CVS Caremark®

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| 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 Indications1

* 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 Uses2

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

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 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 Carcinoma1,2

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.

### NSCLC1,2

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 Cancer2,3

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.