

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Non-small cell lung cancer (NSCLC) with **ONE** of the following
 - a. Resectable (tumors \geq 4 cm and/or node positive) NSCLC
 - i. Used in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi as a single agent as adjuvant treatment after surgery
 - ii. **NO** known EGFR mutations or ALK rearrangements
 - b. Unresectable, stage III NSCLC
 - i. Used as a single agent
 - ii. Disease has **NOT** progressed following concurrent platinum-based chemotherapy and radiation therapy
 - c. Metastatic NSCLC
 - i. **NO** sensitizing EGFR or ALK genomic tumor aberrations
 - ii. Used in combination with tremelimumab-actl and platinum-based chemotherapy
2. Limited-stage small cell lung cancer (LS-SCLC)
 - a. Used as a single agent
 - b. Disease has **NOT** progressed following concurrent platinum-based chemotherapy and radiation therapy
3. Extensive-stage small cell lung cancer (ES-SCLC)
 - a. Used in combination with etoposide and either carboplatin or cisplatin as first-line treatment followed by Imfinzi as a single agent
4. Locally advanced or metastatic biliary tract cancer (BTC)
 - a. Used in combination with gemcitabine and cisplatin followed by Imfinzi as a single agent
5. Unresectable hepatocellular carcinoma (uHCC)
 - a. Used in combination with tremelimumab-actl followed by Imfinzi as a single agent

6. Primary advanced or recurrent endometrial cancer
 - a. Mismatch repair deficient (dMMR) as determined by an FDA-approved test
 - b. Used in combination with carboplatin and paclitaxel followed by Imfinzi as a single agent
7. Muscle invasive bladder cancer (MIBC)
 - a. Used in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy

AND the following for **ALL** indications:

- a. Prescriber agrees to monitor for immune-mediated toxicities

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Non-small cell lung cancer (NSCLC) following resection
 - a. Used as a single agent
2. Metastatic non-small cell lung cancer (NSCLC)
 - a. Used in combination with platinum-based chemotherapy
3. Limited-stage small cell lung cancer (LS-SCLC)
 - a. Used as a single agent
4. Extensive-stage small cell lung cancer (ES-SCLC)
 - a. Used as a single agent
5. Locally advanced or metastatic biliary tract cancer (BTC)
 - a. Used as a single agent

6. Unresectable hepatocellular carcinoma (uHCC)
 - a. Used as a single agent
7. Primary advanced or recurrent endometrial cancer
 - a. Used as a single agent

AND the following for **ALL** indications:

- a. **NO** disease progression or unacceptable toxicity

Prior - Approval *Renewal* Limits

Duration 12 months

NO renewal for unresectable, stage III non-small cell lung cancer (NSCLC)

NO renewal for muscle invasive bladder cancer (MIBC)

ONE renewal for non-small cell lung cancer (NSCLC) following resection

ONE renewal for limited-stage small cell lung cancer (LS-SCLC)