

Medical Policy:

Imjudo® (tremelimumab-actl) intravenous infusion

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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" 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