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

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 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.
2. 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).
3. Imfinzi, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).
4. Imfinzi, in combination with tremelimumab-actl, is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).
5. 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.
6. 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).

B. Compendial Uses
1. Cervical Cancer
2. Non-Small Cell Lung Cancer
3. Small Cell Lung Cancer
4. Ampullary Adenocarcinoma
5. Pleural Mesothelioma
6. Hepatocellular Cancers
7. Esophageal and Esophagogastric Junction Cancer
8. Gastric Cancer
9. Biliary Tract Cancer
    a. Intrahepatic Cholangiocarcinoma
    b. Extrahepatic Cholangiocarcinoma
    c. Gallbladder Cancer

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

II. DOCUMENTATION

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

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

III. EXCLUSIONS

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

IV. CRITERIA FOR INITIAL APPROVAL

A. Non-small cell lung cancer (NSCLC)
Authorization of 6 months may be granted for treatment of NSCLC when either of the following criteria are met:

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

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. 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.

D. Ampullary Adenocarcinoma
Authorization of 6 months may be granted for first-line treatment of unresectable or metastatic ampullary adenocarcinoma when both of the following criteria are met:

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

E. 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.

F. Hepatocellular Carcinoma
Authorization of 6 months may be granted for treatment of hepatocellular carcinoma when either of the following criteria are met:

1. The requested medication will be used for first-line single agent treatment of unresectable/inoperable, metastatic, or extensive liver tumor burden hepatocellular carcinoma.
2. The requested medication will be used in combination with tremelimumab-actl (Imjudo) for first-line treatment of unresectable/inoperable, metastatic, or extensive liver tumor burden hepatocellular carcinoma.

G. 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:

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

H. 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:

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

I. 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 and gemcitabine to treat locally advanced, unresectable or resected 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.

V. CONTINUATION OF THERAPY

A. NSCLC

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

1. 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)**
2. The member has recurrent, advanced or metastatic NSCLC and there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

B. 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.

C. All other indications

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV 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 ≥30kg Initial: 1500mg every 3 weeks for 8 cycles, followed by Maintenance: 1500mg every 4 weeks <30kg Initial: 20mg/kg every 3 weeks for 8 cycles, followed by Maintenance: 20mg/kg every 4 weeks.
Imfinzi (Durvalumab)	Biliary Tract Cancer (Gallbladder Cancer, Intrahepatic/Extrahepatic Cholangiocarcinoma)	Route of Administration: Intravenous ≥30kg Initial: 1500mg every 3 weeks for up to 8 cycles, followed by Maintenance: 1500mg every 4 weeks. <30kg Initial: 20mg/kg every 3 weeks for 8 cycles, followed by Maintenance: 20mg/kg every 4 weeks.
Imfinzi (Durvalumab)	Cervical Cancer	Route of Administration: Intravenous 1500mg every 3 or 4 weeks
Imfinzi (Durvalumab)	Hepatocellular Carcinoma	Route of Administration: Intravenous ≥30kg 1500mg every 4 weeks <30kg 20mg/kg every 4 weeks
Imfinzi (Durvalumab)	Non-Small Cell Lung Cancer (NSCLC)	Route of Administration: Intravenous 10mg/kg every 2 weeks <30kg Initial: 20mg/kg every 3 weeks for 4 cycles, followed by Maintenance: 20mg/kg every 4 weeks
Imfinzi (Durvalumab)	Non-Small Cell Lung Cancer or Small Cell Lung Cancer	Route of Administration: Intravenous ≥30kg 1500mg every 3 or 4 weeks
Imfinzi (Durvalumab)	Small Cell Lung Cancer (SCLC)	Route of Administration: Intravenous <30kg Initial: 20mg/kg every 3 weeks for 4 cycles, followed by Maintenance: 10mg/kg every 2 weeks ≥30kg Initial: 1500mg every 3 weeks Maintenance: 1500mg every 3 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

1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2024.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 1, 2023.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com Accessed December 1, 2023.
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

EFFECTIVE DATE 10/31/2024

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