Clinical Policy: Durvalumab (Imfinzi)

Reference Number: PA.CP.PHAR.339
Effective Date: 01/2018
Last Review Date: 04/2026

Description
Durvalumab (Imfinzi®) is a programmed death-ligand 1 (PD-L1) blocking antibody.

FDA approved indication
Imfinzi is indicated:

- Non-small cell lung cancer (NSCLC):
  - In combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements
  - As a single agent for the treatment of adult patients with unresectable, stage IIINSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
  - In combination with tremelimumab-actl (Imjudo®) and platinum-based chemotherapy, for the treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations.
- Small cell lung cancer (SCLC):
  - As a single agent, for the treatment of adult patients with limited-stage SCLC (LS-SCLS) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
  - In combination with etoposide and either carboplatin or cisplatin as first-line treatment of adults patients with extensive-stage SCLC (ES-SCLC).
- In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).
- In combination with tremelimumab-actl (Imjudo®) as treatment of adults patients with unresectable hepatocellular carcinoma (HCC).
- In combination with carboplatin and paclitaxel followed by Imfinzi as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) as determined by an FDA-approved test.
- Bladder cancer:
  - In combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC).
  - In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer (MIBC).
- In combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel as neoadjuvant and adjuvant treatment, followed by single-agent Imfinzi, for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of PA Health & Wellness® that Imfinzi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a-e):
   a. Disease is unresectable, stage II-III, and all of the following (i, ii, and iii):
      i. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (RT);
      ii. Prescribed as a single agent;
      iii. Disease does not have EGFR exon 19 deletion or L858R mutation;
   b. Disease is recurrent, advanced or metastatic and Imfinzi is prescribed in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy as one of the following (i-ix);
      i. First-line therapy for disease without EGFR exon 19 deletion, EGFR exon 21 L858R mutation,ALK, RET, or ROS1 gene fusion, or other actionable molecular biomarkers (e.g., KRAS, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, ERBB2 (HER2) – note: may be KRAS G12C mutation positive) (see *Appendix E)*;
      ii. First-line therapy for EGFR exon 20 mutation positive disease;
      iii. First-line or subsequent therapy for BRAF V600E mutation positive tumors;
      iv. First-line or subsequent therapy for NRTK1/2/3 gene fusion positive tumors;
      v. First-line or subsequent therapy for MET exon 14 skipping mutation positive tumors;
      vi. First-line or subsequent therapy for RET rearrangement positive tumors;
      vii. First-line therapy for ERBB2 (HER2) mutation positive tumors;
      viii. First-line therapy for NRG1 gene fusion positive tumors;
      ix. Subsequent therapy for EGFR S768I, L861Q, and/or G719X mutation positive tumors and prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib therapy;
   c. Prescribed as continuation maintenance therapy for recurrent, advanced, or metastatic disease that is negative for actionable molecular biomarkers (may be KRAS G12C mutation positive) and no contraindications to PD-1 or PD-L1 inhibitors (see *Appendix D*), and performance status 0-2, that achieved tumor response or stable disease following initial systemic therapy with one of the following (i or ii):

i. Imfinzi/Imjudo/pemetrexed with either carboplatin or cisplatin for nonsquamous cell histology, and Imfinzi for maintenance therapy is prescribed in combination with pemetrexed (off-label);
ii. Imfinzi/Imjudo plus chemotherapy, and Imfinzi for maintenance therapy is prescribed a single agent (off-label);

d. Prescribed as neoadjuvant therapy in combination with platinum-containing chemotherapy, followed by use as a single agent either after surgery as adjuvant therapy or after completion of adjuvant chemoradiation, for disease that meets both of the following (i and ii):
i. Resectable (tumors ≥ 4 cm and/or node positive);
ii. No known EGFR or ALK mutations;

e. Other NCCN category 1, 2A or 2B recommendation;

5. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a-d):
a. For unresectable, stage II-III disease (i or ii):
i. For body weight < 30 kg: dose does not exceed 10 mg/kg every 2 weeks;
ii. For body weight ≥ 30 kg: dose does not exceed 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks;

b. For metastatic disease (i or ii):
i. For body weight < 30 kg: dose does not exceed Imfinzi 20 mg/kg every 3 weeks in combination with Imjudo 1 mg/kg and platinum-based chemotherapy, and then Imfinzi 20 mg/kg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo 1 mg/kg in combination with Imfinzi dose 6 at Week 16;
ii. For body weight ≥ 30 kg: dose does not exceed Imfinzi 1,500 mg every 3 weeks in combination with Imjudo75 mg and platinum-based chemotherapy for 4 cycles, and then Imfinzi 1,500 mg every 4 weeks as a single agent with histology-based pemetrexed maintenance therapy every 4 weeks, and a fifth dose of Imjudo 75 mg in combination with Imfinzi dose 6 at Week 16;

c. For resectable disease (i and ii):
i. Neoadjuvant therapy (1 or 2):
1) For body weight < 30 kg: Dose does not exceed Imfinzi 20 mg/kg every 3 weeks in combination with chemotherapy for up to 4 cycles prior to surgery;
2) For body weight ≥ 30 kg: Dose does not exceed Imfinzi 1,500 mg every 3 weeks in combination with chemotherapy for up to 4 cycles prior to surgery;
ii. Adjuvant therapy (1 or 2):
1) For body weight < 30 kg: Dose does not exceed 20 mg/kg every 4 weeks as a single agent for up to 12 cycles after surgery;
2) For body weight ≥ 30 kg: Dose does not exceed 1,500 mg every 4 weeks as a single agent for up to 12 cycles after surgery;

d. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Extensive-Stage Small Cell Lung Cancer (must meet all):
1. Diagnosis of ES-SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed with etoposide and either carboplatin or cisplatin followed by maintenance with Infimzi as a single agent, for one of the following uses (a or b):
   a. First-line treatment;
   b. Subsequent treatment for progression or relapse if member had prolonged disease free time (off-label);
5. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a, b, or c):
   a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy for 4 cycles, then 10 mg/kg every 2 weeks as a single agent;
   b. For body weight ≥ 30 kg, dose does not exceed 1500 mg every 3 weeks in combination with chemotherapy for 4 cycles, then 1500 mg every 4 weeks as a single agent;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

C. Limited-Stage Small Cell Lung Cancer (must meet all):
1. Diagnosis of LS-SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Both of the following (i and ii):
      i. Prescribed as a single agent;
      ii. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy;
   b. Both of the following (i and ii) (off-label):
      i. Prescribed with etoposide and either carboplatin or cisplatin, followed by maintenance with Imfinzi as a single agent;
      ii. Prescribed as subsequent treatment for progression or relapse if member had prolonged disease free time;
5. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a, b, or c):
   a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks;
   b. For body weight ≥ 30 kg, dose does not exceed 1500 mg every 4 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

D. Biliary Tract Cancer (must meet all)**:**
1. Diagnosis of locally advanced, unresectable, resected gross residual (R2), resectable locoregionally advanced disease, recurrent (> 6 months after surgery with curative intent and/or completion of adjuvant therapy), or metastatic BTC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with gemcitabine and cisplatin or carboplatin if ineligible for cisplatin;
5. Request meets one of the following (a, b, or c):
   a. For body weight < 30 kg, dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy, then 20 mg/kg every 4 weeks as a single agent;
   b. For body weight ≥ 30 kg, dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy, then 1,500 mg every 4 weeks as a single agent;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

E. Hepatocellular Carcinoma (must meet all)**:**
1. Diagnosis of hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in one of the following ways (a or b):
   a. First-line therapy for unresectable, liver-confined, or extrahepatic/metastatic disease;
   b. Subsequent-line therapy following progression on or after systemic therapy;
5. Prescribed as a single agent or in combination with Imjudo;
6. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a, b, or c):
   a. For body weight < 30 kg: dose does not exceed Imfinzi 20 mg/kg in combination with Imjudo4 mg/kg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks;
   b. For body weight ≥ 30 kg: dose does not exceed Imfinzi 1,500 mg in combination with Imjudo300 mg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks;
   c. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

F. Endometrial Cancer (must meet all)**:**
1. Diagnosis of primary advanced, recurrent, metastatic, stage III, or stage IV endometrial cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Disease is dMMR, and (i):

i. Prescribed in combination with carboplatin and paclitaxel, followed by maintenance with Imfinzi as a single agent;
b. Disease is mismatch repair proficient (pMMR) (off-label), and (i):
i. Prescribed in combination with carboplatin and paclitaxel, followed by maintenance with Imfinzi in combination with Lynparza®;
5. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a, b, or c):
a. For body weight < 30 kg: Dose does not exceed 15 mg/kg every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles, then 20 mg/kg every 4 weeks as a single agent;
b. For body weight ≥ 30 kg: Dose does not exceed 1,120 mg every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles, then 1,500 mg every 4 weeks as a single agent;
c. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

G. Muscle Invasive Bladder Cancer (must meet all)**:**
1. Diagnosis of MIBC;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Prescribed as neoadjuvant therapy in combination with gemcitabine and cisplatin, followed by use as adjuvant therapy as a single agent after radical cystectomy;
5. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a, b, or c):
a. For body weight < 30 kg: Dose does not exceed (i and ii):
i. Neoadjuvant: Imfinzi 20 mg/kg in combination with gemcitabine and cisplatin every 3 weeks for 4 cycles prior to surgery;
ii. Adjuvant: Imfinzi 20 mg/kg every 4 weeks as a single agent for up to 8 cycles after surgery;
b. For body weight ≥ 30 kg: Dose does not exceed (i and ii):
i. Neoadjuvant: Imfinzi 1,500 mg in combination with gemcitabine and cisplatin every 3 weeks for 4 cycles prior to surgery;
ii. Adjuvant: Imfinzi 1,500 mg every 4 weeks as a single agent for up to 8 cycles after surgery;
c. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

H. Non-Muscle Invasive Bladder Cancer (must meet all)**:**
1. Diagnosis of NMIBC;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Prescribed in combination with BCG;

5. Disease is characterized as both of the following (a and b):
   a. BCG-naïve (i.e., no prior receipt of BCG or it has been > 3 years since any prior receipt of BCG);
   b. High risk (i.e., T1 tumor, Grade 3/high-grade tumor, carcinoma in situ, or multiple and recurrent and large [≥ 3 cm] tumors);
6. Member has previously undergone transurethral resection of bladder tumor;
7. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. Request meets one of the following (a, b, or c):
   a. For body weight < 30 kg: Dose does not exceed 20 mg/kg every 4 weeks for up to 13 cycles;
   b. For body weight ≥ 30 kg: Dose does not exceed 1,500 mg every 4 weeks for up to 13 cycles;
   c. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

I. Cervical Cancer (off-label) (must meet all)**:**
1. Diagnosis of persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with etoposide and either cisplatin or carboplatin, or continued as a single agent for maintenance therapy;
5. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose;
   b. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

J. Gastric, Esophageal, and Esophagogastric (Gastroesophageal) Junction Cancer (must meet all)**:**
1. Diagnosis of gastric, esophageal, or esophagogastric (gastroesophageal) junction adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in one of the following ways (a, b or c):
   a. In combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) for one of the following uses (i or ii):
      i. For any cancer: As neoadjuvant and adjuvant treatment for resectable disease, followed by use as a single agent;
      ii. For esophageal or esophagogastric (gastroesophageal) junction adenocarcinoma only: As induction therapy for relieving dysphagia, and both of the following (1):

1) Provider attestation that member is medically fit for surgery and planned for esophagectomy;

b. In combination with Imjudo as neoadjuvant therapy, and both of the following (i and ii):
   i. Disease is microsatellite instability-high (MSI-H) or dMMR;
   ii. Provider attestation that member is medically fit for surgery;

c. Other NCCN recommendations listed as category 1, 2A, or 2B;

5. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a, b or c):
   a. For body weight < 30 kg: Dose does not exceed (i and ii):
      i. Neoadjuvant: Imfinzi 20 mg/kg every 4 weeks with FLOT for up to 2 cycles prior to surgery;
      ii. Adjuvant: Imfinzi 20 mg/kg every 4 weeks with FLOT for up to 2 cycles, followed by Imfinzi 20 mg/kg every 4 weeks as a single agent for up to 10 cycles (for a maximum of 12 total cycles after surgery);
   b. For body weight ≥ 30 kg: Dose does not exceed (i and ii):
      i. Neoadjuvant: Imfinzi 1,500 mg every 4 weeks with FLOT for up to 2 cycles prior to surgery;
      ii. Adjuvant: Imfinzi 1,500 mg every 4 weeks with FLOT for up 2 cycles, followed by Imfinzi 1,500 mg every 4 weeks as a single agent for up to 10 cycles (for a maximum of 12 total cycles after surgery);
   c. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

K. Ampullary Adenocarcinoma (off-label) (must meet all)**:**

1. Diagnosis of ampullary adenocarcinoma (pancreatobiliary or mixed type);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with gemcitabine and cisplatin;
5. Disease is metastatic;
6. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose;
   b. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

L. Small Bowel Adenocarcinoma (off-label) (must meet all)**:**

1. Diagnosis of small bowel adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent for one of the following (a, b, or c):
   a. Neoadjuvant treatment of resectable disease;

b. Primary treatment of locally unresectable or medically inoperable disease;
c. Treatment of advanced or metastatic disease;

5. Disease is dMMR/MSI-H or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., tumor mutational burden > 50 mut/Mb);
6. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):
   a. Dose does not exceed the FDA approved maximum recommended dose;
   b. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

M. Other diagnoses/indications:

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via of PA Health & Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.PHARM.01) applies;
2. For unresectable NSCLC requests, member has not received more than 12 months of Imfinzi therapy;
3. For resectable NSCLC requests, member has not received more than 12 cycles of Imfinzi therapy following surgery (i.e., 16 total cycles);
4. For MIBC requests, member has not received more than 8 cycles of Imfinzi therapy following surgery (i.e., 12 total cycles);
5. For NMIBC requests, member has not received more than 13 cycles of Imfinzi therapy;
6. For GC/GEJC requests, member has not received more than 12 cycles of Imfinzi therapy following surgery (i.e., 14 total cycles);
7. Member is responding positively to therapy;
8. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
9. If request is for a dose increase, request meets one of the following (a-j):
   a. For unresectable stage II-II NSCLC (i or ii):
      i. For body weight < 30 kg: new dose does not exceed 10 mg/kg every 2 weeks;
      ii. For body weight ≥ 30 kg: new dose does not exceed 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks
   b. For metastatic NSCLC (i or ii):
      i. For body weight < 30 kg: new dose does not exceed 20 mg/kg every 3 weeks in combination with Imjudoand platinum-based chemotherapy for 4 cycles, then Imfinzi 20 mg/kg every 4 weeks with histology-based pemetrexed maintenance therapy;
      ii. For body weight ≥ 30 kg, new dose does not exceed 1,500 mg every 3 weeks in combination with Imjudoand platinum based chemotherapy for 4 cycles,

then 1,500 mg every 4 weeks with histology-based pemetrexed maintenance therapy;

c. For MIBC or resectable NSCLC (i and ii):
   i. Neoadjuvant therapy (1 or 2):
      1) For body weight < 30 kg: Dose does not exceed Imfinzi 20 mg/kg every 3 weeks in combination with chemotherapy for up to 4 cycles prior to surgery;
      2) For body weight ≥ 30 kg: Dose does not exceed Imfinzi 1,500 mg every 3 weeks in combination with chemotherapy for up to 4 cycles prior to surgery;
   ii. Adjuvant therapy (1 or 2):
      1) For body weight < 30 kg: Dose does not exceed 20 mg/kg every 4 weeks as a single agent for up to 8 (MIBC) or 12 cycles after surgery;
      2) For body weight ≥ 30 kg: Dose does not exceed 1,500 mg every 4 weeks as a single agent for up to 8 (MIBC) or 12 cycles after surgery;
d. For ES-SCLC (i or ii):
   i. For body weight < 30 kg, new dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy for 4 cycles, then 10 mg/kg every 2 weeks as a single agent;
   ii. For body weight ≥ 30 kg, new dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy for 4 cycles, and then 1,500 mg every 4 weeks as a single agent;
e. For NMIBC or LS-SCLS (i or ii):
   i. For body weight < 30 kg, dose does not exceed 20 mg/kg every 4 weeks;
   ii. For body weight ≥ 30 kg, dose does not exceed 1500 mg every 4 weeks;
f. For BTC (i or ii):
   i. For body weight < 30 kg, new dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy, then 20 mg/kg every 4 weeks as a single agent;
   ii. For body weight ≥ 30 kg, new dose does not exceed 1,500 mg every 3 weeks in combination with chemotherapy, then 1,500 mg every 4 weeks as a single agent;
g. For uHCC (i or ii):
   i. For body weight < 30 kg, new dose does not exceed 20 mg/kg in combination with Imjudo, then 20mg/kg every 4 weeks;
   ii. For body weight ≥ 30 kg, new dose does not exceed, 1,500 mg in combination with Imjudo, then 1,500 mg every 4 weeks;
h. For endometrial cancer (i or ii):
   i. For body weight < 30 kg: New dose does not exceed 15 mg/kg every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles, then 20 mg/kg every 4 weeks as a single agent;
   ii. For body weight ≥ 30 kg: New dose does not exceed 1,120 mg every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles, then 1,500 mg every 4 weeks as a single agent;
i. For GC/GEJC (i or ii):
   i. For body weight < 30 kg: New dose does not exceed (1 and 2):

1) Neoadjuvant: Imfinzi 20 mg/kg every 4 weeks with FLOT for up to 2 cycles prior to surgery;
2) Adjuvant: Imfinzi 20 mg/kg every 4 weeks with FLOT for up to 2 cycles, followed by Imfinzi 20 mg/kg every 4 weeks as a single agent for up to 10 cycles (for a maximum of 12 total cycles after surgery);

ii. For body weight ≥ 30 kg: New dose does not exceed (1 and 2):
1) Neoadjuvant: Imfinzi 1,500 mg every 4 weeks with FLOT for up to 2 cycles prior to surgery;
2) Adjuvant: Imfinzi 1,500 mg every 4 weeks with FLOT for up 2 cycles, followed by Imfinzi 1,500 mg every 4 weeks as a single agent for up to 10 cycles (for a maximum of 12 total cycles after surgery);

j. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Unresectable Stage II-III NSCLC: up to a total duration of 12 months
MIBC: up to a total of 12 cycles
NMIBC: up to a total of 13 cycles
GC/GEJC: up to a total of 14 cycles
Resectable NSCLC: up to a total of 16 cycles
LS-SCLC: up to a total duration of 24 months
All other indications: 12 months

B. Other diagnoses/indications:

1. Currently receiving medication via of PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
BCG: Bacillus Calmette-Guérin
BTC: biliary tract cancer
dMMR: mismatch repair deficient
ES-SCLC: extensive-stage small cell lung cancer
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
FLOT: fluorouracil, leucovorin, oxaliplatin, and docetaxel
GC/GEJC: gastric or gastroesophageal junction adenocarcinoma
LS-SCLC: limited-stage small cell lung cancer
MIBC: muscle invasive bladder cancer
MSI-H: microsatellite instability-high
NECC: neuroendocrine carcinoma of the cervix
NMIBC: non-muscle invasive bladder cancer
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand
pMMR: mismatch repair proficient
POLE/POLD1: polymerase epsilon/delta
RT: radiotherapy
uHCC: unresectable hepatocellular carcinoma

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSCLC (examples of concurrent platinum-containing/radiotherapy regimens)		
cisplatin, etoposide, RT	Varies	Varies
Carboplatin/cisplatin, pemetrexed, RT		
paclitaxel, carboplatin, RT		
LS-SCLC (regimen examples as included in the NCCN SCLC guidelines)		
cisplatin and etoposide	Varies	Varies
carboplatin and etoposide	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- On February 22, 2021, AstraZeneca announced the voluntary withdrawal of the indication for Imfinzi for second-line treatment of locally advanced or metastatic bladder cancer. Imfinzi was approved for this indication under the accelerated pathway in 2017, based on study results that showed positive tumor response rates and duration of response. In its announcement, AstraZeneca pointed to results from the DANUBE confirmatory trial, in which Imfinzi failed to meet its key primary endpoint of overall survival.
- For NSCLC, actionable molecular biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1 and ERBB2 (HER2). If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), repeat biopsy and/or plasma testing should be done. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes. For those who require an urgent start to therapy but biomarker testing is pending, consider holding immunotherapy for one cycle, unless confirmed that no driver mutations are present.
- Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, and some oncogenic drivers (i.e., EGFR exon 19 deletion or L858R mutation, ALK, RET, or ROS1 gene fusion) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.
- SCLC stage definitions per NCCN:
    - Limited stage: Stage I-III (T any, N any, M0) that can be safely treated with definitive radiation doses. Excludes T3-4 due to multiple lung nodules that are

too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan
- Extensive stage: Stage IV (T any, N any, M 1a/b/c), or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan

Appendix E: Recommended Combination Regimens for Metastatic NSCLC

Tumor Histology	Patient Weight	Imfinzi Dosage	Tremelimumab-actl Dosage	Platinum-based Chemotherapy Regimen
Non-Squamous	≥ 30 kg	1,500 mg	75 mg	carboplatin & nab-paclitaxel OR carboplatin or cisplatin & pemetrexed
	< 30 kg	20 mg/kg	1 mg/kg	
Squamous	≥ 30 kg	1,500 mg	75 mg	carboplatin & nab-paclitaxel OR carboplatin or cisplatin & gemcitabine
	< 30 kg	20 mg/kg	1 mg/kg	

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	Unresectable Stage III: • Weight ≥ 30 kg: 10 mg/kg IV every 2 weeks or 1,500 mg every 4 weeks • Weight < 30 kg: 10 mg/kg IV every 2 weeks Metastatic: • Weight ≥ 30 kg: 1,500 mg every 3 weeks in combination with Imjudo75 mg and platinum-based chemotherapy for 4 cycles, and then administer Imfinzi 1,500 mg every 4 weeks as a single agent with histology-based pemetrexed maintenance therapy every 4 weeks, and a fifth dose of Imjudo75 mg in combination with Imfinzi dose 6 at week 16* • Weight < 30 kg: 20 mg/kg every 3 weeks in combination with Imjudo1 mg/kg and platinum-based chemotherapy, and then administer Imfinzi 20 mg/kg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo1 mg/kg in combination with Imfinzi dose 6 at week 16* Resectable: • Neoadjuvant therapy: o Weight < 30 kg: 20 mg/kg every 3 weeks in combination with platinum-based	Stage III See regimen; maximum duration of 12 months Metastatic: See regimen

Indication	Dosing Regimen	Maximum Dose
	chemotherapy for up to 4 cycles prior to surgery ○ Weight ≥ 30 kg: 1,500 mg every 3 weeks in combination with platinum-based chemotherapy for up to 4 cycles prior to surgery • Adjuvant therapy: ○ Weight < 30 kg: 20 mg/kg every 4 weeks as a single agent for up to 12 cycles after surgery ○ Weight ≥ 30 kg: 1,500 mg every 4 weeks as a single agent for up to 12 cycles after surgery	Resectable: See regimen; maximum duration of 12 cycles after surgery
LS-SCLC	Following concurrent platinum-based chemotherapy and radiation therapy: • Weight ≥ 30 kg: 1,500 mg IV every 4 weeks • Weight < 30 kg: 20 mg/kg IV every 4 weeks	See regimen; maximum duration of 24 months
ES-SCLC	• Weight ≥ 30 kg: 1,500 mg IV in combination with chemotherapy † every 3 weeks (21 days) for 4 cycles, followed by 1,500 mg every 4 weeks as a single agent • Weight < 30 kg: 20 mg/kg IV in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, following by 10 mg/kg every 2 weeks as a single agent	See regimen
BTC	• Weight ≥ 30 kg: 1,500 mg IV every 3 weeks in combination with chemotherapy †, then 1,500 mg every 4 weeks as a single agent • Weight < 30 kg: 20 mg/kg IV every 3 weeks in combination with chemotherapy †, then 20 mg/kg every 4 weeks as a single agent	See regimen
uHCC	○ Weight ≥ 30 kg: Imfinzi 1,500 mg in combination with Imjudo 300 mg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks • Weight < 30 kg: Imfinzi 20 mg/kg in combination with Imjudo 4 mg/kg as a single dose at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks	See regimen
MIBC	• Neoadjuvant therapy: ○ Weight < 30 kg: 20 mg/kg every 3 weeks in combination with gemcitabine and cisplatin† for up to 4 cycles prior to surgery ○ Weight ≥ 30 kg: 1,500 mg every 3 weeks in combination with gemcitabine and cisplatin† for up to 4 cycles prior to surgery	See regimen; maximum duration of 8 cycles after surgery

Indication	Dosing Regimen	Maximum Dose
	• Adjuvant therapy: o Weight < 30 kg: 20 mg/kg every 4 weeks as a single agent for up to 8 cycles after surgery o Weight ≥ 30 kg: 1,500 mg every 4 weeks as a single agent for up to 8 cycles after surgery	
NMIBC	In combination with BCG induction and maintenance: • Weight ≥ 30 kg: 1,500 mg IV every 4 weeks • Weight < 30 kg: 20 mg/kg IV every 4 weeks	See regimen; maximum duration of 13 cycles
Endometrial cancer	o Weight < 30 kg: 15 mg/kg IV every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles, then 20 mg/kg every 4 weeks as a single agent o Weight ≥ 30 kg: 1,120 mg IV every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles, then 1,500 mg every 4 weeks as a single agent	See regimen
GC/GEJC	• Neoadjuvant therapy: o Weight < 30 kg: Imfinzi 20 mg/kg every 4 weeks with FLOT† for up to 2 cycles prior to surgery o Weight ≥ 30 kg: Imfinzi 1,500 mg every 4 weeks with FLOT† for up to 2 cycles prior to surgery • Adjuvant therapy: o Weight < 30 kg: Imfinzi 20 mg/kg every 4 weeks with FLOT† for up to 2 cycles, followed by Imfinzi 20 mg/kg every 4 weeks as a single agent for up to 10 cycles o Weight ≥ 30 kg: Imfinzi 1,500 mg every 4 weeks with FLOT† for up 2 cycles, followed by Imfinzi 1,500 mg every 4 weeks as a single agent for up to 10 cycles	See regimen; maximum duration of 12 cycles after surgery

* Optional pemetrexed therapy may be initiated from week 12 until disease progression or intolerable toxicity for patients with nonsquamous disease who received treatment with pemetrexed and carboplatin/cisplatin.
†Administer Imfinzi prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with Imfinzi for recommended dosage information, as appropriate. *[For ES-SCLC, see also Appendix B. Therapeutic Alternatives for NCCN regimens as carboplatin, cisplatin, and etoposide are off-label for this indication.]*

V. Product Availability

Single-dose vials: 120 mg/2.4 mL, 500 mg/10 mL

References

1. Imfinzi Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026. Available at: https://www.imfinzi.com. Accessed June 17, 2026.
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7. National Comprehensive Cancer Network. Bladder Cancer Version 1.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed June 17, 2026.
8. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed January 29, 2026.
9. National Comprehensive Cancer Network. Gastric Cancer Version 2.2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed January 29, 2026.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9173	Injection, durvalumab, 10 mg

Reviews, Revisions, and Approvals	Date
2Q 2018 annual review: added new FDA indication for NSCLC; references reviewed and updated.	02/2018
2Q 2019 annual review: references reviewed and updated.	04/2019
2Q 2020 annual review: UC stage III added to encompass NCCN recommended use for locally advanced disease; NCCN recommended use for SCLC added; references reviewed and updated.	04/2020
2Q 2021 annual review: removed criteria for bladder cancer as the FDA labeled indication was withdrawn by the manufacturer based on confirmatory	04/2021

Reviews, Revisions, and Approvals	Date
trial results; added coverage for stage II NSCLC per NCCN 2A recommendation; revised dosing for all indications per updated FDA label; references reviewed and updated.	
2Q 2022 annual review: per prescribing information, for continued therapy, added the following requirement to reemphasize the NSCLC approval duration: "For NSCLC requests, member has not received more than 12 months of Imfinzi therapy"; updated HCPCS code; references reviewed and updated.	04/2022
RT4: added criteria for new FDA approved indication of BTC; for NSCLC and ES-SCLC added age ≥ 18 years to be consistent with prescribing information; added criteria for newly FDA-approved indications for metastatic NSCLC and HCC.	01/2023
2Q 2023 annual review: for NSCLC per NCCN Compendium added recurrent or advanced disease and additional actionable molecular biomarkers that could be negative for use in combination with Imjudo and platinum therapy, added off-label continuation maintenance therapy; added off-label use for cervical cancer; clarified maximum 12 month continued approval duration applies only to stage II-III NSCLC; RT4: added criteria for newly FDA-approved indication of dMMR endometrial cancer; references reviewed and updated.	04/2023
2Q 2024 annual review: per NCCN – for NSCLC, added recommended uses when actionable molecular biomarkers are present; for BTC, added resected gross residual (R2) disease; added off-label uses for gastric, esophageal, esophagogastric junction, and ampullary adenocarcinoma; for all indications, added redirection to generic if available; RT4: added criteria for newly FDA-approved indication of dMMR endometrial cancer; references reviewed and updated.	04/2024
RT4: added criteria for newly FDA-approved indication for use as neoadjuvant/adjuvant therapy in resectable NSCLC and LS-SCLS	09/2024
2Q 2025 annual review: per NCCN – for NSCLC, added that Imfinzi must be prescribed as a single agent and that disease does not have EGFR exon 19 deletion or exon 21 L858R mutation if stage II-III; added use as first-line therapy for NRG1 gene fusion positive tumors; removed use as subsequent therapy for EGFR exon 19 deletion, exon 21 deletion, exon 21 L858R tumors, ALK1 rearrangement, and ROS1 rearrangement positive tumors; for HCC; added additional qualifier of extrahepatic; for endometrial cancer, added additional qualifiers of metastatic, stage III, and stage IV; for cervical cancer, added that Imfinzi can be used as a single agent for maintenance therapy following combination use; for ampullary adenocarcinoma, removed qualifiers of unresectable localized and stage IV resected; for BTC, added "with curative intent" for recurrent definition to align with NCCN compendium wording; RT4: updated FDA approved indication for dMMR endometrial cancer to include FDA approved testing language; references reviewed and updated.	04/2025

Reviews, Revisions, and Approvals	Date
RT4: added criteria for newly FDA-approved indication of MIBC; under continued approval duration, revised maximum number of cycles for resectable NSCLC from 12 to 16 to include neoadjuvant treatment.	
RT4: added criteria for newly FDA-approved indication as neoadjuvant/adjuvant therapy for resectable GC/GEJC in combination with FLOT; added off-label use as induction therapy for esophageal or esophagogastric (gastroesophageal) junction adenocarcinoma per NCCN; extended initial approval durations from 6 to 12 months.	01/2026
2Q 2026 annual review: per NCCN, revised the following – for NSCLC, added option for use after completion of adjuvant chemoradiation; for SCLC, added option for use in combination with etoposide and carboplatin or cisplatin as subsequent treatment for progression or relapse if member had prolonged disease free time; for HCC, added option for use as subsequent-line therapy and added requirement for use as a single agent or in combination with Imjudo; for GC/GEJC, removed requirement for PD-L1 combined positive score or tumor area positivity; added off-label criteria for small bowel adenocarcinoma; RT4: added criteria for newly FDA-approved indication of BCG-naïve, high-risk NMIBC; added urologist prescriber option for MIBC; references reviewed and updated.	04/2026