

Clinical Policy: Tremelimumab-actl (Imjudo)

Reference Number: PA.CP.PHAR.612

Effective Date: 01/2023

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[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 \geq 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 \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 unresectable, liver-confined, or metastatic hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 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 \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

C. 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 \geq 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 \geq 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
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 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	<ul style="list-style-type: none"> 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/2022/761270s0001bl.pdf. Accessed December 1, 2022.
2. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 6.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed December 2, 2022.

3. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed December 2, 2022.

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
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2023	