Imfinzi® (durvalumab)
(Intravenous)

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Document Number: OHSU HEALTHSERVICES-0490

Date Reviewed: 11/2025
Date of Origin: 08/05/2019
Dates Approved: 08/2019, 10/2019, 01/2020, 04/2020, 07/2020, 10/2020, 01/2021, 04/2021, 07/2021, 10/2021, 01/2022, 05/2022, 07/2022, 10/2022, 01/2023, 04/2023, 07/2023, 10/2023, 01/2024, 05/2024, 08/2024, 10/2024, 11/2024, 12/2024, 02/04/2025, 05/05/2025, 06/05/2025, 06/24/2025, 08/05/2025, 11/04/2025, 12/02/2025

I. Length of Authorization Δ [1,23,26]

- Initial: Prior authorization validity will be provided initially for 6 months, unless otherwise specified.
  - Neoadjuvant treatment of Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancer in combination with tremelimumab: Prior authorization validity will be provided for 3 doses.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter, unless otherwise specified.
  - Non-Small Cell Lung Cancer (NSCLC) (single-agent use as consolidation therapy): Prior authorization validity may be renewed for up to a maximum of 12 months of therapy.*
  - Non-Small Cell Lung Cancer (NSCLC) (resectable disease): Prior authorization validity may be renewed for up to a maximum of 12 weeks of neoadjuvant therapy and 48 weeks of adjuvant therapy.*
  - Small Cell Lung Cancer (SCLC) (limited stage disease): Prior authorization validity may be renewed up to a maximum of 24 months of therapy.*
  - Bladder Cancer: Prior authorization validity may be renewed for up to a maximum of 12 weeks of neoadjuvant therapy and 32 weeks of adjuvant therapy.*
  - Gastric Cancer (in combination with FLOT followed by single agent): Prior authorization validity may be renewed for up to a maximum of 14 cycles of treatment (8 weeks of preoperative therapy, 8 weeks of postoperative therapy, and 40 weeks of continued therapy).*

- Esophageal and Esophagogastric Junction Cancers (in combination with FLOT followed by single agent): Prior authorization validity may be renewed for up to a maximum of 14 cycles of treatment (8 weeks of preoperative therapy, 8 weeks of postoperative therapy, and 40 weeks of continued therapy).*
- Prior authorization validity may NOT be renewed for the following indications:
  - ❖ Neoadjuvant treatment of Gastric Cancer in combination with tremelimumab
  - ❖ Neoadjuvant treatment of Esophageal and Esophagogastric Junction Cancers in combination with tremelimumab

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
3 weeks	12 weeks	4 doses
4 weeks	8 weeks	2 doses
	32 weeks	8 doses
	40 weeks	10 doses
	48 weeks	12 doses
	1 year	13 doses
	2 years	26 doses

II. Dosing Limits

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 Cancer: 150 billable units (1,500 mg) every 28 days for 14 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 Carcinoma: 112 billable units (1,120 mg) every 21 days x 6 doses, then 150 billable units (1,500 mg) every 28 days
- Bladder Cancer: 150 billable units (1,500 mg) every 21 days x 4 doses, then 150 billable units (1,500 mg) every 28 days for 8 doses

III. Initial Approval Criteria [1]

Prior authorization validity 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, unless otherwise specified [Δ]; **AND**

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,3-5,16,12e]

- Used as a single agent for consolidation therapy; **AND**
  - Patient has unresectable stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy †; **OR**
- Used as neoadjuvant therapy †; **AND**
  - Patient has resectable disease (tumors ≥4 cm or node positive); **AND**
  - Used in combination with platinum-containing chemotherapy and then continued as a single agent as adjuvant treatment after surgery; **AND**
  - Patient has no known EGFR mutations or ALK rearrangements; **OR**
- Used as adjuvant therapy †; **AND**
  - Used as a single agent following previous neoadjuvant durvalumab plus platinum-containing chemotherapy and surgery; **AND**
  - Patient has no known EGFR mutations or ALK rearrangements; **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* (may be KRAS G12C mutation positive) and PD-L1 ≥ 1% to 49%; **OR**
      - Patients who have tumors that are negative for actionable molecular biomarkers* (may be KRAS G12C mutation positive) and PD-L1 < 1%; **OR**
      - Patients who are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **AND**

➢ Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; **AND**

- **Squamous NSCLC:**

– Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

- **Nonsquamous NSCLC:**

– Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

➢ Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **AND**

– Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

➢ Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **AND**

– Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

- Used as subsequent therapy; **AND**
  - Used for one of the following:
    - Patients who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon-14 skipping; **OR**
    - Patients who are positive for one of the following molecular biomarkers AND received prior targeted therapy**§**: EGFR S768I, L861Q, and/or G719X mutation; **AND**

➢ Used in combination with tremelimumab, albumin-bound paclitaxel, and carboplatin; **AND**

- **Squamous NSCLC:**

– Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

- **Nonsquamous NSCLC:**

– Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

➢ Used in combination with tremelimumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **AND**

– Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

- Used in combination with tremelimumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **AND**

  - Use of durvalumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **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, NRG1, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2) via 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.*

- ***§** Genomic Aberration/Mutational Driver Targeted Therapies: Refer to guidelines for appropriate use*

Small Cell Lung Cancer (SCLC) † ‡ Φ [1,3,7,8,10,24]

- 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; **OR**
- Patient has limited stage disease (LS-SCLC); **AND**
  - Used as single agent therapy; **AND**
  - Used if disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy; **OR**
- Used as subsequent treatment if there is a prolonged disease free interval; **AND**
  - Patient has progressive or relapsed disease; **AND**
  - Used in combination with etoposide and either carboplatin or cisplatin, followed by single agent maintenance

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) † ‡ Φ [1,3,14,18]

- Used in combination with cisplatin (or carboplatin if ineligible for cisplatin) and gemcitabine; **AND**

- Used as primary treatment for unresectable, 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

Hepatocellular Carcinoma (HCC) † ‡ Φ [1,3,11,12,15]

- Patient does not have Child-Turcotte-Pugh (CTP) Class C liver disease; **AND**
  - Used in combination with tremelimumab; **AND**
    - Used as first-line therapy; **AND**
      - Patient has unresectable disease †; **OR**
      - Patient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy; **OR**
    - Used as subsequent therapy for progression on or after systemic therapy; **AND**
      - Patient has not received previous treatment with anti-CTLA4-based combinations; **AND**
      - Patient received previous treatment with sorafenib or lenvatinib, unless contraindicated; **OR**
  - Used as a single agent; **AND**
    - Used as first-line therapy; **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 ‡ [3]

- 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**
- Used for metastatic pancreatobiliary or mixed type disease

Cervical Cancer ‡ [3,17,27e]

- Patient has small cell neuroendocrine carcinoma of the cervix (NECC); **AND**
  - Used 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 Cancer ‡ [3,19,20,28]

- Patient has adenocarcinoma; **AND**

- Patient is medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **AND**
  - Used in combination with FLOT (Fluorouracil, leucovorin, oxaliplatin, and docetaxel) regimen; **AND**
    - Tumor expresses PD-L1 (CPS ≥ 1) or TAP ≥ 1% as determined by an FDA-approved or CLIA compliant test❖; **AND**
      - Used as induction therapy for relieving dysphagia; **OR**
      - Used as perioperative therapy as primary treatment; **OR**
      - Used as postoperative management following R0 resection in patients who have received preoperative therapy with the same regimen; **OR**
  - Used in combination with tremelimumab as neoadjuvant primary immunotherapy; **AND**
    - Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖

Gastric Cancer ‡ [3,19,20,28]

- Used as neoadjuvant immunotherapy 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; **OR**
- Used as perioperative systemic therapy in combination with FLOT (fluorouracil, leucovorin, oxaliplatin, and docetaxel); **AND**
  - Patient has PD-L1 CPS ≥ 1 or TAP ≥ 1% 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 (stage II or higher) in patients who are medically fit for surgery; **OR**
    - Used as postoperative management following R0 resection in patients who have received systemic therapy

Uterine Neoplasms – Endometrial Carcinoma † ‡ [1,21]

- Patient has mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used in combination with carboplatin and paclitaxel, and continued as single agent maintenance therapy; **AND**
  - Used for primary advanced stage III-IV disease †; **OR**

- Used as adjuvant treatment for stage III-IV endometrioid adenocarcinoma; **OR**
- Used as first-line therapy for recurrent disease ‡

Urothelial Carcinoma (Bladder Cancer) † ‡ [1,3,25,26]

- Patient has muscle invasive bladder cancer (MIBC); **AND**
- Patient has stage II (cT2, N0) or IIIA (cT3, N0; cT4a, N0; cT1-4a, N1) disease; **AND**
  - Used in combination with cisplatin and gemcitabine as neoadjuvant therapy prior to cystectomy; **OR**
  - Used as a single-agent as adjuvant therapy following cystectomy; **AND**
    - Patient received initial therapy with durvalumab, cisplatin, and gemcitabine

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

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

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

IV. Renewal Criteria Δ [1,3]

- Prior authorization validity 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**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread λ; **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.

    - λ **Hepatocellular Carcinoma (HCC)** [27]

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

Δ **Notes:**

- Patients responding to therapy who relapse ≥ 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 ≥ 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 Δ [1,7,8,12,17-18,20,23,26,28]

Indication	Dose
Non-Small Cell Lung Cancer (NSCLC)	**Single Agent as Consolidation Therapy:** • Weight ≥30 kg: Administer 10 mg/kg intravenously every 14 days OR 1,500 mg intravenously every 28 days until disease progression, unacceptable toxicity, or a maximum of 12 months • Weight <30 kg: Administer 10 mg/kg intravenously every 14 days until disease progression, unacceptable toxicity, or a maximum of 12 months **Neoadjuvant and Adjuvant Therapy for Resectable Disease** Neoadjuvant Therapy: • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy* every 21 days for up to 4 cycles prior to surgery or until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy* every 21 days for up to 4 cycles prior to surgery or until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity

	Adjuvant Therapy: • Weight ≥30 kg: Administer 1,500 mg intravenously as a single agent every 28 days for up to 12 cycles after surgery or until recurrence or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously as a single agent every 28 days for up to 12 cycles after surgery or until recurrence or unacceptable toxicity ***Note:** Refer to the Prescribing Information for the agent used in combination with Imfinzi dosing information.* **In Combination with Tremelimumab* and Platinum-Based Chemotherapy§:** • Weight ≥30 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 • Weight <30 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 ***Note:** Refer to the Prescribing Information for tremelimumab dosing information* ***§** 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.*
Small Cell Lung Cancer (SCLC)	**Extensive Stage Disease:** • Weight ≥30 kg: 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 • Weight <30 kg: 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 ***Note**: 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)* [8] **Limited Stage Disease:** • Weight ≥30 kg: Administer 1,500 mg intravenously every 4 weeks until disease progression, unacceptable toxicity, or a maximum of 24 months • Weight <30 kg: Administer 20 mg/kg intravenously every 4 weeks until disease progression, unacceptable toxicity, or a maximum of 24 months
Hepatocellular Carcinoma (HCC)	**Single Agent:** Administer 1,500 mg intravenously every 4 weeks until disease progression or unacceptable toxicity **STRIDE (Single Tremelimumab Regular Interval Durvalumab):**

	• 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 • Weight <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 ***Note:** Refer to the Prescribing Information for tremelimumab dosing information*
Biliary Tract Cancers	• Weight ≥30 kg: 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 • Weight <30 kg: 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
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	**Weight ≥30 kg:** 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 **Weight <30 kg:** 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
Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancer	**Neoadjuvant treatment in combination with tremelimumab:** Administer 1,500 mg intravenously on Days 1, 29, and 57 of a 12-week cycle preoperatively for 1 cycle only **In combination with FLOT (fluorouracil, leucovorin, oxaliplatin, and docetaxel):** Administer 1,500 mg intravenously in combination with chemotherapy every 28 days for 2 cycles preoperatively and 2 cycles postoperatively (total 4 cycles), followed by 1,500 mg as a single agent every 4 weeks for 10 additional cycles
Endometrial Carcinoma	**Weight ≥30 kg:** 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 **Weight <30 kg:**

	Administer 15 mg/kg intravenously in combination with carboplatin and paclitaxel every 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
Urothelial Carcinoma (Bladder Cancer)	**Neoadjuvant Therapy:** • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy* every 21 days for 4 cycles prior to surgery or until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy* every 21 days for 4 cycles prior to surgery or until disease progression that precludes definitive surgery, recurrence, or unacceptable toxicity **Adjuvant Therapy:** • Weight ≥30 kg: Administer 1,500 mg intravenously as a single agent every 28 days for up to 8 cycles after surgery or until recurrence or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously as a single agent every 28 days for up to 8 cycles after surgery or until recurrence or unacceptable toxicity ***Note:** Refer to the Prescribing Information for the agents used in combination with Imfinzi dosing information.*

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 ≥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 (STANDARD)

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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 1.2025. National Comprehensive Cancer Network, 2025. 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 September 2025.
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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder
C7A.1	Malignant poorly differentiated neuroendocrine tumors
D09.0	Carcinoma in situ of bladder
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
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
Z85.12	Personal history of malignant neoplasm of trachea
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