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) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

Compendial Uses[2]

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

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

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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 and ALK 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[1,2]

Authorization of 1 month for a one-time single dose may be granted for 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.

NSCLC[1,2]

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 and ALK rearrangements.

Esophageal, Esophagogastric Junction and Gastric Cancer[2,3]

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.

References

1. Imjudo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed December 2, 2024.
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.