

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

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.