Imjudo® (tremelimumab-actl)
(Intravenous)

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I. Length of Authorization Δ [1,7,8]

- Initial:
  - Hepatocellular Carcinoma (HCC) AND Gastric, Esophageal, and Esophagogastric Junction Cancers: Prior authorization validity will be provided initially for one (1) dose only.
  - Non-Small Cell Lung Cancer (NSCLC): Prior authorization validity will be provided initially for up to a maximum of 16 weeks of therapy (5 doses).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- HCC, Gastric Cancer, and Esophageal and Esophagogastric Junction Cancer: 300 billable units (300 mg) one time only
- NSCLC: 75 billable units (75 mg) every 21 days x 4 doses, followed by 75 billable units (75 mg) x 1 dose on day 112

III. Initial Approval Criteria [1]

Prior authorization validity is provided under the following conditions:

- Patient is at least 18 years of age; **AND**

Hepatocellular Carcinoma (HCC) † ‡ Φ [1-5,1e]

- Patient does not have Child-Turcotte-Pugh (CTP) Class C liver disease; **AND**
- Used in combination with durvalumab; **AND**
  - Used as first-line therapy; **AND**

- Patient has unresectable disease †; **OR**
- Patient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy; **OR**

○ Used as subsequent therapy for progression on or after systemic therapy; **AND**

- Patient has not received previous treatment with anti-CTLA4-based combinations; **AND**
- Patient received previous treatment with sorafenib or lenvatinib, unless contraindicated

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,6,9]

- Patient has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Patients with tumors that are negative for actionable molecular biomarkers* (may be KRAS G12C mutation positive) and PD-L1 ≥ 1% to 49%; **OR**
      - Patients who have tumors that are negative for actionable molecular biomarkers* (may be KRAS G12C mutation positive) and PD-L1 < 1%; **OR**
      - Patients who have tumors that are positive for one of the following molecular biomarkers: EGFR exon 20, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **AND**

➢ Used in combination with durvalumab, albumin-bound paclitaxel, and carboplatin; **AND**

- **Squamous NSCLC:**

– Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

- **Nonsquamous NSCLC:**

– Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

➢ Used in combination with durvalumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **AND**

– Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

- Used in combination with durvalumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **AND**

  - Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**

- Used as subsequent therapy; **AND**
  - Used for one of the following:
    - Patients who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, or MET exon 14 skipping; **OR**
    - Patients who are positive for one of the following molecular biomarkers AND received prior targeted therapy**§**:, EGFR S768I, L861Q, and/or G719X mutation; **AND**
  - Used in combination with durvalumab, albumin-bound paclitaxel, and carboplatin; **AND**

    - **Squamous NSCLC:**
    - Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin); **OR**
    - **Nonsquamous NSCLC:**
    - Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

  - Used in combination with durvalumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology; **AND**

    - Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/(paclitaxel or pemetrexed)/(carboplatin or cisplatin); **OR**

  - Used in combination with durvalumab, gemcitabine, and either carboplatin or cisplatin for squamous cell histology; **AND**

    - Use of tremelimumab will be restricted to patients with a contraindication or intolerance to cemiplimab/paclitaxel/(carboplatin or cisplatin)

- ***Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

- *§ Genomic Aberration/Mutational Driver Targeted Therapies: Refer to guidelines for appropriate use.*

Esophageal Cancer and Esophagogastric Junction Cancer ‡ [2,7]

- Used as neoadjuvant immunotherapy in combination with durvalumab; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test**v**; **AND**
- Patient has adenocarcinoma; **AND**
- Used as primary treatment for patients who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease

Gastric Cancer ‡ [2,8]

- Used as neoadjuvant immunotherapy in combination with durvalumab; **AND**
- Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test**v**; **AND**
- Patient has adenocarcinoma; **AND**
- Used as primary treatment for potentially resectable locoregional disease (cT2 or higher, any N) in patients who are medically fit for surgery

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Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

v *If confirmed using an FDA approved assay – http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria Δ 1,7,8

- Duration of authorization has not been exceeded (*refer to Section I*)

Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate checkpoint inhibitor therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate checkpoint inhibitor therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate checkpoint inhibitor therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ 1,7,8

Indication	Dose
Hepatocellular Carcinoma (HCC)	Weight ≥30 kg: – Administer a single dose of tremelimumab 300 mg intravenously (followed by durvalumab) at Day 1-Cycle 1 – Continue durvalumab as a single agent every 4 weeks Weight <30 kg: – Administer a single dose of tremelimumab 4 mg/kg intravenously (followed by durvalumab) at Day 1-Cycle 1 – Continue durvalumab as a single agent every 4 weeks
Non-Small Cell Lung Cancer (NSCLC)	Weight ≥30 kg: – Administer tremelimumab 75 mg intravenously on Day 1 of every 3 week-cycle x 4 cycles (Cycles 1-4) in combination with durvalumab followed by platinum-containing chemotherapy – Administer tremelimumab 75 mg x 1 dose on Day 1 of a 4-week cycle (Cycle 6; Week 16) in combination with durvalumab *(Note: the dosing interval changes from every 3 weeks to every 4 weeks starting at cycle 5)* – Continue durvalumab every 4 weeks with or without platinum-based chemotherapy**§** Weight <30 kg: – Administer tremelimumab 1 mg/kg intravenously on Day 1 of every 3 week-cycle x 4 cycles (Cycles 1-4) in combination with durvalumab followed by platinum-containing chemotherapy – Administer tremelimumab 1 mg/kg x 1 dose on Day 1 of a 4 week-cycle (Cycle 6; Week 16) in combination with durvalumab *(Note: the dosing interval changes from every 3 weeks to every 4 weeks starting at cycle 5)* – Continue durvalumab every 4 weeks with or without platinum-based chemotherapy**§**

Gastric, Esophageal, and Esophagogastric Junction Cancer	Administer tremelimumab 300 mg intravenously x 1 dose on Day 1 of a 12-week cycle in combination with durvalumab

- Administer tremelimumab prior to durvalumab on the same day.
- Refer to the Prescribing Information for durvalumab dosing information

§ If patients receive fewer than 4 cycles of platinum-based chemotherapy, the remaining cycles of tremelimumab (up to a total of 5) should be given after the platinum-based chemotherapy phase, in combination with durvalumab, every 4 weeks. Optional pemetrexed therapy from week 12 until disease progression or intolerable toxicity for patients with non-squamous disease who received treatment with pemetrexed and carboplatin/cisplatin.

VI. Billing Code/Availability Information

HCPCS Code:

- J9347 – Injection, tremelimumab-actl, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Imjudo 25 mg/1.25 mL solution for injection (single-dose vial): 00310-4505-xx
- Imjudo 300 mg/15 mL solution for injection (single-dose vial): 00310-4535-xx

VII. References (STANDARD)

1. Imjudo [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; July 2024. Accessed September 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tremelimumab-actl. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.
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5. Llovet JM, Bru C, Bruix J. Prognosis of hepatocellular carcinoma: the BCLC staging classification. *Semin Liver Dis.* 1999;19:329–38.
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8. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Gastric Cancer. Version 3.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2025.
9. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Non-Small Cell Lung Cancer. Version 8.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2025.

VIII. References (ENHANCED)

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2e. Finn RS, Qin S, Ikeda M, et al; IMbrave150 Investigators. Atezolizumab plus Bevacizumab in Unresectable Hepatocellular Carcinoma. N Engl J Med. 2020 May 14;382(20):1894-1905.
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7e. Pietrantonio F, Raimondi A, Lonardi S, et al. INFINITY: A multicentre, single-arm, multi-cohort, phase II trial of tremelimumab and durvalumab as neoadjuvant treatment of patients with microsatellite instability-high (MSI) resectable gastric or gastroesophageal junction adenocarcinoma (GAC/ GEJAC). Journal of Clinical Oncology 2023;41:358-358

8e. Kelley RK, Sangro B, Harris W, et al. Safety, Efficacy, and Pharmacodynamics of Tremelimumab Plus Durvalumab for Patients With Unresectable Hepatocellular Carcinoma: Randomized Expansion of a Phase I/II Study. J Clin Oncol. 2021 Sep 20;39(27):2991-3001.

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified

ICD-10	ICD-10 Description
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C22.0	Liver cell carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
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
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC