

STANDARD MEDICARE PART B MANAGEMENT

IMJUDO (tremelimumab-actl)

POLICY

I. 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).
2. 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.

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions where applicable: Documentation of the absence of EGFR and ALK genomic aberration (unless testing is not feasible due to insufficient tissue).

III. CRITERIA FOR INITIAL APPROVAL

A. Hepatocellular Carcinoma

Authorization of 1 month for a one-time single dose may be granted for treatment of unresectable hepatocellular carcinoma in combination with durvalumab (Imfinzi).

B. NSCLC

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

1. The requested medication will be used in combination with durvalumab (Imfinzi) and platinum-based chemotherapy
2. The tumor is negative for EGFR and ALK gene mutations.

Reference number(s)
5656-A

IV. SUMMARY OF EVIDENCE

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

1. The prescribing information for Imjudo.
2. The available compendium
 - a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
 - b. Micromedex DrugDex
 - c. American Hospital Formulary Service- Drug Information (AHFS-DI)
 - d. Lexi-Drugs
 - e. Clinical Pharmacology
3. NCCN Guideline: Non-small cell lung cancer
4. NCCN Guideline: Hepatocellular carcinoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Imjudo are covered.

V. EXPLANATION OF RATIONALE

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

VI. REFERENCES

1. Imjudo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2022.