

## 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

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

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. Urothelial carcinoma

Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial carcinoma when any of the following criteria is met:

- 1. Member experienced disease progression during or following platinum-containing chemotherapy.
- 2. Member experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

###### B. Non-small cell lung cancer

Authorization of up to 12 months may be granted for treatment of unresectable, stage III NSCLC following concurrent platinum-based chemotherapy and radiation therapy.

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

- 1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2018.
- 2. The NCCN Drugs & Biologics Compendium® © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed August 3, 2017.

3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Bladder Cancer. Version 5.2017. Accessed August 3, 2017.  
[https://www.nccn.org/professionals/physician\\_gls/pdf/bladder.pdf](https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf).