Tremelimumab-actl (Imjudo®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Imjudo is indicated in combination with durvalumab for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).
- Imjudo is indicated 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.

Compendial Uses

- Recurrent and advanced NSCLC
- Esophageal and esophagogastric junction cancer
- Gastric cancer
- Hepatocellular carcinoma

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of the absence of EGFR exon 19 deletion and exon 21 L858R mutations, ALK, RET, and ROS1 rearrangements, where applicable (unless testing is not feasible due to insufficient tissue).
- Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumor status, where applicable.

COVERAGE CRITERIA

Hepatocellular Carcinoma

Authorization of 1 month for a one-time single dose may be granted for first-line treatment of hepatocellular carcinoma when all of the following criteria are met:

- The requested medication will be used in combination with durvalumab (Imfinzi).

- The disease is unresectable or extrahepatic/metastatic.
- The member is ineligible for transplant.

Authorization of 1 month for a one-time single dose may be granted for subsequent treatment of hepatocellular carcinoma when all of the following criteria are met:

- The requested medication will be used in combination with durvalumab (Imfinzi).
- The disease is unresectable or extrahepatic/metastatic.
- The member has not been previously treated with an anti-CTLA4-based regimen.

NSCLC

Authorization of 6 months for a total of 5 doses may be granted for treatment of recurrent, advanced or metastatic non-small cell lung cancer when all of the following criteria are met:

- The requested medication will be used in combination with durvalumab (Imfinzi) and platinum-based chemotherapy.
- The tumor is negative for EGFR exon 19 deletion and exon 21 L858R mutations, ALK, RET, and ROS1 rearrangements.

Esophageal, Esophagogastric Junction and Gastric Cancer

Authorization of 1 month for a one-time single dose may be granted for treatment of esophageal, esophagogastric junction or gastric cancer when all of the following criteria are met:

- The requested medication will be used in combination with durvalumab (Imfinzi) for neoadjuvant treatment.
- The tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR).
- The member is medically fit for surgery.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Imjudo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 10, 2025.
3. Pietrantonio, Filippo, Raimondi Alessandra, Lonardi Sara, et al. Infinity: A multicenter, single-arm, multi-cohort, phase II trial of tremelimumab and durvalumab as neoadjuvant treatment of patients with microsatellite instability-high (MSI) resectable gastric or gastroesophageal junction adenocarcinoma (GAC/GEJAC). Journal of Clinical Oncology. 2023; 4: 358.

4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf Accessed July 17, 2025.

EFFECTIVE DATE 4/2/2026

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