Evolent Clinical Guideline 3105 for Imfinzi™ (durvalumab)

Guideline Number:	Applicable Codes	
Evolent_CG_3105		
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TABLE OF CONTENTS

STATEMENT **2**
PURPOSE 2
INDICATIONS **2**
BILIARY TRACT CANCER (BTC) 2
BLADDER CANCER 2
ENDOMETRIAL CANCER 3
GASTRIC, ESOPHAGEAL, AND ESOPHAGOGASTRIC JUNCTION CANCERS 3
HEPATOCELLULAR CARCINOMA 3
NON-SMALL CELL LUNG CANCER (NSCLC) 4
SMALL CELL LUNG CANCER (EXTENSIVE STAGE) 4
SMALL CELL LUNG CANCER (LIMITED STAGE) 4
CONTRAINDICATIONS/WARNINGS **5**
EXCLUSION CRITERIA **5**
CODING AND STANDARDS **6**
CODES 6
APPLICABLE LINES OF BUSINESS 6
POLICY HISTORY **7**
LEGAL AND COMPLIANCE **8**
GUIDELINE APPROVAL 8
Committee *8*
DISCLAIMER 8
REFERENCES **9**

STATEMENT

Purpose

To define and describe the accepted indications for Imfinzi (durvalumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Biliary Tract Cancer (BTC)

- Imfinzi (durvalumab) may be used in combination with cisplatin/carboplatin and gemcitabine as first line therapy in members who have not received therapy for unresectable or metastatic biliary tract cancer (e.g., extrahepatic/intrahepatic cholangiocarcinoma, gallbladder carcinoma).

Bladder Cancer

- Imfinzi (durvalumab) may be used as neoadjuvant treatment in combination with gemcitabine and cisplatin for up to 4 cycles in adult members with muscle invasive bladder cancer (MIBC), followed by single agent Imfinzi (durvalumab) after radical cystectomy as adjuvant treatment for a maximum of 8 cycles.
- Imfinzi (durvalumab) may be used in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult members with BCG-naive, high-risk non-muscle-invasive bladder cancer (NMIBC).
    - High-risk NMIBC is defined as having one of the following:
        - T1 tumor

- Grade 3/high-grade tumor
- Carcinoma in situ (CIS)
- Multiple, recurrent and large tumors

Endometrial Cancer

- Imfinzi (durvalumab) may be used in combination with carboplatin and paclitaxel followed by single-agent durvalumab in adult members with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).

Gastric, Esophageal, and Esophagogastric Junction Cancers

- Imfinzi (durvalumab) may be used as neoadjuvant and adjuvant therapy in combination with fluorouracil, leucovorin, oxalipatin, and docetaxel for up to 4 cycles (2 cycles of neoadjuvant therapy and 2 cycles of adjuvant therapy) in adult members with gastric, esophageal, or esophagogastric junction cancers and CPS ≥ 1, followed by single-agent Imfinzi (durvalumab) for a maximum of 10 cycles. Neoadjuvant therapy is required to proceed with adjuvant therapy.

Hepatocellular Carcinoma

- The member has unresectable hepatocellular carcinoma (Child-Pugh Class A score only and/or Barcelona Clinic Liver Cancer stage B or C) with no prior systemic treatment, including prior checkpoint inhibitor (e.g., dostarlimab-gxly, atezolizumab, nivolumab, pembrolizumab, ipilimumab) AND
- Imfinzi (durvalumab) will be used as first line therapy in combination with Imjudo (tremelimumab). Imjudo (tremelimumab) is given for one cycle followed by single agent Imfinzi (durvalumab).

The Barcelona Clinic Liver Cancer (BCLC) Staging System (60)

BCLC stage	ECOG PS	Liver function: Child-Pugh	Tumor stage
Very early stage (0)	0	A	Single ≤2 cm
Early stage (A)	0	A-B	Single ≤3, nodules ≤3 cm
Intermediate stage (B)	0	A-B	Multinodular
Advanced stage (C)	1-2	A-B	Vascular invasion, extrahepatic spread
Terminal stage (D)	3-4	C	Any

CHILD-PUGH SCORE

Chemical and Biochemical Parameters	Scores (Points) for Increasing Abnormality		
	1	2	3
Encephalopathy (grade)[1]	None	1–2	3–4
Ascites	Absent	Slight	Moderate
Albumin (g/dL)	>3.5	2.8–3.5	<2.8
Prothrombin time[2] Seconds over control INR	 <4 <1.7	 4–6 1.7–2.3	 >6 >2.3
Bilirubin (mg/dL) • For primary biliary cirrhosis	<2 <4	2–3 4–10	>3 >10

Class A = 5–6 points; Class B = 7–9 points; Class C = 10–15 points.

Non-Small Cell Lung Cancer (NSCLC)

- Imfinzi (durvalumab) may be used as a single agent for consolidation therapy (for a total of 1 year), after completion of definitive chemoradiation, in members with unresectable (not amendable to surgical treatment) stage II or stage III disease provided that appropriate imaging studies (e.g., CT or PET/CT) performed after the completion of chemoradiation confirm the lack of disease progression and show one of the following: complete response/partial response/stable disease.
- Imfinzi (durvalumab) may be used in combination with Imjudo (tremelimumab) and platinum-based chemotherapy for up to 4 cycles in adult members who have not received prior systemic therapy for metastatic or Stage IV NSCLC and the tumor is negative for EGFR and ALK, regardless of PD-L1 expression. This may be followed by maintenance therapy with Imfinzi (durvalumab), 1 dose of Imjudo (tremelimumab) and optional histology-based pemetrexed.
- Imfinzi (durvalumab) may be used with platinum-containing chemotherapy as neoadjuvant therapy, followed by single-agent Imfinzi (durvalumab) as adjuvant therapy after surgery, for adult members with resectable (tumors ≥ 4 cm and/or node positive) NSCLC and no known EGFR mutations or ALK rearrangements.

Small Cell Lung Cancer (Extensive Stage)

- Imfinzi (durvalumab) may be used in combination with [carboplatin/cisplatin + etoposide] followed by single agent maintenance Imfinzi (durvalumab), for adult members with extensive stage small cell lung cancer.

Small Cell Lung Cancer (Limited Stage)

- Imfinzi (durvalumab) may be used in adult members with limited stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Disease progression while receiving Imfinzi (durvalumab) or prior checkpoint inhibitor (PD-1 or PD-L1 inhibitor).
- There is no imaging study available, after the completion of chemoradiation for NSCLC, to confirm complete response/partial response/stable disease after chemoradiation.
- Members with locally advanced non-small cell lung cancer (NSCLC) with disease progression while receiving concurrent chemoradiotherapy or after chemoradiation.
- Dosing exceeds single dose limit of Imfinzi (durvalumab) 10 mg/kg (every 2 weeks as a single agent), 20 mg/kg (every 3 weeks when used in combination with chemotherapy), 20 mg/kg (every 4 weeks when used as a single agent), 1500 mg (every 3 weeks when used in combination with chemotherapy), or 1500 mg (every 4 weeks when used as a single agent), or maximum duration of 12 months for NSCLC consolidation therapy.
- For use in combination with Imjudo (tremelimumab): If weight is less than 30 kg, the maximum single dose limit is 20 mg/kg every 4 weeks; for weight 30 kg or more, the maximum single dose limit is 1500 mg every 4 weeks.
- Investigational use of Imfinzi (durvalumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    - Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
    - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted

uses of drugs.

- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9173 - Injection, durvalumab, 10 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
June 2026	• Updated bladder cancer indication • Updated references
December 2025	• Updated verbiage under Gastric/Esophageal/Esophagogastric Junction Cancer indication section
October 2025	• Added gastric, esophageal, and esophagogastric junction cancer indications • Updated references
June 2025	• Updated NSCLC indication to allow maintenance therapy with tremelimumab +/- pemetrexed after first-line therapy for recurrent, advanced, or metastatic disease with platinum-based chemotherapy, tremelimumab, and durvalumab if restaging shows stability or response
May 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1314 Imfinzi (durvalumab) • Added new indication for bladder cancer • Updated references
January 2025	• Added Evolent disclaimer language • Added Coding Information section with HCPCS code • Added new indication for limited-stage small cell lung cancer • Updated dosing limits in exclusion criteria • Updated references
September 2024	• Updated NSCLC indication • Updated SCLC indication • Updated references
August 2024	• Added endometrial cancer indication section • Added new reference • Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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