

# STANDARD MEDICARE PART B 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.

##### A. FDA-Approved Indications

1. Imfinzi is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
2. Imfinzi is indicated for the treatment of patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
3. Imfinzi is indicated as first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) in combination with etoposide and either carboplatin or cisplatin.

##### B. Compendial Uses

1. Urothelial carcinoma - bladder cancer: second-line systemic therapy post-platinum for:
  - i. muscle invasive local recurrence or persistent disease in a preserved bladder
  - ii. metastatic or local recurrence post cystectomy
2. Urothelial carcinoma - primary carcinoma of the urethra, recurrent, as second-line systemic therapy post-platinum

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

#### II. CRITERIA FOR INITIAL APPROVAL

##### A. **Urothelial carcinoma**

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

1. The requested drug will be used as subsequent therapy post-platinum for any of the following:
  - i. locally advanced or metastatic urothelial carcinoma
  - ii. urothelial carcinoma of the bladder with muscle invasive local recurrence or persistent disease in a preserved bladder
  - iii. urothelial carcinoma of the bladder with metastatic or local recurrence post cystectomy
  - iv. recurrent primary carcinoma of the urethra.
2. Member has a clinical reason to avoid therapy with platinum-containing chemotherapy.

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

Authorization of 12 months total may be granted for treatment of unresectable, Stage III NSCLC following

<b>Reference number(s)</b>
2131-A

concurrent platinum-based chemotherapy and radiation therapy.

**C. Extensive-stage small cell lung cancer (ES-SCLC)**

Authorization of 12 months may be granted for first-line treatment of extensive-stage small cell lung cancer in combination with etoposide and either carboplatin or cisplatin.

**III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months (or up to a total of 12 months for non-small cell lung cancer) may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Imfinzi
- B. Imfinzi is being used to treat an indication enumerated in Section II
- C. The member is receiving benefit from therapy

**IV. REFERENCES**

- 1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2020.
- 2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed July 17, 2020.