# Medical Policy:

## Imjudo® (tremelimumab-actl) intravenous infusion

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---|---|---|
| MG.MM.PH.371 | February 16, 2024 | January 6, 2023 |



## Definitions

Imjudo, a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) monoclonal antibody is indicated, in combination with Imfinzi (durvalumab intravenous infusion), for the treatment of adults with unresectable hepatocellular carcinoma and non-small cell lung cancer (NSCLC), in combination with Imfinzi and platinum-based chemotherapy, for the treatment of adults with metastatic disease and no epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

## Length of Authorization

- Hepatocellular Carcinoma: Approve for 30 days
- Non-Small Cell Lung Cancer: Approve for 6 months

## Dosing Limits [Medical Benefit]

The recommended dose of Imjudo is weight-based**.**

1. **Hepatocellular carcinoma:**
   a. For patients ≥ 30 kg: Imjudo 300 mg as a single intravenous (IV) dose administered in combination

with Imfinzi 1,500 mg IV on Day 1 of cycle 1. Imfinzi is then continued, as a single agent, once every 4 weeks.

b. For patients < 30 kg: Imjudo 4 mg/kg as a single IV dose administered in combination with Imfinzi 20 mg/kg IV on Day 1 of cycle 1. Imfinzi is then continued, as a single agent, once every 4 weeks.

2. **Non-Small Cell Lung Cancer:**
   a. For patients ≥ 30 kg: Imjudo 75 mg IV administered once every 3 weeks in combination with Imfinzi 1,500 mg IV and platinum-based chemotherapy for 4 cycles. One additional dose of Imfinzi 1,500 mg IV with histology-based pemetrexed is given 3 weeks later (cycle 5), then the schedule for both is switched to once every 4 weeks. A fifth dose of Imjudo 75 mg IV is administered with Imfinzi dose 6 at Week 16. Imfinzi is continued until disease progression or unacceptable adverse events.
   b. For patients < 30 kg: Imjudo 1 mg/kg IV administered once every 3 weeks in combination with Imfinzi 20 mg/kg IV and platinum-based chemotherapy for 4 cycles. One additional dose of Imfinzi 20 mg/kg IV with histology-based pemetrexed is given 3 weeks later (cycle 5), then the schedule for both is switched to once every 4 weeks. A fifth dose of Imjudo 1 mg/kg IV is administered with Imfinzi dose 6 at week 16. Imfinzi is continued until disease progression or unacceptable adverse events.

## Guideline

### I. Initial Criteria

1. **Hepatocellular Carcinoma.** Approve for 30 days if the patient meets ALL-of the following criteria (A, B, C, D, and E):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient meets ONE of the following:
      i. Patient has metastatic or unresectable disease; **OR**
      ii. According to the prescriber, the patient is not a surgical candidate; **AND**
   C. Imjudo is used as first-line systemic therapy; **AND**
   D. Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion); **AND**
   E. The medication is prescribed by or in consultation with an oncologist.

2. **Non-Small Cell Lung Cancer**. Approve for 6 months if the patient meets ALL-of the following criteria (A, B, C, D, E, and F):
   A. Patient is ≥ 18 years of age; **AND**
   B. Patient has metastatic disease; **AND**
   C. The tumor is negative for the following (i **and** ii):
      i. Epidermal growth factor receptor (EGFR) mutation; **AND**
      ii. Anaplastic lymphoma kinase (ALK) genomic tumor aberrations; **AND**
   D. Imjudo is used as first-line systemic therapy; **AND**
   E. Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion) and platinum-based chemotherapy; **AND**
   F. The medication is prescribed by or in consultation with an oncologist.

### II. Renewal Criteria

1. **Non-Small Cell Lung Cancer**: Coverage will be provided for five doses only
2. **Hepatocellular Carcinoma (HCC):** Coverage will be provided for one dose only and may not be renewed.

## Applicable Procedure Codes

| Code | Description |
|---|---|
| J9347 | Injection, tremelimumab-actl, 1 mg; 1 billable unit = 1 mg |

## Applicable NDCs

| Code | Description |
|---|---|
| 00310-4505-25 | Imjudo 25 mg/1.25 mL One single-dose vial |
| 00310-4535-30 | Imjudo 300 mg/15 mL One single-dose vial |

## ICD-10 Diagnoses

| Code | Description |
|---|---|
| C22.0 | Liver cell carcinoma |
| C33 | Malignant neoplasm of trachea |
| C34.00 | Malignant neoplasm of unspecified main bronchus |

## Revision History

| Company(ies) | DATE | REVISION |
|---|---|---|
| EmblemHealth & ConnectiCare | 2/16/2024 | Annual Review :Initial Criteria: Hepatocellular Carcinoma: Added metastatic disease; and "According to the prescriber, the patient is not a surgical candidate; AND"<br>Removed: "Patient has Child-Pugh Class A hepatic impairment"<br>Removed codes C9399 and J9999, added C9147 |
| EmblemHealth & ConnectiCare | 01/06/2023 | New Policy |

## References


1. Imjudo [package insert]. Wilmington, DE; AstraZeneca Pharm.; November 2022. Accessed December 2022.
2. Imjudo IPD Analytics. Available at: http://secure.ipdanalytics.com. Accessed on December 2022