Clinical Policy: Tremelimumab-actl (Imjudo)

Reference Number: LA.PHAR.612
Effective Date: 09.29.23
Last Review Date: 10.11.24 ~~02.10.24~~ Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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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 Louisiana Healthcare Connections® 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months (one dose)

C. NCCN Recommended Uses (off-label) (must meet all):

1. Prescribed for one of the following diagnoses (a or b):
   ~~1.~~a. Gastric cancer;
   ~~2.~~b. 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).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. ~~D.~~ Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

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criterion 1 above does not apply, refer to the off-label use policy ~~for the relevant line of business:~~ LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Hepatocellular Carcinoma

1. Re-authorization is not permitted.

Approval duration: Not applicable

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

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Imjudo for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets ~~once~~either of the following (a~~, b,~~ or ~~c~~b):*
   a. For metastatic NSCLC (i or ii):
      i. For body weight < 30 kg, new 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, new 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.~~b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1~~2~~ above does not apply, refer to the off-label use policy ~~for the relevant line of business:~~ LA.PMN.53 for Medicaid.

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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 – LA.PMN.53 for Medicaid or evidence of coverage documents.

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: Recommended Combination Regimens

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 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	See regimen

Indication	Dosing Regimen	Maximum Dose
	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 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.~~June 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/~~2022/761270s000lbl~~2024/761289s004lbl.pdf. Accessed ~~November 15, 2023~~July 25, 2024.
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-

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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	LDH Approval Date
Policy created	05.01.23	08.28.23
Added updated HCPCS code [J9347]; 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; references reviewed and updated	02.10.24	05.10.24
Revised continued therapy section to not permit re-authorization per package insert for uHCC	10.11.24	

Important Reminder

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This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

CLINICAL POLICY
Tremelimumab-actl

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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