

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 Indications

1. Unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
2. As first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) in combination with etoposide and either carboplatin or cisplatin.
3. In combination with gemcitabine and cisplatin, for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).

##### B. Compendial Uses

1. Non-small cell lung cancer-unresectable stage II disease
2. Hepatocellular Carcinoma
3. Biliary tract cancer

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. **Non-small cell lung cancer (NSCLC)**

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.

##### B. **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.

##### C. **Hepatobiliary Cancers**

Authorization of 6 months may be granted for hepatobiliary cancers when the requested medication will be used as one of the following:

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1. In combination with cisplatin and gemcitabine to treat locally advanced, unresectable, or metastatic biliary tract cancer (gallbladder cancer, intrahepatic/extrahepatic cholangiocarcinoma) or for disease recurrence after surgery and adjuvant therapy.
2. First-line single agent treatment of unresectable or metastatic hepatocellular carcinoma.

#### 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 NSCLC 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; September 2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed September 6, 2022.