

tremelimumab-actl (Imjudo®)

Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Administration

Drug Details

USP Category: ANTINEOPLASTICS

Mechanism of Action: Monoclonal antibody

HCPCS:

J9347:Inj, tremelimumab-actl, 1 mg

How Supplied:

- 25 mg/1.25 mL (20 mg/mL) solution in a single-dose vial
- 300 mg/15 mL (20 mg/mL) solution in a single-dose vial

Condition(s) listed in policy (*see coverage criteria for details*)

- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Hepatocellular carcinoma
- Non-small cell lung cancer (NSCLC)

Special Instructions and pertinent information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

The following condition(s) require Prior Authorization/Preservice:

Esophageal and esophagogastric junction cancers

1. Being used as neoadjuvant immunotherapy, AND
2. Tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR), AND
3. Being used in combination with Imfinzi

Covered Doses:

Promise Health Plan

300 mg given intravenously as a single dose

This is given with Imfinzi (durvalumab) 1,500 mg at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks for 12 weeks.

Coverage Period:

For one dose

Gastric cancer

1. Being used as neoadjuvant immunotherapy, AND
2. Tumor is microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR), AND
3. Being used in combination with Imfinzi

Covered Doses:

300 mg given intravenously as a single dose

This is given with Imfinzi (durvalumab) 1,500 mg at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks for 12 weeks.

Coverage Period:

For one dose

Hepatocellular carcinoma

1. Being used for inoperable, unresectable, or metastatic disease, AND
2. Being used in combination Imfinzi (durvalumab)

Covered Doses:

Weight less than 30 kg: 4 mg/kg given intravenously as a single dose with Imfinzi (durvalumab) 20 mg/kg at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks for 12 weeks

Weight 30 kg and more: 300 mg given intravenously as a single dose with Imfinzi (durvalumab) 1,500 mg at Cycle 1/Day 1, followed by Imfinzi as a single agent every 4 weeks for 12 weeks

Coverage Period:

For one dose

Non-small cell lung cancer (NSCLC)

1. Disease is recurrent, advanced, or metastatic disease, AND
2. Being used in combination with Imfinzi (durvalumab) and platinum-based chemotherapy

Covered Doses:

75 mg given intravenously once every 3 weeks for 12 weeks (4 cycles).

An additional dose of Imjudo may be given in week 16.

Coverage Period:

For up to 5 doses

References

1. AHFS®. Available by subscription at <http://www.lexi.com>
2. DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Imjudo® (tremelimumab-actl) [Prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 6/2023.
4. National Comprehensive Cancer Network Drugs & Biologics Compendium. Imjudo (2024). Available by subscription at: www.nccn.org.
5. National Comprehensive Cancer Network. Hepatocellular Carcinoma (Version 2.2023). Available at <http://www.nccn.org>.
6. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer (Version 1.2024). Available at <http://www.nccn.org>.
7. National Comprehensive Cancer Network. Gastric Cancer (Version 2.2023). Available at <http://www.nccn.org>.
8. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers (Version 3.2023). Available at <http://www.nccn.org>.

Review History

Date of Last Annual Review: 1Q2024

Date of last revision: 02/28/2024

Changes from previous policy version:

- New indication: Added coverage for neoadjuvant immunotherapy as primary combination treatment in certain gastric and esophageal and esophagogastric junction cancers. *Rationale: NCCN category 2A support*

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*