

## Durvalumab (Imfinzi®)

### Place of Service

Office Administration  
Infusion Center Administration  
Outpatient Facility Administration  
Home Infusion

HCPCS: J9173 per 10 mg

### Condition listed in policy (see criteria for details)

- [Ampullary adenocarcinoma](#)
- [Biliary tract cancer](#)
- [Cervical cancer](#)
- [Esophageal and esophagogastric junction cancers](#)
- [Gastric cancer](#)
- [Hepatocellular carcinoma](#)
- [Non-small cell lung cancer](#)
- [Small cell lung cancer](#)

**AHFS therapeutic class:** Antineoplastic agent

**Mechanism of action:** Programmed death ligand-1 (PD-L1) blocking antibody

### **(1) Special Instructions and Pertinent Information**

**Covered under the Medical Benefit**, please submit clinical information for prior authorization review via fax.

### **(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for Imfinzi® (durvalumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

#### Ampullary adenocarcinoma

1. Disease is unresectable, advanced, or metastatic, **AND**
2. Subtype of pancreatobiliary/mixed type, **AND**
3. First-line treatment, **AND**
4. Used in combination with gemcitabine and cisplatin

#### **Covered Dose**

Weight less than 30 kg: Up to 20 mg/kg IV infusion every 3 weeks with cisplatin and gemcitabine for up to 8 cycles, followed by 20 mg/kg every 4 weeks as a single agent

Weight 30 kg or more: 1500 mg IV infusion every 3 weeks with cisplatin and gemcitabine for up to 8 cycles, followed by 1500 mg every 4 weeks as a single agent

#### **Coverage Period**

Indefinitely

#### **ICD-10:**

C24.1, Z85.09

**Biliary tract cancer (gallbladder cancer, intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma):**

1. Disease is locally advanced, recurrent, unresectable, resected gross residual (R2), or metastatic, **AND**
2. Being used in combination with cisplatin and gemcitabine

**Covered Dose**

Weight less than 30 kg: Up to 20 mg/kg IV infusion every 3 weeks with cisplatin and gemcitabine for up to 8 cycles, followed by 20 mg/kg every 4 weeks as a single agent

Weight 30 kg or more: 1500 mg IV infusion every 3 weeks with cisplatin and gemcitabine for up to 8 cycles, followed by 1500 mg every 4 weeks as a single agent

**Coverage Period**

Indefinitely

**ICD-10:**

C22.1, C23, C24.0, C24.8, C24.9

**Cervical cancer**

1. Diagnosis of small cell neuroendocrine carcinoma of the cervix (NECC), **AND**
2. Persistent, recurrent, or metastatic disease, **AND**
3. Being used in combination with an NCCN supported regimen (e.g., etoposide and either cisplatin or carboplatin)

**Covered Dose**

Weight less than 30 kg:

Cycle 1 to 4 (3-week cycle): Up to 1500 mg IV every 3 weeks with platinum-based chemotherapy

Cycle 5 and after (4-week cycle): Up to 1500 mg every 4 weeks thereafter

*\*The dosing interval changes from every 3 weeks to every 4 weeks starting at cycle 5.*

**Coverage Period**

Indefinite

**ICD-10:**

C53.0, C53.1, C53.8, C53.9

**Esophageal and esophagogastric junction cancers**

1. Being used as neoadjuvant immunotherapy, **AND**
2. Tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR), **AND**
3. Being used in combination with Imfinzi

**Covered Dose**

1,500 mg at Cycle 1/Day 1 with Imjudo, followed by Imfinzi as a single agent every 4 weeks for 12 weeks (3 doses)

**Coverage Period**

12 weeks

**ICD-10:**

C15.3-C15.5, C15.8, C15.9, C16.0, D37.8, D37.9, Z85.00, Z85.01

**Gastric cancer**

1. Being used as neoadjuvant immunotherapy, **AND**
2. Tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR), **AND**
3. Being used in combination with Imjudo

**Covered Dose**

1,500 mg at Cycle 1/Day 1 with Imjudo, followed by Imfinzi as a single agent every 4 weeks for 12 weeks (3 doses)

**Coverage Period**

12 weeks

**ICD-10:**

C16.0-C16.6, C16.8, C16.9, D37.1

**Hepatocellular carcinoma**

1. Either of the following:
  - a. Being used as a single agent, and all the following:
    - i. Being used for advanced, unresectable, or metastatic disease, **AND**
    - ii. Being used as first-line therapy
  - OR
  - b. For use in combination with Imjudo (tremelimumab-actl) for unresectable, inoperable, or metastatic disease

**Covered Dose**

Single-agent use:

1,500 mg IV given every 4 weeks

In combination with Imjudo:

Weight less than 30 kg: Imfinzi 20 mg/kg IV given in combination with Imjudo 4 mg/kg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks

Weight 30 kg or more: Imfinzi 1,500 mg IV given in combination with Imjudo 300 mg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks

**Coverage Period**

Indefinite

**ICD-10:**

C22.0, C22.8, C22.9

**Non-small cell lung cancer**

1. Disease is recurrent, advanced, unresectable, or metastatic **AND**
2. One of the following:
  - a. Being used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy, or

- b. Being used in combination with pemetrexed, or
- c. Being used as a single agent

### Covered Dose

#### Single-agent use:

Weight ≥ 30 kg: 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks

Weight < 30 kg: 10 mg/kg every 2 weeks

#### In combination with pemetrexed:

Weight less than 30 kg: Imfinzi 20 mg/kg IV with pemetrexed therapy every 4 weeks

Weight 30 kg or more: 1,500 mg IV with pemetrexed every 4 weeks

#### In combination with Imjudo and platinum-based chemotherapy:

##### Weight less than 30 kg:

Cycle 1 to 4 (3-week cycle): Imfinzi 20 mg/kg IV every 3 weeks with Imjudo 1 mg/kg and platinum-based chemotherapy

Cycle 5 and after (4-week cycle): Imfinzi 20 mg/kg with pemetrexed every 4 weeks, and a fifth dose of Imjudo 1 mg/kg in combination with Imfinzi dose 6 at week 16

*\*The dosing interval changes from every 3 weeks to every 4 weeks starting at cycle 5.*

##### Weight 30 kg or more:

Cycle 1 to 4 (3-week cycle): 1,500 mg IV every 3 weeks with Imjudo 75 mg and platinum-based chemotherapy

Cycle 5 and after (4-week cycle): Imfinzi 1,500 mg IV with pemetrexed every 4 weeks, and a fifth dose of Imjudo 75 mg in combination with Imfinzi dose 6 at week 16

*\*The dosing interval changes from every 3 weeks to every 4 weeks starting at cycle 5.*

### Coverage Period

Indefinite

### ICD-10:

C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92

### Small cell lung cancer

1. First-line therapy for extensive-stage disease, **AND**
2. Being used in combination with etoposide and either cisplatin or carboplatin

### Covered Dose

Weight less than 30 kg: Up to 20 mg/kg every 3 weeks with etoposide and either carboplatin or cisplatin, followed by 10 mg/kg every 2 weeks as a single agent

Weight 30 kg or more: 1500 mg every 3 weeks for 4 cycles with etoposide and either carboplatin or cisplatin, followed by 1500 mg every 4 weeks as a single agent

### Coverage Period

Indefinitely

### ICD-10:

C7A.1, C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, C78.00-C78.02, C79.31, C79.51, C79.52

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

PHP Medi-Cal

Durvalumab (Imfinzi®)

All requests for Imfinzi® (durvalumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

**(4) This Medication is NOT medically necessary for the following condition(s):**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How Supplied:

120 mg, 500 mg (single-dose vials)

**(6) References**

- AHFS®. Available by subscription at <http://www.lexi.com>
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Imfinzi® (durvalumab) [Prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 6/2023.
- National Comprehensive Cancer Network. Hepatobiliary Cancers (Volume 5.2022). Available at <http://www.nccn.org>
- National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Volume 3.2023). Available at <http://www.nccn.org>.
- National Comprehensive Cancer Network. Small Cell Lung Cancer (Volume 2.2022). Available at <http://www.nccn.org>.

**(7) Policy Update**

Date of last revision: 1Q2024

Date of next review: 3Q2024

Changes from previous policy version:

- New indications: Added coverage for neoadjuvant immunotherapy as primary combination treatment in certain gastric and esophageal and esophagogastric junction cancers. *Rationale: NCCN category 2A support*

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*