Imfinzi® (durvalumab)
(Intravenous)

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

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
  - Neoadjuvant treatment of Gastric Cancer, Esophageal Cancer and Esophagogastric Junction Cancers in combination with tremelimumab: Prior authorization validity will be provided for 3 doses.
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) 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.*
  - Non-Muscle Invasive Bladder Cancer (NMIBC): Prior authorization validity may be renewed for up to 1 year (52 weeks) of therapy.*
  - Muscle Invasive Bladder Cancer (MIBC): 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, 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 neoadjuvant/induction therapy, 8 weeks of adjuvant therapy, and 40 weeks of continued therapy).*
  - Prior authorization validity may NOT be renewed for the following indications:
    - Neoadjuvant treatment of Gastric Cancer, Esophageal and Esophagogastric Junction Cancers in combination with tremelimumab
    - Neoadjuvant treatment of Gallbladder Cancer

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

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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 Cancers: 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, Small Bowel Adenocarcinoma, Colon Cancer, and Rectal Cancer: 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
- Uterine Neoplasms – 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 9 doses

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

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

Universal Criteria

- Member 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]

- Used as a single agent for consolidation therapy; **AND**
  - Member has unresectable stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy **†**; **OR**
  - Member has unresectable stage II disease; **AND**

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        - Member has performance status (PS) of 0-1; **AND**
        - Disease has not progressed after definitive concurrent or sequential chemoradiation; **AND**
        - Member does not have EGFR exon 19 deletion or L858R mutations; **OR**
- Used as neoadjuvant therapy **†**; **AND**
    - Member 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**
    - Member has no known EGFR mutations or ALK rearrangements; **OR**
- Used adjuvant therapy **†**; **AND**
    - Used as a single agent following previous neoadjuvant durvalumab plus chemotherapy and surgery; **AND**
    - Member has no known EGFR mutations or ALK rearrangements; **OR**
- Member 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:
            - Members with tumors that are negative for actionable biomarkers***** (may be KRAS G12C mutation positive) and PD-L1 ≥ 1% to 49%; **OR**
            - Members who have tumors that are negative for actionable biomarkers***** (may be KRAS G12C mutation positive) and PD-L1 < 1%; **OR**
            - Members who are positive for one of the following 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; **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:
            - Members who are positive for one of the following biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon 14 skipping or ERBB2 (HER2); **OR**
            - Members who are positive for one of the following biomarkers AND received prior targeted therapy**§**: EGFR S768I, L861Q, and/or G719X mutation; **AND**

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- 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 members 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 biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2). Complete biomarker testing including molecular assessment of 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 members 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 [1,3,7,8,10,24,30]

- Member 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**
- Member 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**
  - Member has progressive or relapsed disease; **AND**
  - Used in combination with etoposide and either carboplatin or cisplatin, followed by single agent maintenance

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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; **OR**
  - Used as subsequent treatment for progression on or after systemic treatment for unresectable, gross residual (R2), or metastatic disease; **OR**
  - Used as neoadjuvant therapy for resectable locoregionally advanced disease *(**NOTE: Only applies to Gallbladder Cancer)*; **AND**
    - Member has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; **OR**
    - Member has incidental finding on pathologic review (cystic duct node positive); **OR**
    - Member has mass on imaging

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

- Used in combination with tremelimumab; **AND**
  - Used as first-line therapy; **AND**
    - Member has unresectable disease **†**; **OR**
    - Member 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**
    - Member has not received previous treatment with anti-CTLA4-based combinations; **OR**
- Used as a single agent; **AND**
  - Used as first-line therapy; **AND**
    - Member has liver-confined, unresectable disease and is deemed ineligible for transplant; **OR**
    - Member 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

Ampullary Adenocarcinoma ‡ [3]

- Used as first-line therapy in combination with gemcitabine and cisplatin; **AND**
- Member has good performance status (ECOG PS 0-1 with good biliary drainage and adequate nutritional intake) or intermediate performance status (ECOG PS 2); **AND**
- Used for metastatic pancreatobiliary or mixed type disease

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Cervical Cancer ‡ [3,17]

- Member 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 † ‡ Φ [1,3,19,20,28]

- Member has adenocarcinoma; **AND**
  - Used in combination with FLOT (fluorouracil, leucovorin, oxaliplatin, and docetaxel); **AND**
    - Used as induction therapy for relieving dysphagia; **AND**
      - Member 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**
        - Tumor expresses PD-L1 (CPS ≥ 1) or TAP ≥ 1% as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test❖; **OR**
    - Used as neoadjuvant and adjuvant therapy; **OR**
  - Used as a single-agent; **AND**
    - Used as adjuvant therapy following resection and previous adjuvant use in combination with FLOT; **OR**
  - Used in combination with tremelimumab as neoadjuvant immunotherapy; **AND**
    - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used as primary treatment for members 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 † ‡ Φ [1,3,19,20,28]

- Member has adenocarcinoma; **AND**
  - Used as neoadjuvant immunotherapy in combination with tremelimumab; **AND**
    - Member has MSI-H or dMMR disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used as primary treatment for potentially resectable locoregional disease (cT2 or higher, any N) in members who are medically fit for surgery; **OR**
  - Used in combination with FLOT (fluorouracil, leucovorin, oxaliplatin, and docetaxel); **AND**
    - Used as neoadjuvant and adjuvant therapy; **OR**

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- Used as a single-agent; **AND**
  - Used as adjuvant therapy following resection and previous adjuvant use in combination with FLOT

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

- Member has 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 or recurrent disease †; **OR**
  - Used as primary treatment for stage III-IV tumors ‡; **OR**
  - Used as adjuvant treatment for stage III-IV tumors ‡; **OR**
  - Used as first-line or subsequent therapy for recurrent disease ‡; **AND**
    - Will not be used for either of the following:
      - ➢ Therapy for locoregional recurrence in members with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**
      - ➢ Therapy after surgical exploration for locoregional recurrence in members with disease confined to the vagina or paravaginal soft tissue

Urothelial Carcinoma (Bladder Cancer) † ‡ [1,3,25,26,34]

- Member has non-muscle invasive bladder cancer (NMIBC); **AND**
  - Member has high-risk disease with one of the following: T1 tumor, Grade 3/high-grade tumor, carcinoma in situ (CIS), or multiple, recurrent, large tumors; **AND**
  - Used in combination with Bacillus Calmette-Guérin (BCG) in members who are BCG-naïve; **OR**
- Member has muscle invasive bladder cancer (MIBC); **AND**
  - Member 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**
      - ➢ Member received initial therapy with durvalumab, cisplatin, and gemcitabine

Small Bowel Adenocarcinoma ‡ [3,31]

- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as single agent treatment; **AND**
  - Member has advanced or metastatic disease; **OR**
  - Member has locally unresectable or medically inoperable disease; **AND**

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- Used as primary treatment

Colon Cancer ‡ [3,32]

- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent for locally unresectable, medically inoperable, advanced or metastatic disease

Rectal Cancer ‡ [3,33]

- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent for locally unresectable, medically inoperable, advanced or metastatic disease

❖ *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:

- Member 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 members 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:

- Members responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Members previously presenting with aggressive disease who are exhibiting stable disease on treatment as

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their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.

- Members who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Members 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 [1,7,8,12,17-18,20,23,26,28,30-33]

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*

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	§ If members 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 or Subsequent Treatment:** • 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: Members 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	**Neoadjuvant Therapy (Gallbladder Cancer only):** • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with chemotherapy every 21 days for 2 to 6 months • Weight <30 kg: Administer 20 mg/kg intravenously in combination with chemotherapy every 21 days for 2 to 6 months **All other treatment settings:** • 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

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	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 Cancers	**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 **Neoadjuvant Therapy (including induction therapy*) in combination with FLOT (fluorouracil, leucovorin, oxaliplatin, and docetaxel):** • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with FLOT every 28 days for up to 2 cycles prior to surgery or until disease progression that precludes definitive surgery or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously in combination with FLOT every 28 days for up to 2 cycles prior to surgery or until disease progression that precludes definitive surgery or unacceptable toxicity ***Note:** Induction therapy applies only to Esophageal and Esophagogastric Junction Cancers.* **Adjuvant Therapy in combination FLOT (fluorouracil, leucovorin, oxaliplatin, and docetaxel) followed by single agent durvalumab:** • Weight ≥30 kg: Administer 1,500 mg intravenously in combination with FLOT for up to 2 cycles postoperatively, followed by 1,500 mg as a single agent every 28 days for up to 10 cycles (maximum of 12 cycles after surgery) or until progression, recurrence or unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously in combination with FLOT for up to 2 cycles postoperatively, followed by 20 mg/kg as a single agent every 28 days for up to 10 cycles (maximum of 12 cycles after surgery) or until progression, recurrence or unacceptable toxicity
Uterine Neoplasms - 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

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	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)	**Non-Muscle Invasive Bladder Cancer (NMIBC):** • Weight ≥30 kg: Administer 1,500 mg intravenously as a single agent every 28 days for up to 13 cycles in combination with BCG* induction and maintenance, or until recurrence of high-risk disease, disease progression, unacceptable toxicity • Weight <30 kg: Administer 20 mg/kg intravenously as a single agent every 28 days for up to 13 cycles in combination with BCG* induction and maintenance, or until recurrence of high-risk disease, disease progression, unacceptable toxicity ***Note:** Refer to the Prescribing Information for the agents used in combination with Imfinzi dosing information* **Muscle Invasive Bladder Cancer (MIBC):** 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.*
Small Bowel Adenocarcinoma, Colon Cancer, Rectal Cancer	Administer 1,500 mg intravenously every 28 days until disease progression or unacceptable toxicity
Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the	

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following:

- Member weight < 30 kg: Use 10 mg/kg dosing
- Member 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

- Member 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. Member-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; May 2026. Accessed June 2026.
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.

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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
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

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ICD-10	ICD-10 Description
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
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

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ICD-10	ICD-10 Description
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
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
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct

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ICD-10	ICD-10 Description
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
Z85.068	Personal history of other malignant neoplasm of small intestine
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		
Jurisdictio	**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

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
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

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