IOWA Health and Human Services

Imjudo (tremelimumab-actl)
PAM – 058

Iowa Medicaid Program	Prior Authorization	**Effective Date**	04/01/2023
Revision Number	4	**Last Reviewed**	01/16/2026
Reviewed By	Medicaid Medical Director	**Next Review**	01/15/2027
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	07/21/2023

Overview

Medication: [1]	tremelimumab-actl
Brand Name:	Imjudo®
Pharmacologic Category:	Antineoplastics; cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody
FDA-Approved Indication(s):	• **Unresectable hepatocellular carcinoma (uHCC):** Indicated in combination with durvalumab (Imfinzi®), for the treatment of adult patients with uHCC. • **Metastatic non-small cell lung cancer** (**mNSCLC):** Indicated in combination with Imfinzi® and platinum-based chemotherapy for the treatment of adult patients with mNSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
How Supplied:	Single-dose vial (containing 20 mg/mL) as either: 25 mg/1.25 mL or 300 mg/15 mL
Dosage and Administration:	Administer via intravenous (IV) infusion; follow dosing schedule (based on indication) in below tables.
Benefit Category:	Medical

Unresectable hepatocellular carcinoma (uHCC)	
Weight	Recommended Dosage and Regimen
≥ 30 kg	• A **single dose** of tremelimumab-actl (Imjudo®) 300 mg followed by durvalumab (Imfinzi®) 1,500 mg on Day 1 of Cycle 1; • Continue Imfinzi® 1,500 mg as a single agent every 4 weeks
< 30 kg	• A **single dose** of tremelimumab-actl (Imjudo®) 4 mg/kg followed by durvalumab (Imfinzi®) 20 mg/kg on Day 1 of Cycle 1; • Continue Imfinzi® 20 mg/kg as a single agent every 4 weeks
Duration of Therapy	After Cycle 1 of combination therapy, administer durvalumab (Imfinzi®) as a single agent every 4 weeks until disease progression or unacceptable toxicity.

Metastatic Non-Small Cell Lung Cancer (mNSCLC)					
Recommended Regimen, Dosage, and Schedule					
DOSAGE	**Tumor Histology**	**Patient Weight**	**Imjudo® Dosage**	**Imfinzi® Dosage [a]**	**Platinum-based chemotherapy regimen [a]**
	Non-Squamous	≥ 30 kg	75 mg	1,500 mg	• carboplatin & nabpaclitaxel OR • carboplatin or cisplatin & pemetrexed
		< 30 kg	1 mg/kg	20 mg/kg	
	Squamous	≥ 30 kg	75 mg	1,500 mg	• carboplatin & nabpaclitaxel OR • carboplatin or cisplatin & gemcitabine
		≤ 30 kg	1 mg/kg	20 mg/kg	

SCHEDULE	**Week** [b, c]	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	Cycle:	**1**			**2**			**3**			**4**			**5**				**6**				**7**				**8**
	Imjudo [d]	X			X			X			X							X								
	Imfinzi [b]	X			X			X			X			X				X				X				X
	Chemotherapy	X			X			X			X			X[e]				X[e]				X[e]				X[e]

[a] Refer to the prescribing information for dosing information.
[b] Continue Imfinzi until disease progression or intolerable toxicity.
[c] Dosing interval change from every 3 weeks to every 4 weeks starting at cycle 5.
[d] If patients receive fewer than 4 cycles of platinum-based chemotherapy, the remaining cycles of Imjudo (up to a total of 5) should be given after the platinum-based chemotherapy phase, in combination with durvalumab, every 4 weeks.
[e] 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.

Descriptive Narrative

Hepatobiliary cancers are highly lethal cancers including a spectrum of invasive carcinomas arising in the liver (hepatocellular carcinoma; HCC), gall bladder, and bile ducts (intrahepatic and extrahepatic cholangiocarcinoma [CCA]). Hepatocellular carcinoma (HCC) is the primary cancer of the liver. In 2025 it was estimated that 42,240 people in the United States would be diagnosed with liver cancer and intrahepatic bile duct cancer. Approximately 30,090 deaths from liver or intrahepatic bile duct cancer were anticipated.[2] In the state of Iowa in 2025, an estimated 340 patients will be diagnosed with liver and intrahepatic bile duct cancer, with 260 estimated deaths.[3]

Lung cancer is the leading cause of cancer deaths in the United States. In the state of Iowa in 2025, an estimated 2,490 new cases of lung and bronchial cancer will be diagnosed, and 1,350 deaths are estimated to occur because of the disease, making it the leading cause of cancer death in Iowa as well.[4] It is estimated that 25.4 percent of all patients with lung cancer are alive 5 years or more after diagnosis; this includes patients with non-small cell lung cancer (NSCLC) and those with small cell lung cancer (SCLC) in the United States from 2013 to 2019. The overall 5-year relative survival rate for NSCLC with adenocarcinoma histology was 32.2 percent in the United States. Since 2006, the incidence of lung cancer has decreased annually by 2.5 percent in men and 1 percent in women.

There have been significant improvements in the treatment of lung cancer, including advances in screening, minimally invasive techniques for diagnosis and treatment, radiation therapy (RT), including stereotactic ablative radiotherapy (SABR), as well as new targeted therapies and immunotherapies. The availability of these new treatments is associated with improved survival rates for patients with NSCLC. From 2015 to 2016, 2-year relative survival for NSCLC was 42 percent compared with 34 percent from 2009 to 2010. Patients with NSCLC who are eligible for targeted therapies or immunotherapies are now surviving longer; 5-year survival rates range from 15 percent to 62.5 percent, depending on the biomarker. Therefore, biomarker testing is critical to guide treatment selection and ensure optimal outcomes in patients with NSCLC, particularly for those with advanced or metastatic disease.[5]

Guidelines

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology document evidence-based, consensus-driven management to ensure that all patients receive preventive, diagnostic, treatment, and supportive services that are most likely to lead to optimal outcomes. The guidelines are developed and updated by 63 individual panels, comprising over 1,900 clinicians and oncology researchers from the 33 NCCN Member Institutions. The categories for recommendations are based on both the level of clinical evidence available and the degree of consensus within the NCCN Guidelines Panel.

The library of NCCN Guidelines® currently apply to more than 97 percent of people living with cancer or anyone at risk for a diagnosis of cancer in the United States. The guidelines incorporate real-time updates in keeping with the rapid advancements in the field of cancer research and management and are intended to assist all individuals who impact decision-making in cancer care, including physicians, nurses, pharmacists, payers, patients and their families, and others.

The NCCN Guidelines® provide recommendations based on the best evidence available at the time they are derived. Because new data are published continuously, it is essential that the NCCN Guidelines also be continuously updated and revised* to reflect new data and clinical information that may add to or alter current clinical practice standards.[6,7]

The information referenced at the time of this policy writing/revision (note version number and effective date) is from the NCCN Guidelines® for:[8]

- Hepatocellular Carcinoma (v.1.2025 – October 22, 2025)
- Non-Small Cell Lung Cancer (v.1.2026 – November 6, 2025)

* To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

NCCN Guidelines® Recommendations – Hepatocellular Carcinoma

(1) First-line systemic therapy
  A. Tremelimumab-actl [Imjudo®] + durvalumab [Imfinzi®]: Category 1, preferred regimen

NCCN Guidelines® Recommendations – Non-Small Cell Lung Cancer (NSCLC)

Imjudo®: tremelimumab-actl **Imfinzi®:** durvalumab **PS:** ECOG Performance Status

(I) Biomarker-directed Therapy for Advanced or Metastatic Disease
  A. PD-L1 ≥ 50% First-line therapy (PS 0-2)
    i. Adenocarcinoma, Large Cell, NSCLC NOS
      1. Albumin-bound Paclitaxel/Carboplatin + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab: Category 2B, other recommended
      2. (Carboplatin or Cisplatin)/Pemetrexed + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab ± Pemetrexed: Category 2B, other recommended
    ii. Squamous cell carcinoma
      1. Albumin-bound Paclitaxel/Carboplatin + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab: Category 2B, other recommended
      2. (Carboplatin or Cisplatin)/Gemcitabine + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab: Category 2B, other recommended
  B. PD-L1 ≥ 1 % - 49 % First-line therapy (PS 0-2)
    i. Adenocarcinoma, large cell, NSCLC NOS
      1. Albumin-bound Paclitaxel/Carboplatin + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab: Category 1, other recommended
      2. (Carboplatin or Cisplatin)/Pemetrexed + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab ± Pemetrexed: Category 1, other recommended
    ii. Squamous cell carcinoma
      1. Albumin-bound Paclitaxel/Carboplatin + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab: Category 2A, other recommended
      2. (Carboplatin or Cisplatin)/Gemcitabine + Durvalumab + Tremelimumab-actl followed by maintenance Durvalumab: Category 2A, other recommended

(II) Systemic Therapy for Advanced or Metastatic Disease
  A. Adenocarcinoma, large cell, NSCLC NOS (PS 0–2); No contraindications to PD-1 or PD-L1 inhibitors [a] and NO *EGFR* exon 19 deletion or L858R mutation; *ALK*, *RET*, or *ROS1* gene fusions
    a. Albumin-bound Paclitaxel/Carboplatin + Durvalumab + Tremelimumab-actl: Category 1, other recommended
    b. (Carboplatin or Cisplatin)/Pemetrexed + Durvalumab + Tremelimumab-actl: Category 1, other recommended
  B. Squamous cell carcinoma (PS 0–2); No contraindications to PD-1 or PD-L1 inhibitors [a] and NO *EGFR* exon 19 deletion or L858R mutation; *ALK*, *RET*, or *ROS1* gene fusions
    a. Albumin-bound Paclitaxel/Carboplatin + Durvalumab + Tremelimumab-actl: Category 1, other recommended: Category 1, other recommended
    b. (Carboplatin or Cisplatin)/Gemcitabine + Durvalumab + Tremelimumab-actl: Category 1, other recommended

a Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents; some oncogenic drivers (i.e., *EGFR exon 19* deletion or *L858R*, *ALK* rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [9]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	**ECOG Performance Status** **[Synonyms: WHO/Zubrod score]**
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Prior authorization is required.

Unresectable Hepatocellular Carcinoma

Imjudo® is considered medically necessary when **ALL** of the following are met:

1. Confirmed diagnosis of unresectable hepatocellular carcinoma (uHCC); **AND**
2. Member is 18 years of age or older; **AND**
3. Member has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
4. Member has not received prior immune-mediated therapy (excluding therapeutic anticancer vaccines); **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Request meets one of the following (a or b):
    a. Imjudo® is prescribed as a one-time, single-administration treatment in combination with durvalumab (Imfinzi®) (reference recommended regimen in Overview section); or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Imjudo® is **NOT** considered medically necessary for continuation of therapy, as FDA-approval and NCCN recommendations support a one-time dose for uHCC.

Metastatic Non-Small Cell Lung Cancer

Imjudo® is considered medically necessary when **ALL** of the following are met:

1. Confirmed diagnosis of metastatic non-small cell lung cancer; **AND**
2. Tumors do **NOT** have sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
5. Member has not received prior immune-mediated therapy (excluding therapeutic anticancer vaccines); **AND**
6. Prescribed by, or in consultation with, an oncologist; **AND**
7. Request meets one of the following (a or b):
    a. Imjudo® is prescribed for up to a total of 5 doses [one dose every 3 weeks in combination with durvalumab (Imfinzi®) and platinum-based chemotherapy for 4 cycles, and a fifth dose of Imjudo® in combination with Imfinzi® (dose 6) at week 16]. See Overview section for dosing recommendations; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Imjudo® is considered medically necessary for continuation of therapy in metastatic non-small cell lung cancer when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Request meets one of the following (a or b):
    a. Member has received less than 5 total doses of Imjudo®. If all other continuation criteria are met, may authorize number of doses sufficient to complete total of 5 doses; or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

- Unresectable hepatocellular carcinoma (uHCC)

	Duration	Quantity Limits
Initial Authorization	30 days	one-time dose, not to exceed 4 mg/kg for body weight less than 30 kg, or 300 mg for body weight of 30 kg or more
Continuation	Not applicable	Not applicable

- Metastatic non-small cell lung cancer (mNSCLC), with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

	Duration	Quantity Limits
Initial	6 months	Not to exceed total of 5 doses (see dosing in Overview section)
Continuation	duration necessary to complete 5 total doses	

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
~~C9147~~	~~Injection, tremelimumab-actl, 1 mg~~ *(code effective 4-1-2023 to 6-30-2023)*
J9347	Injection, tremelimumab-actl, 1 mg *(code effective 7-1-2023)*

ICD-10	Description
C22.0	Liver cell carcinoma
C34.00 – C34.92	Malignant neoplasm of bronchus and lung

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
00310-4505-25 (single-dose vial, 25 mg/1.25 mL)	AstraZeneca Pharmaceuticals LP (00310)	1 mg	1	EA	25
00310-4535-30 (single-dose vial, 300 mg/15 mL)	AstraZeneca Pharmaceuticals LP (00310)	1 mg	1	EA	300

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Imjudo® prescribing information (07/2024). AstraZeneca Pharmaceuticals LP: Wilmington, DE. Available online: www.imfinzihcp.com. Accessed October 27, 2024.

[2] NCCN Guidelines® for Hepatocellular Carcinoma (v.2.2025 – October 22, 2025). The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org.

[3] Cancer Statistics Center – American Cancer Society. Estimated New Cases and Deaths (2025): Iowa. cancerstatisticscenter.cancer.org/states/Iowa. Accessed November 14, 2025.

[4] Cancer Statistics Center – American Cancer Society. Estimated New Cases and Deaths (2025): Iowa. cancerstatisticscenter.cancer.org/states/Iowa. Accessed November 14, 2025.

[5] NCCN Guidelines® for Non-Small Cell Lung Cancer (v.1.2026 – November 6, 2025). The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version of the guidelines, go online to NCCN.org.

[6] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[7] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 20, 2025.

[8] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Hepatocellular Carcinoma (v.2.2025 – October 22, 2025)
- Non-Small Cell Lung Cancer (v.1.2026 – November 6, 2025)

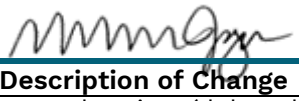
[9] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

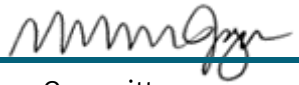
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
01/16/2026	CAC	Annual review. Updated statistics on HCC and NSCLC in Descriptive Narrative. Reviewed and updated NCCN Guidelines. Modified criteria requirements for ECOG Performance Status to “0, 1, or 2” (previously “0, 1”) to align with NCCN Guidelines.	4
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/18/2025	CAC	Annual review (delayed until April this cycle; will return to January review cycle in 2026). Reviewed and updated NCCN recommendations. No criteria changes.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
01/19/2024	CAC	Changed from July to January review cycle (to align with Imfinzi®). Reviewed NCCN Guidelines; no changes to recommendations. Minor formatting changes.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee