Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Durvalumab (Imfinzi)	**MP-RX-FP-39-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	11/30/2023	03/24/2026
			Last Review Date: 03/24/2026	**Frequently Revision:** Annual

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of Imfinzi® (durvalumab) approved by the Food and Drug Administration (FDA) for the treatment of certain patients with non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), biliary tract cancers (BTC), unresectable hepatocellular carcinoma (uHCC), primary advanced or recurrent mismatch repair deficient (dMMR) endometrial cancer, and resectable gastric or gastroesophageal junction (GEJ) adenocarcinoma (perioperative use).

Background Information:

Imfinzi (durvalumab) is a programmed death-ligand 1 (PD-L1) blocking antibody.

The FDA approved indications for Imfinzi include:

- NSCLC:
  - for the treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements 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 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 adults with metastatic NSCLC, with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- Small Cell Lung Cancer
  - in combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)
- Biliary Tract Cancer
  - in combination with gemcitabine and cisplatin, as treatment of adults with locally advanced or metastatic biliary tract cancer (BTC)
- Hepatocellular carcinoma
  - in combination with tremelimumab-actl (Imjudo) for the treatment of adults with unresectable hepatocellular carcinoma
- Endometrial Cancer

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- in combination with carboplatin and paclitaxel followed by IMFINZI as a single agent is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

- Bladder Cancer
  - in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC).
- Gastric/GEJ cancers
  - in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single-agent IMFINZI, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).

The National Comprehensive Cancer Network (NCCN) provides category 1 and 2A recommendations for use in Ampullary adenocarcinoma (pancreatobiliary mixed type disease), NSCLC, hepatocellular carcinoma, SCLC, esophageal/esophagogastric, gastric cancer, and biliary tract cancer also.

NCCN also provides a 2A recommendation for use in persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) in combination with etoposide and a platinum-based chemotherapy. This recommendation cites data which is extrapolated from the studies for the use in extensive stage small cell lung cancer (Horn L, et al 2018, Luis Paz-Ares, et.al. CASPIAN 2019). Though the recommendation provides use to second-line or subsequent therapy, these studies only discuss first-line therapy.

NCCN provides category 2A and 2B recommendations for use of Imfinzi in several types of bladder cancer. However, their Bladder Cancer guidelines have not been updated since the manufacturer's decision in 2/2021 to withdraw this indication from the FDA label due to Imfinzi's inability to meet the overall survival primary outcome measures in the phase 3 DANUBE confirmatory trials (Powles 2020). The FDA had granted Imfinzi with its bladder cancer indication through the accelerated approval program in 2017, with continued approval contingent upon verification of clinical benefit in confirmatory trials. In the current NCCN compendia, NCCN no longer provides these bladder cancer recommendations.

NCCN provides a category 2A recommendation for the use of Imfinzi as adjuvant consolidation therapy as a single agent for limited stage disease if no disease progression following systemic therapy with concurrent radiation therapy for those with good performance status (PS) who are medically inoperable or decision was made not to pursue surgical resection.

Definitions and Measures

- Consolidation therapy: Any drug or medical treatment that is used to kill remaining cancer cells. Also called intensification therapy or post-remission therapy.
- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

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- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

- Extensive-stage small cell lung cancer: Cancer has spread to other parts of the body, and could include the fluid around the lungs.
- Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte–associated antigen (CTLA)-4/B7-1/B7-2.
- Limited-stage small cell lung cancer: Cancer is confined to 1 part of the chest, and radiation therapy could be an option.
- Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.
- Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Programmed death (PD)-1 proteins: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. However, this can also prevent T-cells from attacking cancer cells in the body. Examples of FDA approved anti-PD-1 agents include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab).
- Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved anti-PD-L1 agents include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab).

Approved Indications

A. See background section above.

Other Uses

A. See background section above.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Imfinzi® (durvalumab)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of Ampullary adenocarcinoma (NCCN 2A); **AND**
ii. Individual is using in combination with gemcitabine and cisplatin;

OR

iii. Individual has a diagnosis of Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 1, 2A); **AND**
   A. Disease type is one of the following:
      1. Disease is confirmed (histologically or cytologically) stage III locally advanced, unresectable NSCLC disease; **OR**
      2. Disease is confirmed (histologically or cytologically) stage II, unresectable NSCLC;

   AND
   B. Disease has not progressed after definitive chemoradiation; **AND**
   C. Individual is using as consolidation therapy; **AND**
   D. Individual is using as a single agent; **AND**
   E. Individual is using until disease progression or a maximum of 12 months of treatment (NCCN 2A); **AND**
   F. Individual has not previously received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   G. Individual has a current ECOG performance status of 0-2; **AND**
   H. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

iv. Individual has a diagnosis of NSCLC (Label, NCCN 1, NCCN 2A); **AND**
   A. Individual has recurrent, advanced or metastatic NSCLC disease with no prior chemotherapy or any other systemic therapy; **AND**
   B. Individual is using in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy; **AND**
   C. Negative for actionable molecular biomarkers (including but not limited to EGFR, KRAS, ALK, ROS1, BRAF, NTRK 1/23, MET, RET, and ERBB2 (HER2); **AND**
   D. Individual may be KRAS G12C mutation positive; **AND**
   E. Individual has a PD-L1 expression of greater than or equal to 1 to 49%; **AND**

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F. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
G. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

v. Individual has a diagnosis of NSCLC (NCCN 1); **AND**
A. Individual is using as continuation maintenance therapy in one of the following ways:
1. As a single agent for recurrent, advanced, or metastatic disease after initial systemic therapy with durvalumab/tremelimumab-actl plus chemotherapy; **OR**
2. In combination with pemetrexed for recurrent, advanced, or metastatic disease after initial systemic therapy with durvalumab/tremelimumab-actl and platinum-based chemotherapy; **AND**
B. Individual is using until disease progression or unacceptable toxicity following positive tumor response or stable disease following initial systemic therapy; **AND**
C. Individual has a ECOG performance status of 0-2;

OR

vi. Individual has a diagnosis of NSCLC (Label, NCCN 1); **AND**
A. Individual is using as neoadjuvant therapy in combination with platinum-containing chemotherapy; **AND**
B. Individual has resectable (tumors ≥ 4 cm and/or node positive) NSCLC; **AND**
C. Individual has no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase rearrangements; **AND**
D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

F. Individual is using Imfinzi as single-agent adjuvant therapy; **AND**
G. Individual is using after initial neoadjuvant use of Imfinzi with platinum-containing chemotherapy for completely resected tumors ≥ 4 cm and/or node positive NSCLC and no known EGFR mutations or ALK rearrangements

OR

vii. Individual has a diagnosis of primary advanced or recurrent endometrial cancer (Label); **AND**
A. Individual is using in combination with carboplatin and paclitaxel and followed by durvalumab as a single agent; **AND**
B. Individual has mismatch repair deficient disease (dMMR);

OR

viii. Individual has a diagnosis of limited stage (LS) small-cell lung cancer (Stage I-III) (Label, NCCN 1); **AND**
A. Individual has not progressed after 4 cycles of chemotherapy concurrent with radiotherapy; **AND**

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B. Individual is using durvalumab as a single agent for adjuvant consolidation therapy for up to 24 months (NCCN Small Cell Luncg Cancer Guidelines V3.2025); **AND**
C. Individual has an ECOG performance status of 0-1 (NCCN 1);

OR

ix. Individual has a diagnosis of extensive stage Small Cell Lung Cancer (Label, NCCN 1, 2A); **AND**
A. Individual is using as first line therapy in combination with etoposide and either cisplatin or carboplatin for four (4) cycles (followed by maintenance Imfinzi monotherapy); **AND**
B. Individual is using as a single agent for maintenance therapy of extensive stage SCLC; **AND**
C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

x. Individual has a diagnosis of locally advanced or metastatic biliary tract cancer (including pancreatobiliary and mixed type disease) (Label, NCCN 1, 2A); **AND**
A. Individual is using in combination with gemcitabine and cisplatin or carboplatin; **AND**
B. Individual has a current ECOG performance status of 0-2; **AND**
C. Individual has not previously received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
E. Individual is using in one of the following ways:
1. As Neoadjuvant systemic therapy; **OR**
2. As systemic therapy; **OR**
3. Subsequent systemic therapy;

OR

xi. Individual has a diagnosis of unresectable hepatocellular carcinoma (uHCC) (Label, NCCN 1); **AND**
A. Individual is using in one of the following ways:
1. Individual is using in combination with tremelimumab-actl (Imjudo) as first line therapy; **AND**
a. Individual has unresectable disease; **OR**
b. Individual has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
c. Individual has metastatic disease or extensive liver tumor burden;

OR

2. Individual is using as first-line therapy as a single agent; **AND**
a. Individual has unresectable disease; **OR**

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b. Individual has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
c. Individual has metastatic disease or extensive liver tumor burden;

AND

B. Individual has a current ECOG performance status of 0-1; **AND**
C. Individual has not received treatment with another anti-PD-1 or anti-PDL1 agent; **AND**
D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

xii. Individual has a diagnosis of hepatocellular carcinoma (NCCN 2A); **AND**
A. Individual has progressed on or after systemic therapy; **AND**
B. Individual is using as subsequent-line systemic therapy (if not previously used); **AND**
C. Using in combination with Imjudo (tremelimumab-actl) or as a single agent; **AND**
D. Individual has not received previous treatment with an anti-CTLA4-based combination, anti-PD-1, or anti-PDL1 agent

OR

xiii. Individual has a diagnosis of muscle invasive bladder cancer (MIBC) (Label, NCCN 1, 2A); **AND**
A. One of the following:
1. Individual is using in combination with gemcitabine and cisplatin as neoadjuvant treatment; **OR**
2. Individual is following neoadjuvant treatment with single agent Imfinzi as adjuvant treatment following radial cystectomy; **AND**
B. Individual has not received treatment with another anti-PD-1 or anti-PDL1 agent; **AND**
C. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

xiv. Individual has a diagnosis of persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) (NCCN 2A); **AND**
A. Individual is using as first-line therapy, second-line, or subsequent therapy (if not used previously as first-line); **AND**
B. Individual is using in one of the following ways:
1. Individual is using in combination with etoposide and either cisplatin or carboplatin for four (4) cycles; **OR**
2. Individual is using Imfinzi as monotherapy for maintenance therapy); **AND**
C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**

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D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

OR

xv. Individual has a diagnosis of Esophageal and esophagogastric junction cancers or Gastric Cancer (Label, NCCN 1, 2A): AND A.
   A. Individual has resectable gastric or gastroesophageal junction adenocarcinoma; **AND**
   B. Individual is using in one of the following ways:
      1. Individual is using in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) as neoadjuvant and adjuvant treatment; **OR**
      2. Individual is using Imfinzi as monotherapy post neoadjuvant and adjuvant therapy with FLOT for up to 10 cycles;

OR

xvi. Individual has a diagnosis of Esophageal and esophagogastric junction cancers or Gastric cancer (NCCN 2A); **AND**
   A. Individual is using as neoadjuvant therapy; **AND**
   B. Individual is using in combination with Imjudo (tremelimumab-actl); **AND**
   C. Individual has a current ECOG performance status of 0-1; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   E. Individual has microsatellite instability-high/deficient mismatch repair (MSI-H/dMMR) tumors

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Imfinzi (durvalumab) therapy medically necessary in members requesting reauthorization for an indication listed in Section A Above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the recommended duration of therapy has not been exceeded. The following information should be submitted for reauthorization:
   A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
   B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

Approved Indication	Initial Approval Duration	Reauthorization Approval Duration	Treatment Duration
Neoadjuvant and Adjuvant Treatment of Resectable NSCLC	Up to 3 months (in combination with chemotherapy)	Up to six months (as single therapy), to complete a total duration of therapy of 12 cycles (12 months).	Until disease progression, unacceptable toxicity, or a maximum of 12 months.

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Unresectable Stage III NSCLC	Up to 6 months	Up to six months, to complete a total duration of therapy of 12 months.	Until disease progression, unacceptable toxicity, or a maximum of 12 months.
Metastatic non-small cell lung cancer (NSCLC)	Up to 3 months (in combination with tremelimumab-actl and platinum-based chemotherapy)	Up to 6 months	Until disease progression or unacceptable toxicity
Extensive-stage small cell lung cancer (ES-SCLC)	Up to 3 months (in combination with chemotherapy)	Up to 6 months (as single agent)	Until disease progression or unacceptable toxicity
Locally advanced or metastatic biliary tract cancer (BTC)	Up to 6 months (in combination with chemotherapy)	Up to 6 months (as single agent)	Until disease progression or unacceptable toxicity
Unresectable hepatocellular carcinoma (uHCC)	Up to 6 months (only first cycle is in combination with tremelimumab-actl)	Up to 6 months (as single agent)	Until disease progression or unacceptable toxicity
dMMR endometrial cancer	Up to 6 3-week cycles (18 weeks; 5 months) in combination with carboplatin and paclitaxel	Up to 6 months (as single agent)	Until disease progression or unacceptable toxicity
Neoadjuvant and Adjuvant Treatment of MIBC	Up to 3 months (in combination with chemotherapy)	Up to 8 months (as single therapy), to complete a maximum of 8 adjuvant cycles after surgery	Until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 8 cycles after surgery.
Neoadjuvant and Adjuvant Treatment of Resectable GC/GEJC	Up to 2 months (in combination with FLOT chemotherapy)	Up to 12 months (adjuvant phase), to complete a maximum of 12 cycles after surgery *(includes up to 2 cycles with*	Until progression or recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery.

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		FLOT, then up to 10 cycles as single therapy)	

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Imfinzi (durvulumab) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Approved Indication	Combination Therapy	Recommended Dosing
Neoadjuvant Treatment of Resectable NSCLC	in combination with chemotherapy	• Weight ≥ 30 kg: 1,500 mg every 3 weeks for up to 4 cycles prior to surgery. • Weight < 30 kg: 20 mg/kg every 3 weeks for up to 4 cycles prior to surgery.
Adjuvant Treatment of Resectable NSCLC	Monotherapy	• Weight ≥ 30 kg: 1,500 mg as a single agent every 4 weeks for up to 12 cycles after surgery. • Weight < 30 kg: 0 mg/kg every 4 weeks as a single agent for up to 12 cycles after surgery.
Unresectable Stage III NSCLC	Monotherapy	• Weight ≥ 30 kg: 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks. • Weight < 30 kg: IMFINZI 10 mg/kg every 2 weeks.
Metastatic non-small cell lung cancer (NSCLC)	In combination with tremelimumab-actl and platinum-based chemotherapy, then as single agent	• Weight ≥ 30 kg: 1,500 mg every 3 weeks in combination with tremelimumab-actl 75 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 tremelimumab-actl 75 mg in combination with Imfinzi dose 6 at week 16. • Weight < 30 kg: 20 mg/kg every 3 weeks in combination with tremelimumab-actl 1 mg/kg and platinum-based chemotherapy for 4 cycles, 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 tremelimumab-actl 1 mg/kg in combination with Imfinzi dose 6 at week 16
Extensive-stage small cell lung cancer (ES-SCLC)	In combination with etoposide and either carboplatin or cisplatin	• Weight ≥ 30 kg: 1,500 mg in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 1,500 mg every 4 weeks as a single agent

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	for 4 cycles, then as single agent	• Weight < 30 kg: 20 mg/kg in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 10 mg/kg every 2 weeks as a single agent.
Locally advanced or metastatic biliary tract cancer (BTC)	In combination with chemotherapy for 8 cycles, then as single agent	• Patients with a body weight of ≥ 30 kg: 1,500 mg in combination with chemotherapy every 3 weeks (21 days) up to 8 cycles followed by 1,500 mg every 4 weeks as a single agent. • Patients with a body weight of < 30 kg: 20 mg/kg in combination with chemotherapy every 3 weeks (21 days) up to 8 cycles followed by 20 mg/kg every 4 weeks as a single agent.
Unresectable hepatocellular carcinoma (uHCC)	In combination with tremelimumab-actl for 1 cycle, then as single agent	• Patients with a body weight of ≥ 30 kg: Imfinzi 1,500 mg following a single dose of tremelimumab-actl 300 mg at Day 1 of Cycle 1. Continue Imfinzi 1,500 mg as a single agent every 4 weeks thereafter. • Patients with a body weight of < 30 kg: Initiate Imfinzi 20 mg/kg following a single dose of tremelimumab-actl 4 mg/kg at Day 1 of Cycle 1. Continue Imfinzi 20 mg/kg as a single agent every 4 weeks thereafter.
dMMR endometrial cancer	in combination with carboplatin and paclitaxel for 6 cycles, then as single agent	• Weight ≥ 30 kg: Imfinzi 1,120 mg in combination with carboplatin and paclitaxel every 3 weeks for 6 cycles, followed by Imfinzi 1,500 mg every 4 weeks as a single agent. • Weight < 30 kg: Imfinzi 15 mg/kg in combination with carboplatin and paclitaxel every 3 weeks for 6 cycles, followed by Imfinzi 20 mg/kg every 4 weeks as a single agent.

Muscle invasive bladder cancer (MIBC)	*Neoadjuvant:* in combination with gemcitabine and cisplatin.
	Adjuvant: as a single agent.
		• Weight ≥ 30 kg:
		  ○ Neoadjuvant: 1,500 mg IV every 3 weeks for 4 cycles prior to surgery.
		  ○ Adjuvant: 1,500 mg IV every 4 weeks for up to 8 cycles after surgery.
		• Weight < 30 kg:
		  ○ Neoadjuvant: 20 mg/kg IV every 3 weeks for 4 cycles prior to surgery.
		  ○ Adjuvant: 20 mg/kg IV every 4 weeks for up to 8 cycles after surgery

Resectable GC/GEJC	*Neoadjuvant:* in combination with FLOT chemotherapy.
	Adjuvant: n combination with
		• Weight ≥ 30 kg:
		  ○ Neoadjuvant: 1,500 mg IV every 4 weeks for up to 2 cycles prior to surgery.
		  ○ Adjuvant: 1,500 mg IV every 4 weeks for up to 2 cycles and then 1,500 mg as a single agent every 4

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	FLOT chemotherapy, then as a single agent.	weeks for up to 10 cycles, for a total of up to 12 cycles after surgery. • Weight < 30 kg: o Neoadjuvant: 20 mg/kg IV every 4 weeks for up to 2 cycles prior to surgery. o Adjuvant: 20 mg/kg IV every 4 weeks for up to 2 cycles and then 20 mg/kg as a single agent every 4 weeks for up to 10 cycles, for a total of up to 12 cycles after surgery.
Exceptions		
• Patients should be weighted prior to each infusion. For most indications Imfinzi's frequency of administration and co-administered medications change after the first cycle.		

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C15.0–C15.2	Malignant neoplasm of esophagus (upper / middle / lower third)
C15.3-C15.9	Malignant neoplasm of esophagus
C16.0-C16.9	Malignant neoplasm of stomach
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 extrahepatic bile duct
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-C34.92	Malignant neoplasm of bronchus and lung
C53.0-C53.9	Malignant neoplasm of cervix uteri
C54.0–C54.9	Malignant neoplasm of corpus uteri
C55	Malignant neoplasm of uterus, part unspecified
C67.0-C67.9	Malignant neoplasm of bladder
D09.0	Carcinoma in situ of bladder
Z85.110-Z85.118	Personal history of malignant neoplasm of bronchus and lung
Z92.21	Personal history of antineoplastic chemotherapy
Z92.3	Personal history of irradiation

HCPCS Codes:

Codes	Description
J9173	Injection, durvalumab, 10 mg [Imfinzi]

CPT Codes:

Codes	Description
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Each additional hour (add-on to 99601)

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Durvalumab (Imfinzi)	**MP-RX-FP-39-23**	☒ **MMM MA** ☒ **MMM MultiHealth**	11/30/2023	03/24/2026
			Last Review Date: 03/24/2026	**Frequently Revision:** Annual

Reference Information:

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    c. Biliary Tract Cancers. V2.2025. Revised July 2, 2025.
    d. Cervical Cancer. V2.2026. Revised November 10, 2025.
    e. Esophageal and Esophagogastric Junction Cancers. V4.2025. August 22, 2025.
    f. Gastric Cancer. V3.2025. Revised August 22, 2025.
    g. Hepatocellular Carcinoma. V2.2025. Revised October 22, 2025.
    h. Non-Small Cell Lung Cancer. V2.2026. Revised December 2, 2025.
    i. Small Cell Lung Cancer. V2.2026. Revised September 16, 2025.
    j. Uterine Neoplasms. V2.2026. Revised November 14, 2025.
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Durvalumab (Imfinzi)	MP-RX-FP-39-23	☒ MMM MA ☒ MMM MultiHealth	11/30/2023	03/24/2026
			Last Review Date: 03/24/2026	Frequently Revision: Annual

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
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			Last Review Date: 03/24/2026	Frequently Revision: Annual

Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Focus Review	Updated to reflect the 2025 FDA approval for perioperative treatment of resectable gastric or gastroesophageal junction (GEJ) adenocarcinoma and added the corresponding indications, dosage, and coverage language with durations, including new table rows for MIBC and resectable GC/GEJC to align initial and reauthorization timeframes with labeled perioperative/adjuvant use. Coding reviewed: addition of missing diagnosis codes where applicable (e.g., C15.0–C15.2, C22.9, C33, C54.0–C54.9) and removal of C22.3, C22.4, C22.7 and duplicates; confirmed drug billing under HCPCS J9173 and updated administration coding under applicable CPT infusion codes. Updated reference list. Administrative update to transition the document to the new policy template, with formatting and section organization revised for consistency.	3/17/2026	03/24/2026
Annual Review	Add new FDA indication in bladder cancer (MIBC). Add NCCN recommendation for use in subsequent systemic therapy in hepatocellular carcinoma in combination with Imjudo or as a single agent. Add references. Coding Reviewed: Updated description for ICD-10-CM C16.0-C16.9. Added ICD-10-CM C22.9, C67.0-C67.9, D09.0.	9/5/2025	9/16/2025
Annual Review	Add NCCN 2A criteria for use in recurrent NSCLC in combination with Imjudo and clarify molecular biomarkers. Add NCCN 2A criteria for combination use with Imjudo in esophageal and esophagogastric junction cancers or Gastric cancer; Add NCCN 2A recommendation for use in pancreatobiliary and mixed type ampullary adenocarcinoma; Update existing criteria with recommendations from NCCN compendia and guidelines for use in NSCLC, biliary tract cancer, hepatocellular carcinoma, small NECC, Esophageal/Esophagogastric cancers, and Gastric cancers. Add pancreatobiliary and mixed type disease to existing biliary tract cancer criteria. Removed separate criteria for pancreatobiliary and mixed type disease; Add FDA indication for use in primary advanced or recurrent endometrial cancer. Add criteria for ASCO 2024 review of durvalumab in limited stage small cell lung cancer; Add FDA indication for use 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 individuals with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements. Included NCCN guidance to Limited	2/18/2025	3/6/2025

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	stage SCLC; Updated dosing table and authorization and reauthorization approval duration; Updated references; Coding Reviewed: Added ICD-10-CM C15.3-C15.9, C16.0-C16.9, C23, C53.0-C53.9, C33, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C22.1, C22.3, C22.4, C22.7, C22.8 to complete coding for hepatocellular carcinoma.		
Select Review	Update statement for criteria for initial approval: Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met all approval criteria.	3/25/2024	5/9/2024
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023