Reference number(s)
5652-A

Specialty Guideline 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 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 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.

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.