



## UTILIZATION MANAGEMENT MEDICAL POLICY

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

**REVIEW DATE:** 06/11/2025

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### OVERVIEW

Imfinzi, a programmed cell death ligand 1 (PD-L1) blocking antibody, is indicated for the following uses:<sup>1</sup>

- **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, followed by single-agent Imfinzi, followed by 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.
- **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 with unresectable Stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
  - In combination with platinum-containing chemotherapy, followed by Imfinzi single-agent after surgery, for the treatment of adults with resectable (tumors  $\geq 4$  cm and/or node positive) disease and no known epidermal growth factor receptor (*EGFR*) mutations or anaplastic lymphoma kinase (*ALK*) rearrangements.
  - In adults with 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 combination with etoposide and either carboplatin or cisplatin for the first-line treatment of extensive-stage disease in adults.
  - As a single agent, for the treatment limited-stage disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy in adults.

### 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 or B):

- A) Patient has resectable locoregionally advanced disease:** Approve for 6 months (total) if the patient meets ALL of the following (i, ii, iii, iv, and v):
- i. Patient is  $\geq 18$  years of age; AND
  - ii. Patient has gallbladder cancer; AND
  - iii. The medication is used as neoadjuvant therapy; AND
  - iv. The medication is used in combination with cisplatin and gemcitabine; AND
  - v. The medication is prescribed by or in consultation with an oncologist; OR
- B) Patient has unresectable, resected gross residual, or metastatic disease:** Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, and v):
- i. Patient is  $\geq 18$  years of age; AND
  - ii. If the patient has recurrent disease, recurrence occurred at least 6 months after surgery and at least 6 months after adjuvant therapy; AND
  - iii. Patient has ONE of the following (a, b, or c):
    - a) Gallbladder cancer; OR
    - b) Intrahepatic cholangiocarcinoma; OR
    - c) Extrahepatic cholangiocarcinoma; AND
  - iv. The medication will be used in combination with cisplatin and gemcitabine; AND
  - v. 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  $\geq 30$  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, D, and E):

- A)** Patient is  $\geq 18$  years of age; AND
- B)** Patient has primary advanced or recurrent disease; AND
- C)** Disease is mismatch repair deficient (dMMR); AND
- D)** Patient meets ONE of the following (i or ii):
- i. The medication is used in combination with carboplatin and paclitaxel; OR
  - ii. The medication is used as a single agent; 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 weighing  $\geq 30$  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. Hepatocellular Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

- A) Patient is  $\geq$  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) The medication will be used first-line; AND
- D) 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
- 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 weighing  $\geq$  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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**4. Muscle Invasive Bladder Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A) Patient is  $\geq$  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  $\geq$  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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**5. Non-Small Cell Lung Cancer – Neoadjuvant and Adjuvant.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) Patient is  $\geq 18$  years of age; AND
- B) The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (*EGRF*) exon 19 deletion or exon 21 L858R, anaplastic lymphoma kinase (*ALK*), *RET*, or *ROS1*; AND
- C) Patient has Stage II or 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 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  $\geq 30$  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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**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  $\geq 18$  years of age; AND
- B) The tumor is negative for the following actionable biomarkers: epidermal growth factor receptor (*EGRF*) 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: EFGR exon 19 deletion, EFGR exon 21 L858R, EFGR 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) or (2)]:
    - (1) The medication is used as first-line therapy; OR
    - (2) 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  $\geq 30$  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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**6. Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) Patient is  $\geq 18$  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  $\geq 30$  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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**7. Ampullary Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):

- A) Patient is  $\geq 18$  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 as first-line therapy; AND
- E) The medication is used in combination with gemcitabine and cisplatin; AND
- F) 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  $\geq 30$  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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**8. Cervical Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

- A) Patient is  $\geq 18$  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  $\geq 30$  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. Esophageal and Esophagogastric Junction Cancers.** Approve for 3 months if the patient meets ALL of the following (A, B, C, D, E, F, and G):

- A) Patient is  $\geq 18$  years of age; AND
- B) Patient has adenocarcinoma tumor; AND
- C) Patient has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND
- D) The medication is as neoadjuvant therapy; AND
- E) The medication is used in combination with Imjudo (tremelimumab intravenous infusion); AND
- F) According to the physician, the patient is medically fit for surgery; AND
- G) The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve 1,500 mg administered by intravenous infusion, not more frequently than three times in a single 12 week cycle.

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**10. Gastric Cancer.** Approve for 3 months if the patient meets ALL of the following (A, B, C, D, E, F, and G):

- A) Patient is  $\geq 18$  years of age; AND
- B) Patient has locoregional disease; AND
- C) Patient has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND

- D) The medication is as neoadjuvant therapy; AND
- E) The medication is used in combination with Imjudo (tremelimumab intravenous infusion); AND
- F) According to the physician, the patient is medically fit for surgery; AND
- G) The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve 1,500 mg administered by intravenous infusion, not more frequently than three times in a single 12 week cycle.

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### 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

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3. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 5, 2025.
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7. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 1.2025– March 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 5, 2025.
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13. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 3.2025 – March 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed May 5, 2025.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p><b>Biliary Tract Cancers:</b> Patient has resectable locally advanced disease added as new option of approval with a total duration of approval of 6 months.</p> <p><b>Non-Small Cell Lung Cancer:</b> Exon 21 was added as a descriptor for exon 21 <i>L858R</i> mutation positive disease.</p> <p><b>Ampullary Adenocarcinoma:</b> Added new condition of approval.</p> <p><b>Cervical Cancer:</b> Added new condition of approval.</p>	07/19/2023
Selected Revision	<p><b>Esophageal and Esophagogastric Junction Cancer:</b> Added new condition of approval.</p> <p><b>Gastric Cancer:</b> Added new condition of approval.</p>	10/25/2023
Annual Revision	<p><b>Biliary Tract Cancer:</b> 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”.</p> <p><b>Endometrial Cancer:</b> Added new condition of approval.</p> <p><b>Hepatocellular Carcinoma:</b> 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.</p> <p><b>Non-Small Cell Lung Cancer:</b> Added “<i>KRAS G12C</i> is not considered an actionable mutation (the tumor may be <i>KRAS G12C</i> mutation positive)” to the Note for criterion the tumor is negative for actionable molecular markers. Removed <i>KRAS G12C</i> mutation positive as an option for approval for first-line use of Imfinzi.</p> <p><b>Cervical Cancer:</b> Added medication is used as a single-agent for maintenance therapy as a new option for approval.</p>	07/24/2024

**HISTORY (CONTINUED)**

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p><b>Muscle Invasive Bladder Cancer:</b> This has been added new condition of approval.</p> <p><b>Non-Small Cell Lung Cancer</b> was divided into <b>Non-Small Cell Lung Cancer – Neoadjuvant and Adjuvant</b> and <b>Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease</b>. Dosing was separated into respective treatments.</p> <p><b>Non-Small Cell Lung Cancer – Neoadjuvant and Adjuvant:</b> 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).</p> <p><b>Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease:</b> 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 (EGFR) 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 <math>\geq 30</math> 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 <math>&lt; 30</math> kg, removed 20 mg/kg administered as an intravenous infusion not more frequently than once every 3 weeks from the approval dosing regimens (applies only for neoadjuvant or adjuvant use).</p> <p><b>Small Cell Lung Cancer:</b> Added limited stage disease as a condition for approval. Dosing was added for limited stage disease and was specified for extensive stage disease.</p>	06/11/2025