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.

A. FDA-Approved Indication
1. 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.
2. Unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
3. As first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) in combination with etoposide and either carboplatin or cisplatin.

B. Compendial Indications
1. Urothelial Carcinoma
   a. Bladder cancer
   b. Primary carcinoma of the urethra
   c. Upper genitourinary (GU) tract tumors
   d. Urothelial carcinoma of the prostate
2. Non-small cell lung cancer-unresectable stage II disease

All other indications are considered experimental/investigational and not medically necessary.

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 for treatment of bladder cancer as a single agent for subsequent therapy following platinum-containing chemotherapy for any of the following:
1. Locally advanced or metastatic disease
2. Metastatic or local recurrence post-cystectomy
3. Muscle invasive local recurrence or persistent disease in a preserved bladder

B. Urothelial Carcinoma – Primary Carcinoma of the Urethra
Authorization of 6 months may be granted for the 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.

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 II or III NSCLC that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

E. Extensive-stage small cell lung cancer (ES-SCLC)
Authorization of 6 months may be granted for first-line treatment of extensive-stage small cell lung cancer in combination with etoposide and either carboplatin or cisplatin followed by single agent maintenance.

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 III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

B. All other indications
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 7, 2020.