

## Imfinzi® (durvalumab) (Intravenous)

Document Number: IC-0301

Last Review Date: 07/02/2024

Date of Origin: 05/30/2017

Dates Reviewed: 05/2017, 08/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020, 09/2020, 12/2020, 03/2021, 04/2021, 06/2021, 09/2021, 12/2021, 03/2022, 06/2022, 09/2022, 10/2022, 12/2022, 03/2023, 06/2023, 09/2023, 12/2023, 03/2024, 07/2024

### I. Length of Authorization <sup>Δ 1</sup>

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers: Coverage will be provided for 3 doses
- Non-Small Cell Lung Cancer (NSCLC) (single-agent use as consolidation therapy): Coverage will be provided for 6 months and may be renewed up to a maximum of 12 months of therapy.\*

**\*Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.**

Dosing Frequency	Maximum length of therapy	Maximum number of doses
2 weeks	1 year	26 doses
4 weeks	1 year	13 doses

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- Imfinzi 120 mg/2.4 mL single-dose vial: 4 vials per 14 days
- Imfinzi 500 mg/10 mL single-dose vial: 2 vials per 14 days

#### B. Max Units (per dose and over time) [HCPCS Unit]:

- NSCLC, SCLC: 672 billable units (6,720 mg) every 84 days
- Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers: 150 billable units (1,500 mg) every 28 days for 3 doses
- Biliary Tract Cancers & Ampullary Adenocarcinoma: 150 billable units (1,500 mg) every 21 days x 8 doses, then 150 billable units (1,500 mg) every 28 days
- Hepatocellular Carcinoma: 150 billable units (1,500 mg) every 28 days

- Cervical Cancer: 150 billable units (1,500 mg) every 21 days x 4 doses, then 150 billable units (1,500 mg) every 28 days
- Endometrial Cancer: 112 billable units (1,120 mg) every 21 days x 6 doses, then 150 billable units (1,500 mg) every 28 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

#### Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, tislelizumab, etc.) unless otherwise specified <sup>Δ</sup>; **AND**

#### Non-Small Cell Lung Cancer (NSCLC) † ‡ <sup>1,3-5,16</sup>

- Patient has unresectable stage II-III disease; **AND**
  - Patient has a performance status (PS) of 0-1; **AND**
  - Used as a single agent as consolidation therapy; **AND**
  - Disease has not progressed after definitive concurrent or sequential chemoradiation; **OR**
- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Patients with tumors that are negative for actionable molecular biomarkers\*<sup>¶</sup> and PD-L1 ≥ 1% to 49%
      - Patients with PS of 0-1 who have tumors that are negative for actionable molecular biomarkers\*<sup>¶</sup> and PD-L1 < 1%
      - Patients with PS of 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2); **AND**
  - Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; **OR**
  - Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **OR**
  - Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **OR**

- Used as subsequent therapy; **AND**
  - Used for one of the following:
    - Patients with PS of 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement
    - Patients with PS of 0-1 who are positive for one of the following molecular biomarkers **AND** received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement; **AND**
  - Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; **OR**
  - Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **OR**
  - Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **OR**
- Used as continuation maintenance therapy in patients who have achieved a tumor response or stable disease following initial therapy; **AND**
  - Used as a single agent following a first-line regimen with durvalumab and tremelimumab plus chemotherapy; **OR**
  - Used in combination with pemetrexed following a first-line regimen with durvalumab, tremelimumab, pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology

*\* Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2) via repeat biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

¥ May also be used for patients with KRAS G12C mutation positive tumors

### **Small Cell Lung Cancer (SCLC) † ‡ Φ<sup>1,3,7,8,10</sup>**

- Patient has extensive stage disease (ES-SCLC); **AND**
  - Used as first-line therapy in combination with etoposide and either carboplatin or cisplatin; **OR**
  - Used as single-agent maintenance therapy after initial therapy with durvalumab, etoposide and either carboplatin or cisplatin

### **Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) † ‡ Φ<sup>1,3,14,18</sup>**

- Used in combination with cisplatin and gemcitabine; **AND**

- Used as primary treatment for unresectable, resected gross residual (R2), locally advanced, or metastatic disease; **OR**
- Used for recurrent disease >6 months after surgery with curative intent and >6 months after completion of adjuvant therapy; **OR**
- Used as subsequent treatment for progression on or after systemic treatment for unresectable, resected gross residual (R2), or metastatic disease; **OR**
- Used as neoadjuvant therapy for resectable locoregionally advanced disease (***\*\*NOTE: Only applies to Gallbladder Cancer***); **AND**
  - Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; **OR**
  - Patient has incidental finding on pathologic review (cystic duct node positive); **OR**
  - Patient has mass on imaging

#### **Hepatocellular Carcinoma † ‡ ◊<sup>1,3,11,12,15</sup>**

- Used as first-line therapy in combination with tremelimumab; **AND**
  - Patient has unresectable disease†; **OR**
  - Patient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy; **OR**
- Used as first-line therapy as a single agent; **AND**
  - Patient has liver-confined, unresectable disease and is deemed ineligible for transplant; **OR**
  - Patient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy

#### **Ampullary Adenocarcinoma ‡<sup>3</sup>**

- Used as first-line therapy in combination with gemcitabine and cisplatin; **AND**
- Patient has good performance status (i.e., ECOG 0-1, with good biliary drainage and adequate nutritional intake); **AND**
- Patient has pancreatobiliary or mixed type disease; **AND**
  - Patient has unresectable localized disease; **OR**
  - Patient has stage IV resected ampullary cancer; **OR**
  - Patient has metastatic disease at initial presentation

#### **Cervical Cancer ‡<sup>3,17</sup>**

- Patient has small cell neuroendocrine carcinoma of the cervix (NECC); **AND**
  - Used as first-line or subsequent therapy (if not used previously as first-line therapy) for persistent, recurrent, or metastatic disease; **AND**
    - Used in combination with etoposide and either cisplatin or carboplatin; **OR**

- Used as single-agent maintenance therapy after initial therapy with durvalumab, etoposide and either carboplatin or cisplatin

### Esophageal Cancer and Esophagogastric Junction Cancers ‡<sup>3,19,20</sup>

- Used as neoadjuvant therapy in combination with tremelimumab; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has adenocarcinoma; **AND**
- Used as primary treatment for patients who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease

### Gastric Cancer ‡<sup>3,19,20</sup>

- Used as neoadjuvant therapy in combination with tremelimumab; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has adenocarcinoma; **AND**
- Used as primary treatment for potentially resectable locoregional disease (cT2 or higher, any N) in patients who are medically fit for surgery

### Endometrial Cancer †<sup>1,21</sup>

- Patient has primary advanced or recurrent disease; **AND**
- Patient has mismatch repair deficient (dMMR) disease; **AND**
  - Used in combination with carboplatin and paclitaxel; **OR**
  - Used as single-agent maintenance therapy after initial therapy with durvalumab, carboplatin, and paclitaxel

❖ If confirmed using an FDA approved assay – <http://www.fda.gov/CompanionDiagnostics>

§ Genomic Aberration/Mutational Driver Targeted Therapies (Note: not all inclusive, refer to guidelines for appropriate use)			
EGFR exon 19 deletion or exon 21 L858R tumors	EGFR S768I, L861Q, and/or G719X mutation positive tumors	EGFR exon 20 insertion mutation positive tumors	NTRK1/2/3 gene fusion positive tumors
<ul style="list-style-type: none"> <li>– Afatinib</li> <li>– Erlotinib</li> <li>– Dacomitinib</li> <li>– Gefitinib</li> <li>– Osimertinib</li> <li>– Amivantamab</li> </ul>	<ul style="list-style-type: none"> <li>– Afatinib</li> <li>– Erlotinib</li> <li>– Dacomitinib</li> <li>– Gefitinib</li> <li>– Osimertinib</li> <li>– Amivantamab</li> </ul>	<ul style="list-style-type: none"> <li>– Amivantamab</li> </ul>	<ul style="list-style-type: none"> <li>– Larotrectinib</li> <li>– Entrectinib</li> </ul>
ALK rearrangement-positive tumors	ROS1 rearrangement-positive tumors	BRAF V600E-mutation positive tumors	ERBB2 (HER2) mutation positive tumors
<ul style="list-style-type: none"> <li>– Alectinib</li> <li>– Brigatinib</li> <li>– Ceritinib</li> <li>– Crizotinib</li> </ul>	<ul style="list-style-type: none"> <li>– Ceritinib</li> <li>– Crizotinib</li> <li>– Entrectinib</li> <li>– Lorlatinib</li> </ul>	<ul style="list-style-type: none"> <li>– Dabrafenib ± trametinib</li> <li>– Encorafenib + binimetinib</li> <li>– Vemurafenib</li> </ul>	<ul style="list-style-type: none"> <li>– Fam-trastuzumab deruxtecan-nxki</li> <li>– Ado-trastuzumab emtansine</li> </ul>

– Lorlatinib	– Repotrectinib		
PD-L1 tumor expression $\geq 1\%$	<i>MET</i> exon-14 skipping mutations	<i>RET</i> rearrangement-positive tumors	<i>KRAS</i> G12C mutation positive tumors
<ul style="list-style-type: none"> <li>– Pembrolizumab</li> <li>– Atezolizumab</li> <li>– Nivolumab + ipilimumab</li> <li>– Cemiplimab</li> <li>– Tremelimumab + durvalumab</li> </ul>	<ul style="list-style-type: none"> <li>– Capmatinib</li> <li>– Crizotinib</li> <li>– Tepotinib</li> </ul>	<ul style="list-style-type: none"> <li>– Selpercatinib</li> <li>– Cabozantinib</li> <li>– Pralsetinib</li> </ul>	<ul style="list-style-type: none"> <li>– Sotorasib</li> <li>– Adagrasib</li> </ul>

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

#### IV. Renewal Criteria <sup>Δ 1,3</sup>

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening infusion-related reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatology reactions, pancreatitis, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.; **AND**

##### NSCLC (single-agent use as consolidation therapy)

- Patient has not exceeded a maximum of 12 months of therapy

##### Continuation Maintenance Therapy for NSCLC

- *Refer to Section III for criteria*

##### Hepatocellular Carcinoma

- Cases for patients with HCC who use treatment as part of STRIDE and experience disease progression but who are clinically stable and still deriving clinical benefit will be reviewed on a case-by-case basis.

##### Continuation Maintenance Therapy for SCLC

- *Refer to Section III for criteria*

##### Esophageal Cancer and Esophagogastric Junction Cancers

- Coverage may not be renewed

##### Gastric Cancer

- Coverage may not be renewed

## Continuation Maintenance Therapy for Cervical Cancer

- Refer to Section III for criteria

## Continuation Maintenance Therapy for Endometrial Cancer

- Refer to Section III for criteria

### <sup>Δ</sup> Notes:

- Patients responding to therapy who relapse  $\geq 6$  months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress  $\geq 6$  months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

## V. Dosage/Administration <sup>Δ 1,7,8,12,17,18,20</sup>

Indication	Dose
Non-Small Cell Lung Cancer (NSCLC)	<p><u>Single agent:</u></p> <ul style="list-style-type: none"><li>• Weight <math>\geq 30</math> kg: Administer 10 mg/kg intravenously every 14 days OR 1,500 mg intravenously every 28 days until disease progression or unacceptable toxicity</li><li>• Weight <math>&lt; 30</math> kg: Administer 10 mg/kg intravenously every 14 days until disease progression or unacceptable toxicity</li><li>• <b><i>NOTE:</i></b> Use as consolidation therapy for unresectable stage II-III disease may continue up to a maximum of 12 months in patients without disease progression or unacceptable toxicity.</li></ul> <p><u>In combination with Tremelimumab* and Platinum-Based Chemotherapy§:</u></p> <ul style="list-style-type: none"><li>• Weight <math>\geq 30</math> kg: Administer 1,500 mg intravenously every 21 days x 5 cycles, followed by a maintenance dose of 1,500 mg every 28 days thereafter, until disease progression or unacceptable toxicity</li><li>• Weight <math>&lt; 30</math> kg: Administer 20 mg/kg intravenously every 21 days x 5 cycles, followed by a maintenance dose of 20 mg/kg every 28 days thereafter, until disease progression or unacceptable toxicity</li></ul> <p><b><i>*Note:</i></b> Refer to the Prescribing Information for tremelimumab dosing information</p> <p><b><i>§</i></b> If patients receive fewer than 4 cycles of platinum-based chemotherapy, the remaining cycles of tremelimumab (up to a total of 5) should be given after the platinum-based chemotherapy phase, in combination with durvalumab, every 4 weeks.</p>

Small Cell Lung Cancer (SCLC)	<p><u>Weight ≥30 kg:</u></p> <p>Administer 1,500 mg intravenously in combination with chemotherapy every 21 days x 4 cycles*, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</p> <p><u>Weight &lt;30 kg:</u></p> <p>Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days x 4 cycles*, followed by a maintenance dose of 10 mg/kg as a single agent every 14 days thereafter, until disease progression or unacceptable toxicity</p> <p><b>*Note:</b> <i>Patients may receive up to 2 additional cycles in combination with chemotherapy based on response and tolerability after the initial 4 cycles (6 cycles of combination therapy in total) <sup>8</sup></i></p>
Hepatocellular Carcinoma	<p><u>Single agent:</u></p> <p>Administer 1,500 mg intravenously every 4 weeks until disease progression or unacceptable toxicity</p> <p><u>STRIDE (Single Tremelimumab Regular Interval Durvalumab):</u></p> <ul style="list-style-type: none"> <li>• Weight ≥30 kg: Administer 1,500 mg intravenously following a single dose of tremelimumab* at Day 1 of Cycle 1, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</li> <li>• Weight &lt;30 kg: Administer 20 mg/kg intravenously following a single dose of tremelimumab* at Day 1 of Cycle 1, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</li> </ul> <p><b>*Note:</b> <i>Refer to the Prescribing Information for tremelimumab dosing information</i></p>
Biliary Tract Cancers	<p><u>Weight ≥30 kg:</u></p> <p>Administer 1,500 mg intravenously in combination with chemotherapy every 21 days for up to 8 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</p> <p><u>Weight &lt;30 kg:</u></p> <p>Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days for up to 8 cycles, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</p>
Ampullary Adenocarcinoma	Administer 1,500 mg intravenously in combination with gemcitabine and cisplatin every 21 days for up to 8 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity
Cervical Cancer	<u>Weight ≥30 kg:</u>

	<p>Administer 1,500 mg intravenously in combination with chemotherapy every 21 days x 4 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</p> <p><u>Weight &lt;30 kg:</u></p> <p>Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days x 4 cycles, followed by a maintenance dose of 10 mg/kg as a single agent every 14 days thereafter, until disease progression or unacceptable toxicity</p>
Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers	Administer 1,500 mg intravenously on Day 1, 29, 57 for 12 weeks preoperatively for 1 cycle only
Endometrial Cancer	<p><u>Weight &gt;30 kg:</u></p> <p>Administer 1,120 mg intravenously in combination with carboplatin and paclitaxel every 21 days for 6 cycles, followed by a maintenance dose of 1,500 mg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</p> <p><u>Weight &lt;30 kg:</u></p> <p>Administer 15 mg/kg intravenously in combination with carboplatin and paclitaxel 21 days for 6 cycles, followed by a maintenance dose of 20 mg/kg as a single agent every 28 days thereafter, until disease progression or unacceptable toxicity</p>

Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:

- Patient weight < 30 kg: Use 10 mg/kg dosing
- Patient weight ≥ 30 kg and <75 kg: Use 20 mg/kg dosing

Dosing (mg/kg)	Weight (kg)	Dose (mg)
20	<73	1340
	<72	1320
	<67	1220
	<66	1200
	<60	1100
	<59	1080
	<55	1000
	<53	980
	<52	960
	<47	860
	<46	840
	<40	740
	<39	720

		<34	620
		<33	600

- Patient weight  $\geq 75$  kg: Use 1500 mg flat dosing

*Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Patient-specific variables should be taken into account.*

## VI. Billing Code/Availability Information

### HCPCS Code:

- J9173 – Injection, durvalumab, 10 mg; 1 billable unit = 10 mg

### NDC(s):

- Imfinzi 120 mg/2.4 mL single-dose vial: 00310-4500-xx
- Imfinzi 500 mg/10 mL single-dose vial: 00310-4611-xx

## VII. References

1. Imfinzi [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; June 2024. Accessed June 2024.
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, 2024. 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 June 2024.
4. Antonia SJ, Villegas A, Daniel D, et al. Durvalumab after Chemoradiotherapy in Stage III Non-Small-Cell Lung Cancer. N Engl J Med. 2017 Sep 8.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 5.2024. National Comprehensive Cancer Network, 2024. 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 June 2024.
6. Gupta S, Sonpavde G, Grivas P, et al. Defining “platinum-ineligible” patients with metastatic urothelial cancer (mUC). J Clin Oncol. 2019 Mar 1;37(7\_suppl):451.
7. Paz-Ares L, Dvorkin M, Chen Y, et al. Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a

- randomised, controlled, open-label, phase 3 trial. *Lancet*. 2019 Nov 23;394(10212):1929-1939. Doi: 10.1016/S0140-6736(19)32222-6. Epub 2019 Oct 4.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Cell Lung Cancer. Version 3.2024. National Comprehensive Cancer Network, 2024. 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 June 2024.
  9. Powles T, O'Donnell PH, Massard C, et al. Efficacy and Safety of Durvalumab in Locally Advanced or Metastatic Urothelial Carcinoma: Updated Results From a Phase ½ Open-label Study. *JAMA Oncol*. 2017 Sep 14;3(9):e172411. Doi: 10.1001/jamaoncol.2017.2411. Epub 2017 Sep 14.
  10. Goldman JW, Dvorkin M, Chen Y, et al. Durvalumab, with or without tremelimumab, plus platinum-etoposide versus platinum-etoposide alone in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): updated results from a randomised, controlled, open-label, phase 3 trial. *Lancet Oncol*. 2021 Jan;22(1):51-65. Doi: 10.1016/S1470-2045(20)30539-8.
  11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hepatocellular Carcinoma. Version 1.2024. National Comprehensive Cancer Network, 2024. 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 June 2024.
  12. Abou-Alfa GK, Chan SL, Kudo M, et al. Phase 3 randomized, open-label, multicenter study of tremelimumab (T) and durvalumab (D) as first-line therapy in patients (pts) with unresectable hepatocellular carcinoma (uHCC): HIMALAYA. *Journal of Clinical Oncology* 2022 40:4\_suppl, 379-379.
  13. Govindan R, Aggarwal C, Antonia SJ, et al. Society for Immunotherapy of Cancer (SITC) clinical practice guideline on immunotherapy for the treatment of lung cancer and mesothelioma. *Journal for ImmunoTherapy of Cancer* 2022;10:e003956. Doi: 10.1136/jitc-2021-003956.
  14. Oh DY, He AR, Qin S, et al. A phase 3 randomized, double-blind, placebo-controlled study of durvalumab in combination with gemcitabine plus cisplatin (GemCis) in patients (pts) with advanced biliary tract cancer (BTC): TOPAZ-1. *J Clin Oncol*. 2022 Feb 1;40(4\_suppl):378-378.
  15. Abou-Alfa GK, Chan SL, Furuse J, et al. A randomized, multicenter phase 3 study of durvalumab (D) and tremelimumab (T) as first-line treatment in patients with unresectable hepatocellular carcinoma (HCC): HIMALAYA study. *Journal of Clinical Oncology* 36, no. 15\_suppl. DOI: 10.1200/JCO.2018.36.15\_suppl.TPS4144.
  16. Johnson ML, Cho BC, Luft A, et al; POSEIDON investigators. Durvalumab With or Without Tremelimumab in Combination With Chemotherapy as First-Line Therapy for Metastatic Non-Small-Cell Lung Cancer: The Phase III POSEIDON Study. *J Clin Oncol*. 2022 Nov 3;JCO2200975. doi: 10.1200/JCO.22.00975.

17. Paz-Ares L, Dvorkin M, Chen Y, et al; CASPIAN investigators. Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomised, controlled, open-label, phase 3 trial. *Lancet*. 2019 Nov 23;394(10212):1929-1939. doi: 10.1016/S0140-6736(19)32222-6.
18. Oh D-Y, Ruth He A, Qin S, et al. Durvalumab plus Gemcitabine and Cisplatin in Advanced Biliary Tract Cancer. *NEJM Evidence* 2022; 1:EVIDoa2200015. Available at <https://doi.org/10.1056/EVIDoa2200015>.
19. Kelly R, Lee J, Bang Y, et al. Safety and Efficacy of Durvalumab and Tremelimumab Alone or in Combination in Patients with Advanced Gastric and Gastroesophageal Junction Adenocarcinoma. *Clin Cancer Res*. 2020 Feb 15;26(4):846-854. doi: 10.1158/1078-0432.CCR-19-2443. Epub 2019 Nov 1. PMID: 31676670; PMCID: PMC7748730.
20. Raimondi A, Palermo F, Prisciandaro M, et al. Tremelimumab and Durvalumab Combination for the Non-Operative Management (NOM) of Microsatellite Instability (MSI)-High Resectable Gastric or Gastroesophageal Junction Cancer: The Multicentre, Single-Arm, Multi-Cohort, Phase II INFINITY Study. *Cancers (Basel)*. 2021 Jun 7;13(11):2839. doi: 10.3390/cancers13112839. PMID: 34200267; PMCID: PMC8201030.
21. Westin S, Moore K, Chon H, et al. Durvalumab Plus Carboplatin/Paclitaxel Followed by Maintenance Durvalumab With or Without Olaparib as First-Line Treatment for Advanced Endometrial Cancer: The Phase III DUO-E Trial. Publication: *Journal of Clinical Oncology* Volume 42, Number 3. <https://doi.org/10.1200/JCO.23.02132>

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type

### IMFINZI® (durvalumab) Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2024, Magellan Rx Management

**MagellanRx**  
MANAGEMENT™

ICD-10	ICD-10 Description
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
C33	Malignant neoplasm of trachea
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
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C7A.1	Malignant poorly differentiated neuroendocrine tumors
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs

ICD-10	ICD-10 Description
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.42	Personal history of malignant neoplasm of other parts of uterus

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC