Clinical Policy: Tremelimumab-actl (Imjudo)

Reference Number: PA.CP.PHAR.612
Effective Date: 01/2023
Last Review Date: 01/2025

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 ≥ 18 years;
4. Prescribed in combination with durvalumab and platinum-based therapy *(see Appendix D)* as one of the following (a-k):*

   **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 NRTK1/2/3 gene fusion positive tumors;
   e. First-line or subsequent therapy for MET exon 14 skipping mutation positive tumors;
   f. First-line or subsequent therapy for RET rearrangement positive tumors;
   g. First-line therapy for ERBB2 (HER2) mutation positive tumors;

h. Subsequent therapy for EGFR exon 19 deletion or exon 21 L858R tumors and prior erlotinib (with or without ramucirumab or bevacizumab), afatinib, gefitinib, osimertinib, amivantamab-vmjw + lazertinib, or dacomitinib therapy;
i. Subsequent therapy for EGFR S768I, L861Q, and/or G719X mutation positive tumors and prior afatinib, osimertinib, erlotinib, gefitinib, or dacomitinib therapy;
j. Subsequent therapy for ALK rearrangement positive tumors and prior crizotinib, ceritinib, alectinib, brigatinib, or lorlatinib therapy;
k. Subsequent therapy for ROS1 rearrangement positive tumors and prior crizotinib, entrectinib, repotrectinib, ceritinib, or lorlatinib 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 ≥ 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 unresectable, liver-confined, or metastatic hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 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 ≥ 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 ≥ 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;
   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

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. Hepatocellular Carcinoma

1. Re-authorization is not permitted.

Approval duration: Not applicable

B. All Other Indications in Section I (must meet all)**:**

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;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. For metastatic NSCLC (i or ii):
      i. For body weight < 30 kg, dose does not exceed 1 mg/kg every 3 weeks in combination with durvalumab 20 mg/kg and platinum-based chemotherapy for 4 cycles and a fifth dose of Imjudo 1 mg/kg in combination with durvalumab dose 6 at week 16;
      ii. For body weight ≥ 30 kg, dose does not exceed 75 mg every 3 weeks in combination with durvalumab 1,500 mg and platinum-based chemotherapy for 4 cycles, and a fifth dose of Imjudo 75 mg in combination with durvalumab dose 6 at week 16;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

C. 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
dMMR: deficient mismatch repair
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
MSI-H: microsatellite instability-high
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NSCLC: non-small cell lung cancer
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 carboplatin or cisplatin & pemetrexed
	< 30 kg	20 mg/kg	1 mg/kg	
Squamous	≥ 30 kg	1,500 mg	75 mg	carboplatin & nab-paclitaxel OR carboplatin or cisplatin & gemcitabine
	< 30 kg	20 mg/kg	1 mg/kg	

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	• 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	See regimen

Indication	Dosing Regimen	Maximum Dose
	• 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	
uHCC	• 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 durvalumab as a single agent every 4 weeks	See regimen

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 October 22, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed October 22, 2024.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 11.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed October 22, 2024.
4. National Comprehensive Cancer Network. Hepatocellular Carcinoma Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed October 22, 2024.
5. National Comprehensive Cancer Network. Gastric Cancer Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed October 22, 2024.
6. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed October 22, 2024.

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
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.	01/2025