Clinical Policy: Durvalumab (Imfinzi)

Reference Number: PA.CP.PHAR.339
Effective Date: 01/2018
Last Review Date: 04/2024

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

FDA approved indication
Imfinzi is indicated:

- For the treatment of adult patients with unresectable, stage III non-small cell lung cancer (NSCLC) 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 epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- In combination with etoposide and either carboplatin or cisplatin as first-line treatment of adults patients with extensive-stage small cell lung cancer (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 (uHCC).
- 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).

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-d):
   a. Disease is unresectable, stage II-III, and has not progressed following concurrent platinum-based chemotherapy and radiation therapy (RT);

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-xi);
   i. First-line therapy for disease without sensitizing EGFR mutations, ALK genomic tumor aberrations, or other actionable molecular biomarkers (e.g., KRAS, ROS1, BRAF, NTRK1/2/3, MET, RET, 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. Subsequent therapy for EGFR exon 19 deletion or exon 21 L858R tumors and prior erlotinib ± (ramucirumab or bevacizumab), afatinib, gefitinib, osimertinib, or dacomitinib therapy;
   ix. Subsequent therapy for EGFR S768I, L861Q, and/or G719X mutation positive tumors and prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib therapy;
   x. Subsequent therapy for ALK rearrangement positive tumors and prior crizotinib, ceritinib, alectinib, brigatinib, or lorlatinib therapy;
   xi. Subsequent therapy for ROS1 rearrangement positive tumors and prior crizotinib, entrectinib, repotrectinib, or ceritinib therapy;

c. 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. 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 body weight ≥ 30 kg: dose does not exceed Imfinzi 1,500 mg every 3 weeks in combination with tremelimumab-actl 75 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;

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

Approval duration: 6 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 as first-line treatment with etoposide and either carboplatin or cisplatin followed by maintenance with Infimzi as a single agent;
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: 6 months

C. 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 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;
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: 6 months

D. Hepatocellular Carcinoma (must meet all)**:**
1. Diagnosis of unresectable, liver-confined, or metastatic hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. 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: 6 months

E. Endometrial Cancer (must meet all)**:**
1. Diagnosis of primary advanced or recurrent endometrial cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with carboplatin and paclitaxel for the first 6 cycles;
5. Disease is dMMR;
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 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: 6 months

F. 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;
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: 6 months

G. Gastric, Esophageal, and Esophagogastric Junction Cancer (off-label) (must meet all)**:**

1. Diagnosis of gastric, esophageal, or esophagogastric junction adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with Imjudo as neoadjuvant therapy;
5. Disease is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR);
6. Provider attestation that member is medically fit for surgery;
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 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: 6 months

H. 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 unresectable localized, stage IV resected, or 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: 6 months

I. 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.LTSS.PHAR.01) applies;
2. For unresectable NSCLC requests, member has not received more than 12 months of Imfinzi therapy;
3. Member is responding positively to therapy;
4. For brand Imfinzi requests, member must use generic durvalumab, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, request meets one of the following (a, b, c, d, e, f or g):*
   a. For 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 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;
   d. 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;
   e. 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;
   f. 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;

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

Approval duration:
Stage II-III NSCLC: up to a total duration of 12 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.LTSS.PHAR.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
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
NECC: neuroendocrine carcinoma of the cervix
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand
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		
ES-SCLC (regimen examples as included in the NCCN SCLC guidelines)		
(carboplatin or cisplatin) and etoposide and Imfinzi	Carboplatin AUC 5-6 day 1 and etoposide 80-100 mg/m^2 days 1, 2, 3 and Imvinzi 1,500 mg day 1 every 21 days x 4 cycles followed by maintenance Imfinzi 1,500 mg day 1 every 28 days	See dosing regimens

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Cisplatin 75-80 mg/m^2 day 1 and etoposide 80-100 mg/m^2 days 1, 2, 3 and Imvinzi 1,500 mg day 1 every 21 days x 4 cycles followed by maintenance Imfinzi 1,500 mg day 1 every 28 days	

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, 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. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.
- 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 exon 21 L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.

Appendix E: Recommended Combination Regimens for 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	Stage II-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*	Stage II-III See regimen; maximum duration of 12 months Metastatic: See regimen
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

Indication	Dosing Regimen	Maximum Dose
Endometrial cancer	• 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 • 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

* 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

VI. References

1. Imfinzi Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2024. Available at: https://www.imfinzi.com. Accessed June 20, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 20, 2024.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 6, 2024.
4. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed February 6, 2024.
5. National Comprehensive Cancer Network. Hepatocellular Carcinoma Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed February 6, 2024.
6. National Comprehensive Cancer Network. Biliary Tract Cancers Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf. Accessed February 6, 2024.

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 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.	04/2021
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