Utilization Review Policy 291

POLICY: Oncology (Injectable – CTLA-4 Antibody) – Imjudo Utilization Management Medical Policy
- Imjudo® (tremelimumab-actl intravenous infusion – AstraZeneca)

EFFECTIVE DATE: 01/15/2023
LAST REVISION DATE: 10/08/2025

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Imjudo, a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) monoclonal antibody, is indicated for the following uses:[1]

- **Hepatocellular carcinoma**, in combination with Imfinzi® (durvalumab intravenous infusion), for the treatment of adults with unresectable disease.
- **Non-small cell lung cancer** (NSCLC), in combination with Imfinzi and platinum-based chemotherapy, for the treatment of adults with metastatic disease and no epidermal growth factor receptor (*EGFR*) mutations or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations.

Dosing Information

The recommended dose of Imjudo is weight-based. For patients with hepatocellular carcinoma, the recommended dose is as follows:[1]

- For patients ≥ 30 kg: Imjudo 300 mg as a single intravenous (IV) dose administered in combination with Imfinzi 1,500 mg IV on Day 1 of cycle 1. Imfinzi is then continued, as a single agent, once every 4 weeks until disease progression or unacceptable adverse events.
- For patients < 30 kg: Imjudo 4 mg/kg as a single IV dose administered in combination with Imfinzi 20 mg/kg IV on Day 1 of cycle 1. Imfinzi is then continued, as a single agent, once every 4 weeks until disease progression or unacceptable adverse events.

The recommended dose for NSCLC is as follows:

- For patients ≥ 30 kg: Imjudo 75 mg IV administered once every 3 weeks in combination with Imfinzi 1,500 mg IV and platinum-based chemotherapy for 4 cycles. One additional dose of Imfinzi 1,500 mg IV with histology-based pemetrexed is given 3 weeks later (cycle 5), then the schedule for both is switched to once every 4 weeks. A fifth dose of Imjudo 75 mg IV is administered with Imfinzi dose 6 at Week 16. Imfinzi is continued until disease progression or unacceptable adverse events.
- For patients < 30 kg: Imjudo 1 mg/kg IV administered once every 3 weeks in combination with Imfinzi 20 mg/kg IV and platinum-based chemotherapy for 4 cycles. One additional dose of Imfinzi 20 mg/kg IV with histology-based pemetrexed is given 3 weeks later (cycle 5), then the schedule for both is switched to once every 4 weeks. A fifth dose of Imjudo 1 mg/kg IV is administered with Imfinzi dose 6 at week 16. Imfinzi is continued until disease progression or unacceptable adverse events.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Imjudo. Approval is recommended for those who meet 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. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Imjudo as well as the monitoring required for adverse events and long-term efficacy, approval requires Imjudo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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1. **Hepatocellular Carcinoma.** Approve for 30 days 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.** The medication will be used as first-line therapy and the patient meets ONE of the following (a or b):
       - **a)** Patient has liver-confined unresectable disease and according to the prescriber, the patient is deemed ineligible for transplant; OR
       - **b)** Patient has extrahepatic or metastatic disease and according to the prescriber, the patient is deemed ineligible for resection, transplant, or locoregional therapy; OR
     - **ii.** The medication will be used for subsequent therapy; AND
   - **C)** The medication is used in combination with Imfinzi (durvalumab intravenous infusion); AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve ONE of the following dosing regimens (A or B):
   - **A)** Patient weighs ≥ 30 kg: Approve a single dose of 300 mg administered by intravenous infusion; OR
   - **B)** Patient weighs < 30 kg: Approve a single dose of 4 mg/kg administered by intravenous infusion.

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2. **Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D, and E):
   - **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)** The medication is used in combination with Imfinzi (durvalumab intravenous infusion); AND
   - **D)** 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)** *EGFR* exon 20 mutation positive; OR
         - **(2)** *ERBB2* (*HER2*) mutation positive; OR
         - **(3)** *NRG1* gene fusion positive; AND
       - **b)** The 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 *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) The medication is used as first-line therapy; AND

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

Dosing. Approve ONE of the following dosing regimens (A or B):
A) Patient weighs ≥ 30 kg: Approve 75 mg administered by intravenous infusion no more frequently than once every 3 weeks; OR
B) Patient weighs < 30 kg: Approve 1 mg/kg administered by intravenous infusion no more frequently than once every 3 weeks.

Other Uses with Supportive Evidence

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3. Esophageal and Esophagogastric Junction Cancers. Approve for 30 days 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 has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND
D) The medication is used as neoadjuvant therapy; AND
E) The medication is used in combination with Imfinzi (durvalumab 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 a single dose of 300 mg administered by intravenous infusion.

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4. Gastric Cancer. Approve for 30 days 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 locoregional disease; AND
C) Patient has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND
D) The medication is used as neoadjuvant therapy; AND
E) The medication is used in combination with Imfinzi (durvalumab 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 a single dose of 300 mg administered by intravenous infusion.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Imjudo 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. Imjudo® intravenous infusion [prescribing information]. Wilmington, DE: AstraZeneca; July 2024.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 30, 2025. Search term: tremelimumab.
3. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – March 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 30, 2025.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 8.2025 – August 15, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed September 30, 2025.
5. 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 September 30, 2025.
6. 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 September 30, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/02/2022
Selected Revision	**Non-Small Cell Lung Cancer:** This was added as a new condition of approval.	11/30/2022
Selected Revision	**Hepatocellular Carcinoma:** The descriptor "metastatic" was added to the requirement that the patient has unresectable or metastatic disease. According to the prescriber, the patient is not a surgical candidate was added as an additional option for approval. **Non-Small Cell Lung Cancer:** The descriptors "recurrent" and "advanced" were added to the requirement that the patient has recurrent, advanced, or metastatic disease. Removed requirement that Imjudo is used as first-line therapy. Added options for approval for patients without actionable molecular markers and for patients positive for epidermal growth factor receptor (EGFR) exon 20 mutation; KRAS G12C mutation; ERBB2 (HER2) mutation; BRAF V600E mutation; NTRK1/2/3 gene fusion; MET exon 14 skipping mutation; RET rearrangement; EGFR exon 19 deletion or L858R mutation; EGFR S768I, L861Q and/or G719X mutation; ALK rearrangement; or ROS1 rearrangement.	12/21/2022
Annual Revision	**Non-Small Cell Lung Cancer:** Added descriptor "exon 21" to option of approval "EGFR exon 19 deletion or exon 21 L858R mutation positive". **Esophageal and Esophagogastric Junction Cancer:** Added new condition of approval. **Gastric Cancer:** Added new condition of approval.	10/25/2023
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025
Annual Revision	**Hepatocellular Carcinoma:** The medication will be used as subsequent therapy was added as an approval option. **Non-Small Cell Lung Cancer – Recurrent, Advanced, or Metastatic Disease:** This condition of approval was changed to as listed. Previously, listed more generally under Non-Small Cell Lung Cancer. A requirement was added 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".	10/08/2025

	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 options of approval "EGFR exon 19 deletion or exon 21 L858R mutation positive, ALK rearrangement positive, or ROS1 rearrangement" were removed and the requirement that "the patient has received targeted drug therapy for the specific mutation" was removed as an approval option. 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.	