherapy; **AND**
    - Used as first-line therapy for metastatic disease; **AND**
    - Patient had no EGFR mutations or ALK genomic tumor aberrations

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 † ‡ Φ [1,3,11,14]

- Patient has hepatocellular carcinoma (HCC); **AND**
  - Used as first-line therapy as a single agent; **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**
  - Used as first-line therapy in combination with tremelimumab-actl; **AND**
    - Patient has unresectable disease; **AND**
    - Patient has Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments); **AND**
      - Patient has intermediate disease (i.e., multinodular, PS 0) and is not eligible for locoregional therapy; **OR**
      - Patient has advanced disease (i.e., portal invasion, regional lymph node metastasis, distant metastasis, PS 1-2); **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, locally advanced, 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.

† 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, pancreatitis, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.; **AND**

NSCLC (single-agent use)

- Patient has not exceeded a maximum of 12 months of therapy

Hepatobiliary Cancers

- Cases for patients with HCC who use treatment as part of STRIDE and experience disease progression but who are clinically stable and still deriving clinical benefit will be reviewed on a case-by-case basis.

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)	Single agent: • Weight ≥30 kg: 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 • Weight <30 kg: Administer 10 mg/kg intravenously every 14 days until disease progression, unacceptable toxicity, or a maximum of 12 months of therapy In combination with Tremelimumab-actl* and Platinum-Based Chemotherapy§: • Weight ≥30 kg: Administer 1,500 mg intravenously every 21 days x 4 cycles, followed by a maintenance dose of 1,500 mg every 28 days thereafter, until disease progression or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously every 21 days x 4 cycles, followed by a maintenance dose of 20 mg/kg every 28 days thereafter, until disease progression or unacceptable toxicity ***Note**: Refer to the Prescribing Information for tremelimumab-actl dosing information* *§ If patients receive fewer than 4 cycles of platinum-based chemotherapy, the remaining cycles of Tremelimumab-actl (up to a total of 5) should be given after the platinum-based chemotherapy phase, in combination with IMFINZI, every 4 weeks.*
Small Cell Lung Cancer (SCLC)	Weight ≥30 kg: 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 Weight <30 kg: 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 ***Note**: 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	Single agent: Administer 1,500 mg intravenously every 4 weeks until disease progression or unacceptable toxicity STRIDE (Single Tremelimumab Regular Interval Durvalumab): • Weight ≥30 kg: Administer 1,500 mg intravenously following a single dose of tremelimumab-actl* at Day 1 of Cycle 1, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity

	• Weight <30 kg: Administer 20 mg/kg intravenously following a single dose of tremelimumab-actl* at Day 1 of Cycle 1, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity ***Note**: Refer to the Prescribing Information for tremelimumab-actl dosing information*
Biliary Tract Cancer	Weight ≥30 kg: 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 Weight <30 kg: 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
Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following: • Patient weight > 30 kg and <75 kg: Use 20 mg/kg dosing *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:

- 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

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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

ICD-10	ICD-10 Description
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
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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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