CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death-Ligand 1) – Imfinzi Utilization Management Medical Policy
- Imfinzi® (durvalumab intravenous infusion – AstraZeneca)

REVIEW DATE: 12/17/2025

OVERVIEW

Imfinzi, a programmed cell death ligand 1 (PD-L1) blocking antibody, is indicated for the following uses:[1]

- **Biliary tract cancers**, in combination with gemcitabine and cisplatin for the treatment of locally advanced or metastatic disease in adults.
- **Bladder cancer**, in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single-agent Imfinzi as adjuvant treatment, following radical cystectomy for the treatment of adults with muscle invasive bladder cancer.
- **Endometrial cancer**, in combination with carboplatin and paclitaxel, followed by single-agent Imfinzi for the treatment of adults with mismatch repair deficient (dMMR), primary advanced or recurrent disease.
- **Gastric or gastroesophageal junction adenocarcinoma**, in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy as a neoadjuvant and adjuvant treatment, followed by single agent Imfinzi in adults.
- **Hepatocellular carcinoma**, in combination with Imjudo® (tremelimumab-actl intravenous infusion) for the treatment of unresectable disease in adults.
- **Non-small cell lung cancer (NSCLC)**, in adults:
  - Treatment of unresectable Stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy as a single agent.
  - In combination with platinum-containing chemotherapy, followed by Imfinzi single-agent after surgery, for the treatment of resectable (tumors ≥ 4 cm and/or node positive) disease and no known epidermal growth factor receptor (*EGFR*) mutations or anaplastic lymphoma kinase (*ALK*) rearrangements.
  - Treatment of metastatic disease with no sensitizing *EGFR* mutations or anaplastic *ALK* genomic tumor aberrations, in combination with Imjudo and platinum-based chemotherapy.
- **Small cell lung cancer**, in adults:
  - In combination with etoposide and either carboplatin or cisplatin for the first-line treatment of extensive-stage disease.
  - As a single agent, for the treatment limited-stage disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Imfinzi. Approval is recommended for those who meet the conditions of coverage in the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Imfinzi, as

well as the monitoring required for adverse events and long-term efficacy, approval requires Imfinzi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Imfinzi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. Biliary Tract Cancer. Approve for the duration noted if the patient meets ONE of the following (A, B, and C):

- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Approve for 1 year if the patient meets BOTH of the following (a and b):
    - **a)** Patient has unresectable, resected gross residual, or metastatic disease; AND
    - **b)** The medication is used in combination with cisplatin and gemcitabine; OR
  - **ii.** Approve for a total of 6 months if the patient meets ALL of the following (a, b, and c):
    - **a)** Patient has resectable locoregionally advanced gallbladder cancer; AND
    - **b)** The medication is used for neoadjuvant therapy; AND
    - **c)** The medication is used in combination with cisplatin and gemcitabine; AND
- **C)** The medication is prescribed by or in consultation with an oncologist

Dosing. Approve ONE of the following doses (A or B):

- **A)** For a patient with a body weight ≥ 30 kg: Approve 1,500 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
- **B)** For a patient with a body weight < 30 kg: Approve 20 mg/kg administered as an intravenous infusion not more frequently than once every 3 weeks.

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2. Endometrial Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has primary advanced or recurrent disease; AND
- **C)** Patient meets ONE of the following (i or ii):
  - **i.** Disease is mismatch repair deficient (dMMR); OR
  - **ii.** The disease is mismatch repair proficient (pMMR);AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):

- **A)** For a patient weighing ≥ 30 kg approve BOTH of the following (i and ii):
  - **i.** 1,120 mg administered as an intravenous infusion not more frequently than once every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles; AND
  - **ii.** 1,500 mg administered by intravenous infusion no more frequently than once every 4 weeks as a single agent; OR
- **B)** For a patient weighing < 30 kg approve BOTH of the following (i and ii):
  - **i.** 15 mg/kg administered as an intravenous infusion not more frequently than once every 3 weeks in combination with carboplatin and paclitaxel for 6 cycles; AND

ii. 20 mg/kg administered by intravenous infusion not more frequently than once every 4 weeks as a single agent.

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3. Gastric Cancer. Approve for the duration noted if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. Approve for 3 months if the patient meets ALL of the following (a, b, and c):

a) Patient has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND

b) The medication is as neoadjuvant therapy; AND

c) The medication is used in combination with Imjudo (tremelimumab intravenous infusion); OR

ii. Approve for 1 year if the patient meets BOTH of the following (a and b):

a) The tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) ≥ 1%; AND

b) Patient meets ONE of the following [(1) or (2)]:

(1) The medication is used as single agent; OR

(2) The medication is used in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT); AND

C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):

A) For a patient weighing ≥ 30 kg, approve 1,500 mg administered by intravenous infusion no more frequently than once every 4 weeks; OR

B) For a patient weighing < 30 kg, approve 20 mg/kg administered by intravenous infusion not more frequently than once every 4 weeks.

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4. Hepatocellular Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. Patient meets BOTH of the following (a and b):

a) Patient has liver-confined, unresectable disease; AND

b) According to the prescriber, the patient is not eligible for transplant; OR

ii. Patient meets BOTH of the following (a and b):

a) Patient has metastatic disease; AND

b) According to the prescriber, the patient is not eligible for resection, transplant, or locoregional therapy; AND

C) Patient meets ONE of the following (i or ii):

i. The medication is used as monotherapy; OR

ii. The medication is used in combination with Imjudo (tremelimumab-actl intravenous infusion); AND

D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):

A) For a patient weighing ≥ 30 kg: 1,500 mg administered as an intravenous infusion not more frequently than once every 4 weeks; OR
B) For a patient weighing < 30 kg: 20 mg/kg administered as an intravenous infusion not more frequently than once every 4 weeks.

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5. Muscle Invasive Bladder Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
  i. Patient meets BOTH of the following (a and b):
    a) The medication as neoadjuvant treatment; AND
    b) The medication is used in combination with chemotherapy; OR
    Note: Examples of chemotherapy are gemcitabine and cisplatin.
  ii. Patient meets BOTH of the following (a and b):
    a) The medication is used as monotherapy for adjuvant treatment; AND
    b) Patient had radical cystectomy; AND
C) The medication is prescribed by or in consultation with an oncologist.

Dosing: Approve ONE of the following doses (A or B):
A) For a patient weighing ≥ 30 kg: 1,500 mg administered as an intravenous infusion not more frequently than once every 3 weeks for up to 12 cycles; OR
B) For a patient weighing < 30 kg: 20 mg/kg administered as an intravenous infusion not more frequently than once every 3 weeks for up to 12 cycles.

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6. Non-Small Cell Lung Cancer – Neoadjuvant, Adjuvant, and Consolidation Therapy. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (*EGFR*) *exon 19 deletion or exon 21 L858R*, anaplastic lymphoma kinase (*ALK), RET, or ROS1*; AND
C) Patient has Stage IB to Stage III disease and meets ONE of the following (i or ii):
  i. The medication is used as neoadjuvant therapy in combination with platinum chemotherapy; OR
  Note: Examples of platinum chemotherapy agents include cisplatin and carboplatin.
  ii. The medication is used as adjuvant or consolidation therapy and meets BOTH of the following (a and b)
    a) Medication is used as a single-agent; AND
    b) Patient has not had disease progression following treatment with concurrent platinum-based chemotherapy and radiation therapy; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):
A) For a patient with a body weight ≥ 30 kg, approve ONE of the following (i or ii):
  i. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks; OR
  ii. Approve 1,500 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR

B) For a patient with a body weight < 30 kg, approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.

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6. Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

A) Patient is ≥ 18 years of age; AND

B) The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor *(EGFR)* exon 19 deletion or exon 21 *L858R*, anaplastic lymphoma kinase *(ALK), RET, and ROS1*; AND

C) Patient meets ONE of the following (i, ii, iii, or iv):

i. Patient meets BOTH of the following (a and b):

a) The tumor is positive for ONE of the following [(1), (2), or (3)]:

(1) Epidermal growth factor receptor (*EGFR*) exon 20 mutation positive; OR

(2) *ERBB2* (*HER2*) mutation positive; OR

(3) *NRG1* gene fusion positive*;* AND

b) Medication is used as first-line therapy; OR

ii. Patient meets BOTH of the following (a and b):

a) The tumor is positive for ONE of the following [(1), (2), or (3)]:

(1) *BRAF V600E* mutation positive; OR

(2) *NTRK1/2/3* gene fusion positive; OR

(3) *MET* exon 14 skipping mutation positive; AND

b) The medication is used as first-line or subsequent therapy; OR

iii. Patient meets BOTH of the following (a and b):

a) The tumor is positive for *EGFR S768I*, *L861Q*, and/or *G719X* mutation positive; AND

b) The medication is used as subsequent therapy; OR

iv. Patient meets BOTH of the following (a and b):

a) The tumor has no actionable mutations; AND

Note: The tumor does NOT have the following mutations: *EGFR exon 19* deletion*, EGFR exon 21 L858R, EGFR S768I, EGFR L861Q, EGFR G719X, EGFR exon 20* insertion*, ALK* rearrangement, *ROS1* rearrangement*, BRAF V600E, NTRK 1/2/3* gene fusion*, METex14* skipping*, RET* rearrangement, *ERBB2 (HER2), and NRG1* gene fusion.

b) Patient meets ONE of the following [(1), (2), or (3)]:

(1) The medication is used as consolidation therapy; OR

(2) The medication is used as first-line therapy; OR

(3) The medication is used as continuation maintenance therapy; AND

D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):

A) For a patient with a body weight ≥ 30 kg, approve ONE of the following (i or ii):

i. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks; OR

ii. Approve 1,500 mg administered as an intravenous infusion not more frequently than once every 4 weeks; OR

B) For a patient with a body weight < 30 kg, approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks

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7. Small Cell Lung Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

A) Patient is ≥ 18 years of age; AND
B) Patient meets one of the following (i. or ii)
  i. Patient has extensive stage disease and meets one of the following (a or b):
    a) The medication is used in combination with etoposide and platinum chemotherapy; OR
    Note: Examples of platinum chemotherapy agents include cisplatin and carboplatin.
    b) The medication is used as a single-agent for maintenance after chemotherapy; OR
  ii. Patient has limited stage disease and meets BOTH of the following (a and b):
    a) The medication is being used for adjuvant therapy; AND
    b) The medication is being used as a single agent; AND
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):
A) For a patient with a body weight ≥ 30 kg: Approve 1,500 mg administered as an intravenous infusion not more frequently than once every 3 weeks; OR
B) For a patient with a body weight < 30 kg approve ONE of the following (i, ii, or iii):
  i. Approve 20 mg/kg administered as an intravenous infusion, in combination with chemotherapy, not more frequently than once every 3 weeks; OR
  ii. Approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks for extensive stage disease; OR
  iii. Approve 20 mg/kg administered as an intravenous infusion not more frequently than once every 4 weeks for limited stage disease.

Other Uses with Supportive Evidence

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8. Ampullary Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has pancreatobiliary/mixed type disease; AND
C) Patient has unresectable localized disease or metastatic disease; AND
D) The medication is used in combination with gemcitabine and cisplatin; AND
E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):
A) For a patient with a body weight ≥ 30 kg: Approve 1,500 mg administered as an intravenous infusion, in combination with chemotherapy, not more frequently than once every 3 weeks; OR
B) For a patient with a body weight < 30 kg: Approve 20 mg/kg administered as an intravenous infusion, in combination with chemotherapy, not more frequently than once every 3 weeks.

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9. Cervical Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has small cell neuroendocrine carcinoma of the cervix; AND
C) Patient has persistent, recurrent, or metastatic disease; AND
D) Patient meets ONE of the following (i or ii):
  i. The medication is used in combination with etoposide and platinum chemotherapy; OR
  Note: Examples of platinum chemotherapy agents include cisplatin and carboplatin
  ii. The medication is used as a single agent for maintenance therapy; AND
E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A or B):

A) For a patient with a body weight ≥ 30 kg: Approve 1,500 mg administered as an intravenous infusion, in combination with chemotherapy, not more frequently than once every 3 weeks; OR

B) For a patient with a body weight < 30 kg: Approve 20 mg/kg administered as an intravenous infusion, in combination with chemotherapy, not more frequently than once every 3 weeks.

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11. Esophageal and Esophagogastric Junction Cancers. Approve for the duration noted if the patient meets ALL of the following (A, B, C, D, E, F, and G):

A) Patient is ≥ 18 years of age; AND

B) Patient has adenocarcinoma tumor; AND

C) Patient meets ONE of the following (i or ii):

i. Approve for 3 months if the patient meets ALL of the following (a, b, and c):

a) Patient has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND

b) The medication is as neoadjuvant therapy; AND

c) The medication is used in combination with Imjudo (tremelimumab intravenous infusion); OR

ii. Approve for 1 year if the patient meets BOTH of the following (a and b):

a) The tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) ≥ 1%; AND

b) Patient meets ONE of the following [(1) or (2)]:

(1) The medication is used as single agent; OR

(2) The medication is used in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT); AND

D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 1,500 mg administered by intravenous infusion, not more frequently than every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Imfinzi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Imfinzi® intravenous infusion [prescribing information]. Wilmington, DE: AstraZeneca; November 2025.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 2, 2025. Search term: durvalumab.
3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – December 2, 2025). © 2025National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
4. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – September 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
5. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – October 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
6. The NCCN Cervical Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – November 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
7. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 2.2025– July 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.

8. The NCCN Ampullary Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2025 – January 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
9. Oh D-Y, Ruth HE A, Qin S, et al. Durvalumab plus gemcitabine and cisplatin in advanced biliary tract cancer. *NEJM Evid*. 2022;1:EVIDoa2200015.
10. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 4.2025 – August 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
11. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – August 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
12. The NCCN Blader Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – October 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 2, 2025.
13. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2026 – November 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 14, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Biliary Tract Cancers:** Patient has resectable locally advanced disease added as new option of approval with a total duration of approval of 6 months. **Non-Small Cell Lung Cancer:** Exon 21 was added as a descriptor for exon 21 *L858R* mutation positive disease. **Ampullary Adenocarcinoma:** Added new condition of approval. **Cervical Cancer:** Added new condition of approval.	07/19/2023
Selected Revision	**Esophageal and Esophagogastric Junction Cancer:** Added new condition of approval. **Gastric Cancer:** Added new condition of approval.	10/25/2023
Annual Revision	**Biliary Tract Cancer:** Revised locally to locoregionally in "patient has resectable locoregionally advanced disease". Removed recurrent and added resected gross residual in "patient has unresectable, resected gross residual, or metastatic disease". **Endometrial Cancer:** Added new condition of approval. **Hepatocellular Carcinoma:** Removed "metastatic" and added "liver-confined" to criterion patient has "liver-confined, unresectable disease"; and added "according to the prescriber, the patient is not eligible for transplant", as a new option for approval. Added "patient has metastatic disease" and "according to the prescriber, the patient is not eligible for resection, transplant, or locoregional therapy" as a new option for approval. Removed criterion that the patient is not a surgical candidate. **Non-Small Cell Lung Cancer:** Added "*KRAS G12C* is not considered an actionable mutation (the tumor may be *KRAS G12C* mutation positive)" to the Note for criterion the tumor is negative for actionable molecular markers. Removed *KRAS G12C* mutation positive as an option for approval for first-line use of Imfinzi. **Cervical Cancer:** Added medication is used as a single-agent for maintenance therapy as a new option for approval.	07/24/2024
Annual Revision	**Muscle Invasive Bladder Cancer:** This has been added new condition of approval. **Non-Small Cell Lung Cancer** was divided into **Non-Small Cell Lung Cancer – Neoadjuvant and Adjuvant** and **Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease.** Dosing was separated into respective treatments. **Non-Small Cell Lung Cancer – Neoadjuvant and Adjuvant:** Indication was changed to as listed. Previously, all non-small cell lung cancer (NSCLC) was addressed more generally under NSCLC. Added a requirement that the "tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1." For a patient who has Stage II or Stage III disease, added a requirement that the "medication is used as neoadjuvant therapy in combination with platinum chemotherapy" and "medication is used as adjuvant therapy as a single-agent." Removed 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks from the approval dosing regimens (applies only for recurrent, advanced, or metastatic disease). **Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease:** Indication was changed to as listed. Previously, all non-small cell lung cancer (NSCLC) was addressed more generally under NSCLC. Added a requirement that the "the tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (EGFE) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (ALK), RET, and ROS1". Added "the tumor has no actionable mutations; Note: The tumor does NOT have the following mutations: EGFR exon 19 deletion, EGFR exon 21 L858R, EGFR S768I, EGFR L861Q, EGFR G719X, EGFR exon 20 insertion, ALK rearrangement, ROS1 rearrangement, BRAF V600E, NTRK 1/2/3 gene fusion, METex14 skipping, RET rearrangement, ERBB2 (HER2), and NRG1 gene fusion." as a condition for approval, if the medication is used as first-line therapy or as continuation maintenance therapy. Added "NRG1 gene fusion positive" as an approval condition for first-line therapy. Removed "RET rearrangement positive" as an approvable mutation, if used as first-line or subsequent therapy. For subsequent therapy, the option of approval "EGFR exon 19 deletion or exon 21 L858R mutation positive, ALK rearrangement positive, or ROS1 rearrangement" added and the requirement that "the patient has received targeted drug therapy for the specific mutation" was removed as approval option. Dosing for a patient with a body weight ≥ 30 kg was changed to "approve 1,500 mg administered as an intravenous infusion not more frequently than once every 4 weeks," previously every 3 weeks. For a patient < 30 kg, removed 20 mg/kg administered as an intravenous infusion	06/11/2025

	not more frequently than once every 3 weeks from the approval dosing regimens (applies only for neoadjuvant or adjuvant use). **Small Cell Lung Cancer:** Added limited stage disease as a condition for approval. Dosing was added for limited stage disease and was specified for extensive stage disease.	
Selected Revision	**Non-Small Cell Lung Cancer – Neoadjuvant, Adjuvant, and Consolidation Therapy:** Indication was changed to as listed. Previously, listed as Non-Small Cell Lung Cancer – Neoadjuvant and Adjuvant. The medication is used as adjuvant therapy was modified to the medication is used as adjuvant or consolidation therapy. **Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease:** In the criterion referring to tumor has no actionable biomarkers, the medication is used as consolidation therapy was added as an option for approval.	09/03/2025
Selected Revision	**Non-Small Cell Lung Cancer – Neoadjuvant, Adjuvant, and Consolidation Therapy:** Added 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks to the approval dosing regimens for patients with a body weight ≥ 30 kg. Modified the dosing regimen for a patient with a body weight < 30 kg, approve 20 mg/kg administered as an intravenous infusion not more frequently than once every 3 weeks to approve 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.	09/24/2025
Early Annual Revision	**Biliary Tract Cancer:** When a patient has unresectable, resected gross residual, or metastatic disease, the options that if the patient has recurrent disease, recurrence occurred at least 6 months after surgery and at least 6 months after adjuvant therapy; AND the patient has ONE of the following: gallbladder cancer; OR intrahepatic cholangiocarcinoma; OR extrahepatic cholangiocarcinoma were removed. The approval option that the patient has resectable locoregionally advanced disease was modified to the patient has resectable locoregionally advanced gallbladder cancer. **Endometrial Cancer:** The approval option that the disease is mismatch repair proficient (pMMR) was added. The requirement the patient meets ONE of the following: the medication is used in combination with carboplatin or the medication is used as a single agent was removed. **Gastric Cancer:** This condition was moved from "Other Uses with Supported Evidence" to "FDA-Approved Indications." The approval option to approve for 1 year if the patient meets BOTH of the following: the tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) ≥ 1% AND the medication is used as single agent OR the medication is used in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) was added. The requirement that according to the physician, the patient is medically fit for surgery was removed. Dosing was modified for a patient with a body weight ≥ 30 kg, to approve 1,500 mg administered as an intravenous infusion not more frequently than once every 4 weeks, and for a patient < 30 kg, removed 20 mg/kg administered as an intravenous infusion not more frequently than once every 4 weeks. Previously, dosing approved 1,500 mg administered by intravenous infusion, not more frequently than three times in a single 12-week cycle. **Hepatocellular Carcinoma:** The requirement that the medication will be used as first-line was removed. **Non-Small Cell Lung Cancer – Neoadjuvant, Adjuvant, and Consolidation Therapy**: The requirement that the patient has Stage II or Stage III disease was modified to the patient has Stage IB to Stage III disease. **Ampullary Adenocarcinoma:** The requirement that the medication is used as first-line therapy was removed. **Esophageal and Esophagogastric Junction Cancers:** The approval option to approve for 1 year if the patient meets BOTH of the following: the tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) ≥ 1% AND the medication is used as single agent OR the medication is used in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) was added. The requirement that according to the physician, the patient is medically fit for surgery was removed. Dosing was modified to approve 1,500 mg administered by intravenous infusion, not more frequently than every 4 weeks. Previously, dosing approved 1,500 mg administered by intravenous infusion, not more frequently than three times in a single 12-week cycle.	12/17/2025