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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/12/2026

Imjudo[®] (tremelimumab-actl)

HCPCS: J9347

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved age
 - b. Prescribed by or in consultation with an oncologist
 - c. Diagnosis of unresectable hepatocellular carcinoma (uHCC)
 - i. Must be used in combination with Imfinzi[™]
 - ii. Must be previously untreated
 - iii. Must have Child-Pugh Score class A
 - d. Diagnosis of metastatic non-small cell lung cancer (mNSCLC)
 - i. Must be used in combination with Imfinzi and platinum-based chemotherapy
 - ii. Must not have any sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
 - iii. Must be previously untreated
 - e. ECOG performance score of 0 – 2
 - f. Patient is not receiving therapy for a chronic condition, such as autoimmune disease, that requires treatment with a systemic immunosuppressant
 - g. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list.
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

Background Information:

- Imjudo is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody indicated in combination with Imfinzi for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC) and in combination with Imfinzi and platinum-based chemotherapy for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
- The HIMALAYA trial was a randomized, open-label, multicenter, phase III study of 1,324 patients with unresectable, advanced HCC who had not been treated with prior systemic therapy and were not eligible for locoregional therapy. Patients were randomized to either Imfinzi alone, a single priming dose of Imjudo 300 mg added to Imfinzi 1500 mg followed by Imfinzi monotherapy every four weeks, or sorafenib 400 mg twice daily. The study excluded patients with co-infection of viral hepatitis B and hepatitis C; active or prior documented gastrointestinal (GI) bleeding within 12 months; ascites requiring non-pharmacologic intervention within 6 months; hepatic encephalopathy within 12 months before the start of treatment; and active or prior documented autoimmune or inflammatory disorders. All subjects had a Child-Pugh Score class A and an ECOG performance score of 0 – 1. The primary endpoint was overall survival (OS) between the Imjudo plus Imfinzi arm versus the sorafenib arm. OS improved from a median 13.8 months with sorafenib to 16.4 months with the dual immunotherapy representing a 22% reduction in the risk for death during the study period (HR 0.78; 95% CI: 0.66 - 0.92; p-value = 0.0035). At 3 years, OS rates were an estimated 31% with Imjudo in combination with Imfinzi versus 20% with sorafenib.
- The POSEIDON trial was a randomized, multicenter, active-controlled, open-label, phase III study of 1,013 previously untreated patients with EGFR/ALK wild-type mNSCLC. Patients were randomized to either Imjudo plus Imfinzi and platinum-based chemotherapy for up to four 21-day cycles, followed by Imfinzi once every 4 weeks until progression and one additional Imjudo dose; Imfinzi plus chemotherapy for up to four 21-day cycles, followed by Imfinzi once every 4 weeks until progression; or chemotherapy for up to six 21-day cycles. Chemotherapy options for all arms included carboplatin plus nab-paclitaxel regardless of histology, cisplatin or carboplatin plus gemcitabine for patients with squamous histology, and cisplatin or carboplatin plus pemetrexed for patients with non-squamous histology. Patients with non-squamous histology who received pemetrexed-platinum doublet could receive pemetrexed maintenance therapy if eligible. The study excluded patients with active infection, another primary malignancy, a medical contraindication to platinum-based doublet therapy, and active or prior documented autoimmune or inflammatory disorders. All subjects had an ECOG performance score of 0 – 1. The primary endpoints were progression-free survival (PFS) and OS for Imfinzi + chemotherapy versus chemotherapy. Key alpha-controlled secondary end points were PFS and OS for Imjudo plus Imfinzi and chemotherapy versus chemotherapy. PFS was significantly improved with Imfinzi plus chemotherapy versus chemotherapy (HR = 0.74; 95% CI: 0.62, 0.89; p-value = 0.0009; median 5.5 v 4.8 months); a trend for improved OS did not reach statistical significance (HR = 0.86; 95% CI: 0.72, 1.02; p-value = 0.0758; median 13.3 v 11.7 months; 24-month OS 29.6% v 22.1%). PFS (HR = 0.72; 95% CI: 0.60, 0.86; p-value = 0.0003; median 6.2 v 4.8 months) and OS (HR = 0.77; 95% CI: 0.65, 0.92; p-value = 0.0030; median 14.0 v 11.7 months; 24-month OS 32.9% v 22.1%) were significantly improved with Imjudo plus Imfinzi and chemotherapy versus chemotherapy alone.
- There are no studies to support use of Imjudo following failure of its use in combination with Imfinzi. NCCN guidelines also do not recommend use of Imjudo or PD-L1 checkpoint inhibitors following a previous failure. Imjudo has only been studied as first-line therapy for HCC.

References:

1. Imjudo [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2024.
2. Abou-Alfa GK, Chan SL, Kudo M, et al. Tremelimumab plus durvalumab in unresectable hepatocellular carcinoma. *NEJM Evid.* 2022 June 6; 8 (1): 1 – 12.
3. National Comprehensive Cancer Network. Hepatocellular carcinoma (Version 2.2025). 2025 Oct 22. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf. Accessed on December 12, 2025.
4. Johnson ML, Cho BC, Luft A, et al. Durvalumab with or without tremelimumab in combination with chemotherapy as first-line therapy for metastatic non–small-cell lung cancer: The phase III POSEIDON study. *J Clin Oncol.* 2022 Nov 3: JCO2200975. doi: 10.1200/JCO.22.00975.
5. National Comprehensive Cancer Network. Non-small cell lung cancer (Version 2.2026). 2025 Dec 2. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed on December 12, 2025.

Policy History												
#	Date	Change Description										
1.5	Effective Date: 02/12/2026	Annual review of criteria was performed, no changes were made										
1.4	Effective Date: 02/13/2025	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 02/08/2024	Annual review of criteria was performed, no changes were made										
1.2	Effective Date: 08/23/2023	UM medical management system update for BCNA, MAPPO, BCN, and BCBS <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.1	Effective Date: 02/02/2023	Updated to include the new indication of metastatic non-small cell lung cancer										
1.0	Effective Date: 12/01/2022	New policy										

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.