Reference number(s)
5656-A

Standard Medicare Part B Management
Imjudo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Imjudo	tremelimumab-actl

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[1]

- 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) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Compendial Uses[2]

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

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

The following documentation must be available, upon request, for all submissions where applicable:

- Documentation of the absence of EGFR exon 19 deletion and exon 21 L858R mutations, ALK, RET, and ROS1 gene fusions, where applicable.
- Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumor status, where applicable.

Coverage Criteria

Hepatocellular Carcinoma[1,2,3]

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[1,2]

Authorization of 6 months for a total of 5 doses may be granted for treatment of recurrent, advanced, or metastatic NSCLC 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 gene fusions (unless testing is not feasible due to insufficient tissue).

Esophageal, Esophagogastric Junction and Gastric Adenocarcinoma[2,4]

Authorization of 1 month for a one-time single dose may be granted for treatment of esophageal, esophagogastric junction, or gastric adenocarcinoma 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 mismatch repair deficient (dMMR).
- The member is medically fit for surgery.

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Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Imjudo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Non-small cell lung cancer
- NCCN Guideline: Hepatocellular carcinoma
- NCCN Guideline: Gastric cancer
- NCCN Guideline: Esophageal and esophagogastric junction cancers

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Imjudo to treat gastric cancer and esophageal and esophagogastric junction cancers can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Imjudo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed December 5, 2025.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Hepatocellular Carcinoma. Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed December 4, 2025.
4. Pietrantonio F, Raimondi A, Lonardi S, 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). J Clin Oncol. 2023;41:358.

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