

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	N/A	N/A	X	N/A	X	N/A	X	X	X	X	N/A	N/A	X

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# Imfinzi (durvalumab)

DRUG.00109

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Imfinzi (durvalumab)

## APPROVAL CRITERIA

Requests for Imfinzi (durvalumab) may be approved for the treatment of locally advanced or metastatic urothelial carcinoma when the following criteria are met:

- I. Individual is using Imfinzi (durvalumab) for the treatment of locally advanced or metastatic urothelial carcinoma; **AND**
- II. Individual has inoperable or metastatic transitional-cell urothelial carcinoma histologically or cytologically confirmed; **AND**
- III. One of the following:
  - A. Disease has progressed during or following platinum-containing therapy; **OR**
  - B. Disease has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing therapy;
- AND**
- IV. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
- V. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- VI. Individual does not have *any* of the following:
  - A. History of immunodeficiency; **OR**
  - B. History of severe autoimmune disease; **OR**
  - C. Require systemic immunosuppression; **OR**
  - D. Active immune-mediated disease; **OR**
  - E. Severe or life-threatening infection; **OR**
  - F. Untreated central nervous system (CNS) metastases.

Requests for Imfinzi (durvalumab) may be approved as consolidation therapy in the treatment of unresectable stage III non-small cell lung cancer when all of the following criteria are met:

- I. Individual has stage III locally advanced, unresectable non-small cell lung cancer histologically or cytologically confirmed; **AND**
- II. Disease has not progressed after definitive chemoradiation; **AND**

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New Program Date 06/19/2017

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

CRX-ALL-0035-18

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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- III. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
- IV. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- V. Individual does not have *any* of the following:
  - A. History of immunodeficiency; **OR**
  - B. History of severe autoimmune disease; **OR**
  - C. Require systemic immunosuppression; **OR**
  - D. Active immune-mediated disease; **OR**
  - E. Severe or life-threatening infection; **OR**
  - F. Untreated central nervous system (CNS) metastases; **AND**
- VI. Imfinzi (durvalumab) is being used until disease progression or a maximum of 12 months of treatment.

Requests for Imfinzi (durvalumab) **may not be** approved when the above criteria are not met and for all other uses.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

American Cancer Society (ACS).

Key Statistics for Bladder Cancer. Revised on January 5, 2017. Available at: <https://www.cancer.org/cancer/bladder-cancer/about/key-statistics.html>. Accessed on March 20, 2017.

Key Statistics for Lung Cancer. Revised January 5, 2017. Available at: <https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/key-statistics.html>. Accessed on November 9, 2017.

NCCN Clinical Practice Guidelines in Oncology™. © 2017 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 4, 2017.

Bladder Cancer. V2.2017. Revised February 15, 2017.

Non-Small Cell Lung Cancer. V9.2017. Revised September 28, 2017.

IMFINZI™ (durvalumab) [Product Information]. Wilmington, DE. AstraZeneca. April 2017. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2017/761069s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761069s000lbl.pdf). Accessed on May 1, 2017.

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