Medical Policy:

Imfinzi™ (durvalumab) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.40	April 1, 2025	

Definitions

Imfinzi™ is a programmed death ligand-1 (PD-L1) blocking antibody administered intravenously as immunotherapy.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Guideline

I. Initial

Imfinzi is considered medically necessary for members ≥ 18 years of age, when prescribed by an oncologist for the following indications:

1. **Non-Small Cell Lung Cancer (NSCLC)**
   - A. Unresectable Stage III **non-small cell lung cancer (NSCLC)** whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy*
   - B. 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 or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

C. In combination with tremelimumab-actl and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

2. **Small Cell Lung Cancer (ES-SCLC)**
   A. First-line treatment, extensive-stage **small cell lung cancer (ES-SCLC)** when given along with chemo that includes etoposide and either carboplatin or cisplatin*; **OR**
   B. 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 (cCRT).

3. **Biliary Tract Cancers**
   A. In combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).

4. **Hepatocellular Carcinoma**
   A. In combination with tremelimumab-actl is indicated for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).

5. **Endometrial Cancer**
   A. 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).

*= FDA-approved indication

++ = Compendia-recommended indication

II. Renewal Criteria

1. Renewal based upon all:
   A. Member continues to meet criteria above; **AND**
   B. Tumor response with stabilization of disease or decrease in tumor or tumor spread; **AND**
   C. Absence of unacceptable toxicity (i.e., immune-mediated adverse reactions, severe infections, severe infusion-related reactions, hepatitis, etc.)

Dosing and Administration

Please see Package Insert

Applicable Procedure Codes

Code	Description
J9173	Injection, durvalumab, 10mg, 1 billable unit = 10mg

Applicable NDCs

Code	Description

0310-4611-50	Durvalumab 500mg/10ml vial, 50 units
0310-4500-12	Durvalumab 120mg/2.4ml vial, 12 units

ICD-10 Diagnoses

Code	Description
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of other and unspecified parts of biliary tract
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C54.1	Malignant Neoplasm Of Endometrium
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
Z85.05	Personal history of malignant neoplasm of liver
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z92.3	Personal history of irradiation

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/01/2025	Annual Review: added: Small Cell Lung Cancer (ES-SCLC) As a single agent, is indicated for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose

<table>
<tr><td></td><td></td><td>disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (cCRT). Removed Limitations/Exclusions. Updated ICD-10 Codes.</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>8/30/2024</td><td>Revision: added: NSCLC: “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 or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.”
Added Endometrial Cancer indication and criteria</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>2/16/2024</td><td>Annual Review: No criteria changes</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>6/23/2023</td><td>Annual Review: Removed Criteria and codes for Urothelial Carcinoma and Bladder Cancer. Added Initial Criteria for Biliary Tract Cancers and Hepatocellular Cancers.
NSCLC Initial Criteria: Added “b. In combination with tremelimumab-actl and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.”
Added ICD-10 Codes:
<table>
<tr><td>C22.0</td><td>Liver cell carcinoma</td></tr>
<tr><td>C22.1</td><td>Intrahepatic bile duct carcinoma</td></tr>
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<tr><td>C7A.1</td><td>Malignant poorly differentiated neuroendocrine tumors</td></tr>
<tr><td>C78.00</td><td>Secondary malignant neoplasm of unspecified lung</td></tr>
<tr><td>C78.01</td><td>Secondary malignant neoplasm of right lung</td></tr>
<tr><td>C78.02</td><td>Secondary malignant neoplasm of left lung</td></tr>
<tr><td>C79.31</td><td>Secondary malignant neoplasm of brain</td></tr>
<tr><td>C79.51</td><td>Secondary malignant neoplasm of bone</td></tr>
<tr><td>C79.52</td><td>Secondary malignant neoplasm of bone marrow</td></tr>
<tr><td>Z85.118</td><td>Personal history of other malignant neoplasm of bronchus and lung</td></tr>
</table></td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>7/7/2022</td><td>Transferred policy to new template</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>04/06/2020</td><td>Added under covered indications: as first-line treatment, along with chemo that includes etoposide and either carboplatin or cisplatin, for adults who have extensive-stage small cell lung cancer (ES-SCLC).</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>01/01/2019</td><td>Added J9173 – effective January 1, 2019, Removed J3590, J9999, Added Applicable NDCs</td></tr>
</table>

References

1. Imfinzi [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; August 2019. Accessed December 2019.

2. Massard C, Gordon MS, Sharma S, et al. Safety and Efficacy of Durvalumab (MEDI4736), an Anti-Programmed Cell Death Ligand-1 Immune Checkpoint Inhibitor, in Patients With Advanced Urothelial Bladder Cancer. J Clin Oncol. 2016 Sep 10;34(26):3119-25.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) durvalumab. National Comprehensive Cancer Network, 2017. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2017.
4. Specialty matched clinical peer review.