

Clinical Policy: Tremelimumab-actl (Imjudo)

Reference Number: PA.CP.PHAR.612

Effective Date: 01/2023

Last Review Date: 01/2026

Description

Tremelimumab-actl (Imjudo[®]) is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody.

FDA Approved Indication(s)

Imjudo is indicated for the treatment of:

- In combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC);
- In combination with durvalumab and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Imjudo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of recurrent, advanced, or metastatic NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Prescribed in combination with durvalumab and platinum-based therapy (*see Appendix D*) as one of the following (a-h):*

**Prior authorization may be required.*

- a. First-line therapy for disease without sensitizing EGFR mutations, ALK genomic tumor aberrations, or other actionable molecular biomarkers (e.g., KRAS, ROS1, BRAF, NTRK1/2/3, MET, RET, ERBB2 (HER2) – note: may be KRAS G12C mutation positive) (*see Appendix D*);
- b. First-line therapy for EGFR exon 20 insertion mutation positive disease;
- c. First-line or subsequent therapy for BRAF V600E mutation positive tumors;
- d. First-line or subsequent therapy for NTRK1/2/3 gene fusion positive tumors;
- e. First-line or subsequent therapy for MET exon 14 skipping mutation positive tumors;
- f. First-line therapy for ERBB2 (HER2) mutation positive tumors;
- g. First-line therapy for NRG1 gene fusion positive tumors;
- h. Subsequent therapy for EGFR S768I, L861Q, and/or G719X mutation positive tumors and prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib therapy;

5. Request meets one of the following (a, b, or c):
 - a. For body weight < 30 kg, dose does not exceed Imjudo 1 mg/kg every 3 weeks in combination with durvalumab 20 mg/kg and platinum-based chemotherapy for 4 cycles, and then durvalumab 20 mg/kg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo 1 mg/kg in combination with durvalumab dose 6 at week 16;
 - b. For body weight \geq 30 kg, dose does not exceed Imjudo 75 mg every 3 weeks in combination with durvalumab 1,500 mg and platinum-based chemotherapy for 4 cycles, and then durvalumab 1,500 mg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo 75 mg in combination with durvalumab dose 6 at week 16
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Hepatocellular Carcinoma (must meet all):

1. Diagnosis of one of the following (a or b):
 - a. Unresectable, liver-confined, or metastatic hepatocellular carcinoma;
 - b. Progression on or after systemic therapy;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Prescribed in combination with durvalumab*;
**Prior authorization may be required.*
5. Request meets one of the following (a, b, or c):
 - a. For body weight < 30 kg, new dose does not exceed 4 mg/kg as a single dose in combination with durvalumab 20 mg/kg at Cycle 1/Day 1, followed by durvalumab as a single agent every 4 weeks;
 - b. For body weight \geq 30 kg, new dose does not exceed, 300 mg as a single dose in combination with durvalumab 1,500 mg at Cycle 1/Day 1, followed by durvalumab as a single agent every 4 weeks;
 - c. Dose supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months (one dose)

C. Gastric, Esophageal, and Esophagogastric Junction Cancer (off-label) (must meet all):

1. Prescribed for one of the following diagnoses (a or b):
 - a. Gastric cancer;
 - b. Esophageal and esophagogastric junction adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Prescribed in combination with durvalumab as neoadjuvant therapy*;
**Prior authorization may be required.*
5. Request meets one of the following (a or b):
 - a. Dose is within FDA approved maximum recommended dose as a single dose;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months (one dose)

D. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I

1. Re-authorization is not permitted.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies – PA.CP.PMN.53.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase

BRAF: B-Raf proto-oncogene,
serine/threonine kinase

CTLA-4: cytotoxic T-lymphocyte-
associated antigen 4

dMMR: deficient mismatch repair

EGFR: epidermal growth factor receptor

ERBB2: Erb-B2 receptor tyrosine kinase
2

FDA: Food and Drug Administration

HER2: human epidermal growth factor
receptor-2

KRAS: KRAS proto-oncogene

MET: mesenchymal-epithelial
transition

MSI-H: microsatellite instability-high

MSI-H: microsatellite instability-high

NSCLC: non-small cell lung cancer

NTRK: neurotrophic tyrosine receptor
kinase

ROS1: ROS proto-oncogene 1

uHCC: unresectable hepatocellular
carcinoma

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

| Tumor Histology | Patient Weight | Imfinzi Dosage | Tremelimumab-actl Dosage | Platinum-based Chemotherapy Regimen |
|-----------------|----------------|----------------|--------------------------|--|
| Non-Squamous | ≥ 30 kg | 1,500 mg | 75 mg | carboplatin & nab-paclitaxel OR |
| | < 30 kg | 20 mg/kg | 1 mg/kg | carboplatin or cisplatin & pemetrexed |
| Squamous | ≥ 30 kg | 1,500 mg | 75 mg | carboplatin & nab-paclitaxel OR |
| | < 30 kg | 20 mg/kg | 1 mg/kg | carboplatin or cisplatin & gemcitabine |

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|------------|---|--------------|
| NSCLC | <ul style="list-style-type: none"> Weight < 30 kg: 1 mg/kg IV every 3 weeks in combination with durvalumab 20 mg/kg and platinum-based chemotherapy for 4 cycles, and then durvalumab 20 mg/kg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo 1mg/kg in combination with durvalumab dose 6 at week 16 Weight ≥30 kg: 75 mg IV every 3 weeks in combination with durvalumab 1,500 mg and platinum-based chemotherapy for 4 cycles, and then durvalumab 1,500 mg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of Imjudo 75 mg in combination with durvalumab dose 6 at week 16 | See regimen |
| uHCC | <ul style="list-style-type: none"> Weight < 30 kg: 4 mg/kg IV as a single dose in combination with durvalumab 20 mg/kg at Cycle 1/Day 1, followed by durvalumab as a single agent every 4 weeks Weight ≥30 kg: 300 mg IV as a single dose in combination with durvalumab 1,500 mg at Cycle 1/Day 1, followed by | See regimen |

| Indication | Dosing Regimen | Maximum Dose |
|------------|--|--------------|
| | durvalumab as a single agent every 4 weeks | |

VI. Product Availability

Single-dose vials: 25 mg/1.25 mL, 300 mg/15 mL

VII. References

1. Imjudo Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2024. Available at: <https://www.imfinzihcp.com>. Accessed November 5, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 5, 2025.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 8.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 5, 2025.
4. National Comprehensive Cancer Network. Hepatocellular Carcinoma Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed November 5, 2025.
5. National Comprehensive Cancer Network. Gastric Cancer Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed November 5, 2025.
6. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers Version 4.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed November 5, 2025.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|-------------|------------------------------------|
| J9347 | Injection, tremelimumab-actl, 1 mg |

| Reviews, Revisions, and Approvals | Date |
|---|---------|
| Policy created | 01/2023 |
| 1Q 2024 annual review: in initial approval criteria, added section C to include gastric, esophageal and esophagogastric junction cancer for off-label NCCN recommended uses per NCCN compendium; removed inactive HCPCS codes and added updated HCPCS code [J9347]; references reviewed and updated | 01/2024 |

| Reviews, Revisions, and Approvals | Date |
|---|----------------|
| <p>1Q 2025 annual review: For uHCC, revised continued therapy section to not permit re-authorization per package insert, per NCCN compendium– for NSCLC, added recommended uses for present and negative actionable molecular biomarkers; revised NCCN recommended uses section to Gastric, Esophageal, and Esophagogastric Junction Cancer, added requirement that disease is MSI-H or dMMR, and added provider attestation that member is medically fit for surgery; clarified prior authorization may be required for durvalumab; references reviewed and updated.</p> | <p>01/2025</p> |
| <p>1Q 2026 annual review: per NCCN compendium– for NSCLC, removed uses for RET rearrangement positive, EGFR exon 19 deletion, exon 21 L858R, ALK rearrangement positive, and ROSI rearrangement positive tumors; added recommended uses for NRG1 gene fusion positive tumors; for gastric, esophageal, and esophagogastric junction cancer, clarified approval is for one dose; for all indications, revised continued therapy section to not permit reauthorizations per PI; references reviewed and updated.</p> | <p>01/2026</p> |