

Imfinzi™ (durvalumab)

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Medical Guideline Disclaimer

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Definition

Imfinzi™ is a programmed death ligand-1 (PD-L1) blocking antibody administered intravenously as immunotherapy.

Related Medical Guidelines

[Bavencio® \(avelumab\)](#)

[Keytruda® \(pembrolizumab\)](#)

[Opdivo® \(nivolumab\)](#)

[Off-Label Use of FDA-Approved Drugs and Biologicals](#)

Dosing and Administration

[Imfinzi Package Insert](#)

Guideline

Imfinzi is considered medically necessary for members ≥ 18 years of age, for use as a single agent, when prescribed by an oncologist for the following indications:

- A. Urothelial Carcinoma (MCC); **either**:*
 - a. Disease must have progressed during or following platinum-containing chemotherapy
 - b. Disease must have progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
- B. Bladder Cancer/Urothelial Carcinoma; **both**: **
 - a. Must be used as subsequent therapy
 - b. Member is diagnosed with **one**:
 - i. Disease recurrence post-cystectomy

- ii. Recurrent or metastatic Primary Carcinoma of the Urethra
- iii. Metastatic Urothelial Carcinoma of the Prostate
- iv. Metastatic Upper GU Tract Tumors
- v. Locally advanced or metastatic Urothelial Carcinoma

C. Unresectable Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy*

*= FDA-approved indication

**= Compendia-recommended indication

Authorization

- Initial authorization period of 6 months
- Renewal based upon all:
 - Member continues to meet criteria above
 - Tumor response with stabilization of disease or decrease in tumor or tumor spread
 - Absence of unacceptable toxicity (i.e., immune-mediated adverse reactions, severe infections, severe infusion-related reactions, hepatitis, etc.)

Limitations/Exclusions

Imfinzi is considered investigational when used for any indication not listed above; including but not limited to:

- Adrenocortical cancer
- Breast cancer
- Chordoma
- Gastro-intestinal cancers (e.g., colorectal, esophageal, and gastric cancers)
- Mesothelioma
- Neuroendocrine cancer
- Ovarian cancer
- Pancreatic cancer
- Prostate cancer
- Renal cell cancer
- Spindle cell cancer

Revision History

1/1/2019	Added J9173 – effective January 1, 2019, Removed J3590, J9999, Added Applicable NDCs
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Applicable Procedure Codes

J9173	Injection, durvalumab, 10mg, 1 billable unit = 10mg
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Applicable NDCs

0310-4611-50	Durvalumab 500mg/10ml vial, 50 units
0310-4500-12	Durvalumab 120mg/2.4ml vial, 12 units

Applicable Diagnosis Codes

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
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
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
D09.0	Carcinoma in situ of bladder
Z85.51	Personal history of malignant neoplasm of bladder
Z85.53	Personal history of malignant neoplasm of renal pelvis
Z85.54	Personal history of malignant neoplasm of ureter
Z85.59	Personal history of malignant neoplasm of other urinary tract organ

References

1. Imfinzi [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; February 2018. Accessed March 12, 2018.
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, 2017. 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 2017.
4. Specialty matched clinical peer review.