# Durvalumab (Imfinzi®)

## IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

## POLICY

## 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 Indications

- Imfinzi, as a single agent, is indicated for the treatment of adult patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- Imfinzi, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- Imfinzi, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).
- Imfinzi, in combination with tremelimumab-actl, is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).
- Imfinzi, in combination with tremelimumab-actl and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- Imfinzi, in combination with carboplatin and paclitaxel followed by Imfinzi as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).
- Imfinzi, in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, is indicated for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
- Imfinzi, as a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- Imfinzi, in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC).

Compendial Uses

- Cervical Cancer

- Non-Small Cell Lung Cancer
- Small Cell Lung Cancer
- Ampullary Adenocarcinoma
- Pleural Mesothelioma
- Hepatocellular Carcinoma
- Esophageal and Esophagogastric Junction Cancer
- Gastric Cancer
- Biliary Tract Cancer
  - Intrahepatic Cholangiocarcinoma
  - Extrahepatic Cholangiocarcinoma
  - Gallbladder Cancer
- Bladder Cancer
- Endometrial carcinoma

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

**DOCUMENTATION**

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of the absence of EGFR exon 19 deletion and exon 21 L858R mutations, where applicable (unless testing is not feasible due to insufficient tissue).
- Documentation of the absence of ALK, RET, and ROS1 rearrangements, where applicable (unless testing is not feasible due to insufficient tissue).
- Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumor status, where applicable.

**EXCLUSIONS**

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

**COVERAGE CRITERIA**

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

Authorization of 6 months may be granted for treatment of NSCLC when any of the following criteria are met:

- The member has unresectable stage II or III NSCLC that has not progressed following concurrent platinum-based chemotherapy and radiation therapy and meets all of the following criteria:
  - The tumor is negative for EGFR exon 19 deletion and exon 21 L858R mutations
  - The requested medication will be used as a single agent
- The member has recurrent, advanced or metastatic NSCLC negative for EGFR exon 19 deletion and exon 21 L858R mutations and ALK, RET, and ROS1 rearrangements and meets either of the following criteria:
  - The requested medication will be used in combination with tremelimumab-actl (Imjudo) and platinum-based chemotherapy
  - The requested medication will be used as maintenance therapy as a single agent or in combination with pemetrexed

- The member has resectable NSCLC and meets all of the following criteria:
  - The requested medication will be used as neoadjuvant treatment in combination with platinum-containing chemotherapy and continued as adjuvant treatment after surgery as a single agent
  - The tumor is negative for EGFR exon 19 deletion and exon 21 L858R mutations and ALK, RET, and ROS1 rearrangements

**Small cell lung cancer (SCLC)**

Authorization of 6 months may be granted for treatment of small cell lung cancer when either of the following criteria is met:

- The requested medication will be used 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.
- The requested medication will be used for adjuvant consolidation therapy as a single agent for treatment of limited stage small cell lung cancer and the member did not experience disease progression after systemic therapy with concurrent radiation therapy.

**Cervical Cancer**

Authorization of 6 months may be granted for treatment of persistent, recurrent or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) when used in combination with etoposide and either cisplatin or carboplatin and continued as single agent maintenance therapy.

**Ampullary Adenocarcinoma**

Authorization of 6 months may be granted for first-line treatment of metastatic ampullary adenocarcinoma when both of the following criteria are met:

- The disease is pancreatobiliary or mixed type
- The requested medication will be used in combination with cisplatin and gemcitabine

**Pleural Mesothelioma**

Authorization of 6 months may be granted for first-line treatment of unresectable pleural mesothelioma when used in combination with pemetrexed and either cisplatin or carboplatin.

**Hepatocellular Carcinoma**

Authorization of 6 months may be granted for first-line treatment of hepatocellular carcinoma as a single agent or in combination with tremelimumab-actl (Imjudo) when both of the following criteria are met:

- The disease is unresectable or extrahepatic/metastatic
- The member is ineligible for transplant

Authorization of 6 months may be granted for subsequent treatment of unresectable or extrahepatic/metastatic hepatocellular carcinoma when either of the following criteria are met:

- The requested medication will be used as a single agent or
- The requested medication will be used in combination with tremelimumab-actl (Imjudo) and the member has not been previously treated with an anti-CTLA4-based regimen.

**Esophageal, Esophagogastric Junction and Gastric Cancer**

Authorization of 3 months for a total of 3 doses may be granted for treatment of esophageal, esophagogastric junction or gastric cancer when all of the following criteria are met:

- The requested medication will be used in combination with tremelimumab (Imjudo) for neoadjuvant treatment
- The tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR)
- The member is medically fit for surgery

**Endometrial Cancer**

Authorization of 6 months may be granted for treatment of advanced or recurrent endometrial cancer when all of the following criteria are met:

- The requested medication will be used in combination with carboplatin and paclitaxel followed by use as a single agent
- The tumor is deficient mismatch repair (dMMR)

**Biliary Tract Cancer**

Authorization of 6 months may be granted for treatment of biliary tract cancer when the requested medication will be used in combination with cisplatin or carboplatin and gemcitabine to treat locally advanced, locoregionally advanced, unresectable, gross residual (R2) disease, or metastatic biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, or gallbladder cancer) or for disease recurrence after surgery and adjuvant therapy.

**Bladder Cancer**

Authorization of 6 months may be granted for perioperative/sandwich treatment of stage II or IIIA bladder cancer when used in combination with gemcitabine and cisplatin prior to cystectomy followed by durvalumab after surgery.

**CONTINUATION OF THERAPY**

**NSCLC**

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for NSCLC when any of the following criteria are met:

- The member has unresectable stage II or III NSCLC and there is no evidence of unacceptable toxicity or disease progression while on the current regimen. (up to 12 months total)
- The member has recurrent, advanced or metastatic NSCLC and there is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- The member has resectable NSCLC and there is no evidence of unacceptable toxicity or disease progression while on the current regimen (up to 12 cycles after surgery).

**Limited Stage SCLC**

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for limited stage SCLC when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. (up to 24 months total).

**Esophageal, Esophagogastric Junction and Gastric Cancer**

Authorization of 3 months for a total of 3 doses may be granted for treatment of esophageal, esophagogastric junction or gastric cancer. Reauthorization may be granted only when the member did not receive a total of 3 doses from the initial approval.

**Bladder Cancer**

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for bladder cancer when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. (Up to 12 cycles)

**All other indications**

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

**MEDICATION QUANTITY LIMITS**

| Drug Name | Diagnosis | Maximum Dosing Regimen |
|---|---|---|
| Imfinzi (Durvalumab) | Ampullary Adenocarcinoma | Route of Administration: Intravenous<br>≤29kg<br>Initial: 20mg/kg every 3 weeks for up to 8 cycles<br>Maintenance: 20mg/kg every 4 weeks.<br><br>≥30kg<br>Initial: 1500mg every 3 weeks for up to 8 cycles<br>Maintenance: 1500mg every 4 weeks |
| Imfinzi (Durvalumab) | Biliary Tract Cancer: Gallbladder Cancer, Intrahepatic/Extrahepatic Cholangiocarcinoma | Route of Administration: Intravenous<br>≤29kg<br>Initial: 20mg/kg every 3 weeks for up to 8 cycles<br>Maintenance: 20mg/kg every 4 weeks.<br><br>≥30kg<br>Initial: 1500mg every 3 weeks for up to 8 cycles<br>Maintenance: 1500mg every 4 weeks. |
| Imfinzi (Durvalumab) | Cervical Cancer | Route of Administration: Intravenous<br>Initial: 1500mg every 3 weeks for 4 cycles<br>Maintenance: 1500mg every 4 weeks |
| Imfinzi (Durvalumab) | Endometrial Cancer | Route of Administration: Intravenous<br><30kg<br>Initial: 15mg/kg every 3 weeks for 6 doses<br>Maintenance: 20mg/kg every 4 weeks<br><br>≥30kg<br>Initial: 1120mg every 3 weeks for 6 doses<br>Maintenance: 1500mg every 4 weeks |

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|---|---|---|
| Imfinzi (Durvalumab) | Esophageal Cancer, Esophagogastric Junction Cancer, or Gastric Cancer | Route of Administration: Intravenous<br>1500mg every 4 weeks for 3 doses |
| Imfinzi (Durvalumab) | Hepatocellular Carcinoma | Route of Administration: Intravenous<br><29kg<br>20mg/kg every 4 weeks<br><br>≥30kg<br>1500mg every 4 weeks |
| Imfinzi (Durvalumab) | Non-Small Cell Lung Cancer (NSCLC) | Route of Administration: Intravenous<br>≤29kg<br>10mg/kg every 2 weeks<br>Initial: 20mg/kg every 3 weeks for 4 cycles<br>Maintenance: 20mg/kg every 4 weeks<br><br>≥30kg<br>10mg/kg every 2 weeks |
| Imfinzi (Durvalumab) | Non-Small Cell Lung Cancer or Small Cell Lung Cancer | Route of Administration: Intravenous<br>≥30kg<br>Initial: 1500mg every 3 weeks for 4 cycles<br>Maintenance: 1500mg every 4 weeks |
| Imfinzi (Durvalumab) | Pleural Mesothelioma | Route of Administration: Intravenous<br>1120mg every 3 weeks |
| Imfinzi (Durvalumab) | Small Cell Lung Cancer (SCLC) | Route of Administration: Intravenous<br><29kg<br>Initial: 20mg/kg every 3 weeks for 4 cycles, followed by<br>Maintenance: 10mg/kg every 2 weeks |

## APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

## ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

## REFERENCES

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3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com Accessed July 10, 2025.
4. Pietrantonio, Filippo, Raimondi Alessandra, Lonardi Sara, et al. Infinity: A multicenter, single-arm, multi-cohort, phase II trial of tremelimumab and durvalumab as neoadjuvant treatment of patients with microsatellite instability-high (MSI) resectable gastric or gastroesophageal junction adenocarcinoma (GAC/GEJAC). Journal of Clinical Oncology. 2023; 4: 358.
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7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Hepatocellular Carcinoma. Version 1.2025. Accessed July 22, 2025. https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf.

**EFFECTIVE DATE** 4/2/2026

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