

Reference number(s)
1820-A

# SPECIALTY GUIDELINE MANAGEMENT

## IMFINZI (durvalumab)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

- A. Locally advanced or metastatic urothelial carcinoma in patients with disease progression during or following platinum-containing chemotherapy or with disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- B. Unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

##### Compendial Indications

- A. Bladder cancer as subsequent systemic therapy post-platinum as a single agent
- B. Metastatic upper GU tract tumors as a single agent for subsequent systemic therapy post platinum
- C. Metastatic carcinoma of the prostate as a single agent for subsequent therapy post platinum
- D. Recurrent or metastatic carcinoma of the urethra as a single agent for subsequent systemic therapy post platinum

All other indications are considered experimental/investigational and are not a covered benefit.

#### II. EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

#### III. CRITERIA FOR INITIAL APPROVAL

##### **A. Urothelial Carcinoma – Bladder Cancer**

Authorization of 6 months may be granted as a single agent for treatment of bladder cancer when any of the following criteria is met:

1. As subsequent therapy following platinum-containing chemotherapy for locally advanced or metastatic disease.
2. Member has metastatic or local recurrence post-cystectomy.

##### **B. Urothelial Carcinoma – Primary Carcinoma of the Urethra**

Authorization of 6 months may be granted as a single agent for treatment of primary carcinoma of the urethra as a single agent for subsequent therapy for recurrent, locally advanced, or metastatic disease following platinum-containing chemotherapy.

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**C. Urothelial Carcinoma – Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate**  
Authorization of 6 months may be granted as a single agent for the treatment of upper genitourinary (GU) tract tumors or urothelial carcinoma of the prostate as subsequent therapy for locally advanced or metastatic disease as a single agent following platinum-containing chemotherapy.

**D. Non-small cell lung cancer**

Authorization of 6 months may be granted for treatment of unresectable, Stage III NSCLC that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

**IV. CONTINUATION OF THERAPY**

**A. NSCLC**

Authorization of 6 months may be granted (up to 12 months total) for continued treatment in members requesting reauthorization for an indication listed in Section IV who have not experienced disease progression or unacceptable toxicity.

**B. All other indications**

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV who have not experienced disease progression or an unacceptable toxicity.

**V. REFERENCES**

1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2018.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 19, 2019.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Bladder Cancer (Version 4.2019) © 2019 National Comprehensive Cancer Network, Inc. Available at <http://www.nccn.org>. Accessed July 16, 2019.