Medical Policy:

Imjudo® (tremelimumab-actl) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.371	April 1, 2025	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 liver-confined unresectable disease and according to the prescriber, the patient is deemed ineligible for transplant**; OR**
      ii. Patient has extrahepatic or metastatic disease and according to the prescriber, the patient is deemed ineligible for resection, transplant, or locoregional therapy**; 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 recurrent, advanced, or 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 in combination with Imfinzi (durvalumab intravenous infusion); **AND**
   E. Patient meets **ONE** of the following (i, ii, iii, or iv):
      i. Patient meets **BOTH** of the following (a and b):
         a. The tumor is negative for actionable molecular markers; **AND**
         Note: Examples of actionable molecular markers include epidermal growth factor receptor (EGFR) mutations, anaplastic lymphoma kinase (ALK) genomic tumor aberrations, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). Patient may be KRAS G12C mutation positive.
         b. Imjudo is used as first-line therapy; **OR**
      ii. Patient meets **BOTH** of the following (a and b):
         a. The tumor is positive for **ONE** of the following [(1) or (2)]:
            (1) Epidermal growth factor receptor (EGFR) exon 20 mutation positive; **OR**

(2) *ERBB2* (HER2) mutation positive; **AND**

b. Imjudo is used as first-line therapy; **OR**

iii. Patient meets **BOTH** of the following (a and b):

a. The tumor is positive for **ONE** of the following [(1), (2), (3), or (4)]:

(1) *BRAF V600E* mutation positive; **OR**

(2) *NTRK1/2/3* gene fusion positive; **OR**

(3) *MET* exon 14 skipping mutation positive; **OR**

(4) *RET* rearrangement positive; **AND**

b. Imjudo is used as first-line or subsequent therapy; **OR**

iv. Patient meets **ALL** of the following (a, b, and c):

a. The tumor is positive for **ONE** of the following [(1), (2), (3), or (4)]:

(1) *EGFR* exon 19 deletion or exon 21 L858R mutation positive; **OR**

(2*) EGFR S768I, L861Q*, and/or *G719X* mutation positive; **OR**

(3) *ALK* rearrangement positive; **OR**

(4) *ROS1* rearrangement; **AND**

b. The patient has received targeted drug therapy for the specific mutation; **AND**

Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), Alecensa (alectinib capsules), Alunbrig (brigatinib tablets), Lorbrena (lorlatinib tablets), Rozlytrek (entrectinib capsules), or Vizimpro (dacomitinib tablets).

c. Imjudo is used as subsequent therapy; **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
C22.1	Intrahepatic bile duct carcinoma
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus

C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
Z85.05	Personal history of malignant neoplasm of liver

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	04/01/2025	Annual Review: Updated ICD-10 codes. Initial Criteria: Hepatocellular Carcinoma. Removed: "Patient has metastatic or unresectable disease; OR" replaced with: " Patient has liver-confined unresectable disease and according to the prescriber, the patient is deemed ineligible for transplant; OR" removed: "According to the prescriber, the patient is not a surgical candidate; AND" replaced with: " Patient has extrahepatic or metastatic disease and according to the prescriber, the patient is deemed ineligible for resection, transplant, or locoregional therapy; AND" Non-Small Cell Lung Cancer. Removed: "Patient has metastatic disease; AND" replaced with: "Patient has recurrent, advanced, or metastatic disease; AND" removed: "Imjudo is used as first-line systemic therapy; AND" removed: "and platinum-based chemotherapy " from the following: "Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion) and platinum-based chemotherapy" Added: "Patient meets ONE of the following (i, ii, iii, or iv): Patient meets BOTH of the following (a and b): The tumor is negative for actionable molecular markers; AND *Note: Examples of actionable molecular markers include epidermal growth factor receptor (EGFR) mutations, anaplastic lymphoma kinase (ALK) genomic tumor aberrations, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). Patient may be KRAS G12C mutation positive*. Imjudo is used as first-line therapy; OR Patient meets BOTH of the following (a and b): The tumor is positive for ONE of the following [(1) or (2)]: Epidermal growth factor receptor (EGFR) exon 20 mutation positive; OR *ERBB2* (HER2) mutation positive; AND Imjudo is used as first-line therapy; OR Patient meets BOTH of the following (a and b): The tumor is positive for ONE of the following [(1), (2), (3), or (4)]: *BRAF V600E* mutation positive; OR *NTRK1/2/3* gene fusion positive; OR *MET* exon 14 skipping mutation positive; OR *RET* rearrangement positive; AND Imjudo is used as first-line or subsequent therapy; OR Patient meets ALL of the following (a, b, and c): The tumor is positive for ONE of the following [(1), (2), (3), or (4)]: *EGFR* exon 19 deletion or exon 21 L858R mutation positive; OR *EGFR S768I, L861Q*, and/or *G719X* mutation positive; OR *ALK* rearrangement positive; OR *ROS1* rearrangement; AND The patient has received targeted drug therapy for the

		specific mutation; AND *Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), Alecensa (alectinib capsules), Alunbrig (brigatinib tablets), Lorbrena (lorlatinib tablets), Rozlytrek (entrectinib capsules), or Vizimpro (dacomitinib tablets).* Imjudo is used as subsequent therapy; AND"
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" Removed: "Patient has Child-Pugh Class A hepatic impairment" 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