Imfinzi® (durvalumab)
(Intravenous)

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I. Length of Authorization[1]

- Bladder Cancer/Urothelial Carcinoma and Non-Small Cell Lung Cancer: Coverage will be provided for six months and may be renewed up to a maximum of 12 months of therapy.
- Small Cell Lung Cancer: Coverage will be provided for six months and may be renewed.

II. Dosing Limits

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

- Imfinzi 120 mg single-dose vial: 2 vials per 14 days
- Imfinzi 500 mg single-dose vial: 2 vials per 14 days

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

- Bladder Cancer/Urothelial Carcinoma and NSCLC: 112 billable units (1120 mg) every 14 days
- SCLC (for use in combination with chemotherapy): 150 billable units (1500 mg) every 21 days
- SCLC (for use as a single agent therapy): 150 billable units (1500 mg) every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient must be at least 18 years old; **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, etc.) unless otherwise specified; **AND**

Bladder Cancer/Urothelial Carcinoma † [1,3,6,10]

- Used as a single agent; **AND**

- Used as subsequent therapy after previous platinum treatment*; **AND**
- Patient has a diagnosis of one of the following:
  - Locally advanced or metastatic urothelial carcinoma; **OR**
  - Local bladder cancer recurrence or persistent disease in a preserved bladder; **OR**
  - Local or metastatic bladder cancer recurrence post-cystectomy; **OR**
  - Metastatic upper genitourinary (GU) tract tumors; **OR**
  - Metastatic urothelial carcinoma of the prostate; **OR**
  - Recurrent or metastatic primary carcinoma of the urethra; **AND**
    - Patient does not have recurrence of stage T3-4 disease or palpable inguinal lymph nodes

Note:

- *If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy if the patient is still platinum eligible (see below for cisplatin- or carboplatin-ineligible comorbidities).*
  - *Cisplatin-ineligible comorbidities may include the following: GFR < 60 mL/min, PS ≥ 2, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, or grades ≥ 2 peripheral neuropathy. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR <60 mL/min or a PS of 2.*
  - *Carboplatin-ineligible comorbidities may include the following: GFR < 30 mL/min, PS ≥ 3, grade ≥ 3 peripheral neuropathy, or NYHA class ≥ 3, etc.*

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 did not progress after 2 or more cycles of definitive chemoradiation; **AND**
- Patient has a performance status (PS) of 0-1

Small Cell Lung Cancer (SCLC) † Φ [3,8,9]

- Patient has extensive stage disease (ES-SCLC) (excluding patients with poor PS 3-4 not due to 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; **AND**
- Must not be used for relapsed disease in patients on maintenance therapy with atezolizumab or durvalumab at the time relapse (**NOTE:** If relapse occurred >6 months after atezolizumab or durvalumab maintenance therapy, patient should be re-treated with carboplatin + etoposide alone or cisplatin + etoposide alone)

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

IV. Renewal Criteria[1,3-6,8-10]

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: severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, skin reactions, aseptic meningitis, hemolytic anemia, immune thrombocytopenic purpura, myocarditis, myositis, and ocular inflammatory toxicity, including uveitis and keratitis etc.), serious infection, etc.; **AND**
- For Bladder Cancer/Urothelial Carcinoma 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[1,8,9]

Indication	Dose
Bladder Cancer/Urothelial Carcinoma and NSCLC	Administer 10 mg/kg intravenously every 14 days, until disease progression or unacceptable toxicity (or a maximum of 12 months of therapy)
SCLC	Administer 1,500 mg intravenously in combination with chemotherapy on day 1 of every 21 day cycle x 4 cycles followed by a maintenance dose of 1,500 mg as a single agent on day 1 of every 28 day cycle thereafter, until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- 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

1. Imfinzi [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; March 2020. Accessed May 2020.
2. 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 Sep 10;34(26):3119-25.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) durvalumab. National Comprehensive Cancer Network, 2020. 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 May 2020.
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6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 4.2020. National Comprehensive Cancer Network, 2020. 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 May 2020.
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9. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Cell Lung Cancer. Version 3.2020. National Comprehensive Cancer Network, 2020. 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 May 2020.

10. Powles T, O'Donnell PH, Massard C, et al. Efficacy and Safety of Durvalumab in Locally Advanced or Metastatic Urothelial Carcinoma: Updated Results From a Phase 1/2 Open-label Study. JAMA Oncol. 2017 Sep 14;3(9):e172411. doi: 10.1001/jamaoncol.2017.2411. Epub 2017 Sep 14.
11. CGS Administrators, LLC. Local Coverage Article (LCA): Billing and Coding: Durvalumab (Imfinzi)-J9173 (A56543). Centers for Medicare & Medicaid Services, Inc. Updated on 09/18/2019 with effective date 09/26/2019. Accessed May 2020.
12. Palmetto GBA. Local Coverage Article (LCA): Billing and Coding: Chemotherapy (A56141). Centers for Medicare & Medicaid Services, Inc. Updated on 03/24/2020 with effective date 04/30/2020. Accessed May 2020.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
C61	Malignant neoplasm of prostate
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter

ICD-10	ICD-10 Description
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
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
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ

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: http://www.cms.gov/medicare-coverage-database/search/advanced-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):

Jurisdiction(s): 15	**NCD/LCD/Article Document (s):** A56543
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A56543&bc=gAAAAAAAAAAA&	

Jurisdiction(s): J&M	NCD/LCD/Article Document (s): A56141
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56141&bc=gAAAAAAAAAAA	

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