Clinical Policy: Tremelimumab-actl (Imjudo)

Reference Number: PA.CP.PHAR.612
Effective Date: 01/2023
Last Review Date: 01/2024

Revision Log

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 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)*;
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;
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

C. NCCN Recommended Uses (off-label) (must meet all):
1. Prescribed for one of the following diagnoses (a or b):
   1. Gastric cancer;
   2. Esophageal and esophagogastric junction cancers;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with durvalumab;
5. Dose is within FDA maximum limit for any FDA-approved indication or 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. All 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.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):
   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. For uHCC (i or ii):
   i. For body weight < 30 kg, new dose does not exceed Imjudo 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;
   ii. For body weight ≥ 30 kg, new dose does not exceed, Imjudo 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. 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

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.LTSS.PHAR.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
EGFR: epidermal growth factor receptor
FDA: Food and Drug Administration
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
	≥ 30 kg	1,500 mg	75 mg	carboplatin & nab-paclitaxel

Non-Squamous	< 30 kg	20 mg/kg	1 mg/kg	OR carboplatin or cisplatin & pemetrexed
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 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 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	• Weight < 30 kg: 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 Weight ≥30 kg: 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	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; November 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761270s000lbl.pdf. Accessed November 15, 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 15, 2023.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 5.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed November 15, 2023.
4. National Comprehensive Cancer Network. Hepatocellular Carcinoma Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed November 15, 2023.
5. National Comprehensive Cancer Network. Gastric Cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed November 15, 2023.
6. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers Version 3.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed November 15, 2023.

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