Reference number(s)
2131-A

Standard Medicare Part B Management Imfinzi

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Imfinzi	durvalumab

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Non-Small Cell Lung Cancer (NSCLC)

- Imfinzi, in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, is indicated 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.
- Imfinzi, as a single agent, is indicated for the treatment of adult patients with unresectable, Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- Imfinzi, in combination with tremelimumab-actl and platinum-based chemotherapy, is indicated for the treatment of adult patients with metastatic NSCLC with no sensitizing EGFR mutations or ALK genomic tumor aberrations.

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Small Cell Lung Cancer (SCLC)

- Imfinzi, as a single agent, is indicated for the treatment of adult patients with limited-stage SCLC (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- Imfinzi, in combination with etoposide and either carboplatin or cisplatin, is indicated for the first-line treatment of adult patients with extensive-stage SCLC (ES-SCLC).

Biliary Tract Cancer (BTC)

- Imfinzi, in combination with gemcitabine and cisplatin, is indicated for the treatment of adult patients with locally advanced or metastatic BTC.

Hepatocellular Carcinoma (HCC)

- Imfinzi, in combination with tremelimumab-actl, is indicated for the treatment of adult patients with unresectable HCC (uHCC).

Endometrial Cancer

- Imfinzi, 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

- Imfinzi 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 or Gastroesophageal Junction Adenocarcinoma (GC/GEJC)

- Imfinzi 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 GC/GEJC.

Compendial Uses[2-6]

- Cervical Cancer
- Non-Small Cell Lung Cancer
- Small Cell Lung Cancer
- Ampullary Adenocarcinoma
- Pleural Mesothelioma
- Hepatocellular Carcinoma
- Esophageal Adenocarcinoma
- Gastric and Gastroesophageal Junction Adenocarcinoma
- Biliary Tract Cancer
- Bladder Cancer
- Endometrial Carcinoma
- Small Bowel Adenocarcinoma
- Colorectal Adenocarcinoma

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All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions where applicable:

- Documentation of the absence of EGFR exon 19 deletion and exon 21 L858R mutations, where applicable.
- Documentation of the absence of ALK, RET, and ROS1 gene fusions, where applicable.
- Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) with ultra-hypermutated tumor mutational burden [TMB] (greater than 50 mutations/megabase [mut/Mb]) tumor status, where applicable.
- Documentation of laboratory report confirming proficient mismatch repair (pMMR) tumor status, where applicable.
- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.

Exclusions

Coverage will not be provided for members who have experienced progression while on PD-1 or PD-L1 therapy.

Coverage Criteria

Non-Small Cell Lung Cancer (NSCLC)[1,2]

Authorization of 12 months may be granted for treatment of NSCLC when any of the following criteria are met:

- The member has unresectable stage II or III NSCLC that has not progressed following concurrent platinum-based chemotherapy and radiation therapy and meets all of the following criteria:
    - The tumor is negative for EGFR exon 19 deletion and exon 21 L858R mutations (unless testing is not feasible due to insufficient tissue).
    - The requested medication will be used as a single agent.
- The member has recurrent, advanced, or metastatic NSCLC negative for EGFR exon 19 deletion and exon 21 L858R mutations and ALK, RET, and ROS1 gene fusions (unless testing is not feasible due to insufficient tissue) and meets either of the following criteria:
    - The requested medication will be used in combination with tremelimumab-actl (Imjudo) and platinum-based chemotherapy.
    - The requested medication will be used as maintenance therapy as a single agent or in combination with pemetrexed.

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- The member has resectable NSCLC and meets all of the following criteria:
  - The requested medication will be used as neoadjuvant treatment in combination with platinum-containing chemotherapy and continued as adjuvant treatment after surgery as a single agent.
  - The tumor is negative for EGFR exon 19 deletion and exon 21 L858R mutations and ALK, RET, and ROS1 gene fusions (unless testing is not feasible due to insufficient tissue).

Small Cell Lung Cancer (SCLC)[1,2,5]

Authorization of 12 months may be granted for treatment of SCLC when any of the following criteria is met:

- The requested medication will be used for first-line treatment of extensive-stage SCLC cancer in combination with etoposide and either carboplatin or cisplatin followed by single agent maintenance.
- The requested medication will be used for adjuvant consolidation therapy as a single agent for treatment of limited stage SCLC and the member did not experience disease progression after systemic therapy with concurrent radiation therapy.
- The requested medication will be used for subsequent therapy for progression or relapse in combination with etoposide and either carboplatin or cisplatin followed by single agent maintenance.

Cervical Cancer[2]

Authorization of 12 months may be granted for treatment of persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) when the requested medication will be used in combination with etoposide and either cisplatin or carboplatin and continued as single agent maintenance therapy.

Ampullary Adenocarcinoma[2]

Authorization of 12 months may be granted for first-line treatment of metastatic ampullary adenocarcinoma when both of the following criteria are met:

- The disease is pancreatobiliary or mixed type.
- The requested medication will be used in combination with cisplatin and gemcitabine.

Pleural Mesothelioma[3]

Authorization of 12 months may be granted for first-line treatment of unresectable pleural mesothelioma when the requested medication will be used in combination with pemetrexed and either cisplatin or carboplatin.

Hepatocellular Carcinoma[1,2,7]

Authorization of 12 months may be granted for first-line treatment of hepatocellular carcinoma when all of the following criteria are met:

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- The disease is unresectable or extrahepatic/metastatic.
- The member is ineligible for transplant.
- The requested medication will be used as a single agent or in combination with tremeliumumab-actl (Imjudo).

Authorization of 6 months may be granted for subsequent treatment of unresectable or extrahepatic/metastatic hepatocellular carcinoma when either of the following criteria are met:

- The requested medication will be used as a single agent.
- The requested medication will be used in combination with tremelimumab-actl (Imjudo) and the member has not been previously treated with an anti-CTLA4-based regimen.

Gastric, Gastroesophageal Junction (GEJ), and Esophageal Adenocarcinoma[1,2,4]

Authorization of 3 months for a total of 3 doses may be granted for treatment of gastric, GEJ, or esophageal adenocarcinoma when all of the following criteria are met:

- The tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR).
- The member is medically fit for surgery.
- The requested medication will be used in combination with tremelimumab-actl (Imjudo) for neoadjuvant treatment.

Authorization of 6 months may be granted as perioperative therapy in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) for members with gastric, GEJ, or esophageal adenocarcinoma with PD-L1 ≥ 1.

Endometrial Carcinoma[1,2]

Authorization of 12 months may be granted for treatment of advanced or recurrent endometrial carcinoma when all of the following criteria are met:

- The tumor is deficient mismatch repair (dMMR) and the requested medication will be used in combination with carboplatin and paclitaxel followed by use as a single agent.
- The tumor is proficient mismatch repair (pMMR) and the requested medication will be used in combination with carboplatin and paclitaxel followed by use in combination with olaparib (Lynparza).

Biliary Tract Cancer[1,2]

Authorization of 12 months may be granted for treatment of locally advanced, unresectable, gross residual (R2) disease, or metastatic biliary tract cancer when the requested medication will be used in combination with cisplatin or carboplatin and gemcitabine.

Authorization of 12 months may be granted for adjuvant treatment of biliary tract cancer when the requested medication will be used in combination with cisplatin or carboplatin and gemcitabine.

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Authorization of 12 months may be granted for treatment of resectable locoregionally advanced gallbladder cancer when the requested medication will be used in combination with cisplatin or carboplatin and gemcitabine as neoadjuvant therapy.

Bladder Cancer[1,2,6]

Authorization of 12 months may be granted for perioperative/sandwich treatment of stage II or IIIA bladder cancer when the requested medication will be used in combination with gemcitabine and cisplatin prior to cystectomy followed by single agent therapy after surgery.

Small Bowel Adenocarcinoma[2]

Authorization of 12 months may be granted for treatment of resectable, locally unresectable, medically inoperable, advanced, or metastatic small bowel adenocarcinoma when all of the following criteria are met:

- The tumor is mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta POLE/POLD1) mutation with ultra-hypermutated phenotype (TBM > 50 mut/Mb).
- The requested medication will be used as a single agent.

Colorectal Adenocarcinoma[2]

Authorization of 12 months may be granted for treatment of resectable, locally unresectable, medically inoperable, or metastatic colorectal adenocarcinoma when all of the following criteria are met:

- The tumor is mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta POLE/POLD1) mutation with ultra-hypermutated phenotype (TBM > 50 mut/Mb).
- The requested medication will be used as a single agent.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested medication.

NSCLC

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- For members requesting reauthorization for treatment of unresectable stage II or III NSCLC, the maximum treatment duration is 12 months.
- For members requesting reauthorization for treatment of resectable NSCLC, the maximum treatment duration is up to 12 cycles after surgery.
- The member is receiving benefit from therapy. Benefit is defined as:

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- No evidence of unacceptable toxicity while on the current regimen AND
- No evidence of disease progression while on the current regimen.

Limited Stage SCLC

Authorization for 12 months (up to 24 months) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen AND
  - No evidence of disease progression while on the current regimen.

Gastric, Gastroesophageal Junction (GEJ), and Esophageal Adenocarcinoma

Authorization for 12 months (up to 12 cycles after surgery) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- For members requesting reauthorization for neoadjuvant treatment, the maximum treatment duration is 3 months for a total of 3 doses.
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen AND
  - No evidence of disease progression while on the current regimen.

Bladder Cancer

Authorization for 12 months (up to 12 cycles) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen AND
  - No evidence of disease progression while on the current regimen.

All Other Indications

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen AND
  - No evidence of disease progression while on the current regimen.

Summary of Evidence

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The contents of this policy were created after examining the following resources:

- The prescribing information for Imfinzi.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Small cell lung cancer
- NCCN Guideline: Non-small cell lung cancer
- NCCN Guideline: Hepatocellular carcinoma
- NCCN Guideline: Biliary tract cancers
- NCCN Guideline: Cervical cancer
- NCCN Guideline: Ampullary adenocarcinoma
- NCCN Guideline: Gastric cancer
- NCCN Guideline: Esophageal and esophagogastric junction cancers
- NCCN Guideline: Bladder cancer
- NCCN Guideline: Uterine neoplasms
- NCCN Guideline: Small bowel adenocarcinoma
- NCCN Guideline: Colon cancer
- NCCN Guideline: Rectal cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Imfinzi are covered in addition to the following:

- Unresectable stage II non-small cell lung cancer
- Limited stage, progressive, and relapsed small cell lung cancer
- Gallbladder cancer
- Hepatocellular carcinoma
- Cervical cancer
- Ampullary adenocarcinoma
- Esophageal adenocarcinoma
- Gastric and gastroesophageal junction adenocarcinoma
- Pleural mesothelioma
- Bladder cancer
- Endometrial carcinoma
- Small bowel adenocarcinoma
- Colorectal adenocarcinoma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Imfinzi to treat unresectable stage II NSCLC; limited stage, progressive, and relapsed SCLC; gallbladder cancer; hepatocellular carcinoma; cervical cancer; ampullary adenocarcinoma;

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esophageal, gastroesophageal junction, and gastric adenocarcinoma; bladder cancer; endometrial carcinoma; small bowel adenocarcinoma; and colorectal adenocarcinoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Imfinzi to treat pleural mesothelioma can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

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