Medical Policy

Imjudo ™ (tremelimumab)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-135
POLICY OWNER	A. Bartley Bryt, MD, Chief Medical Officer
ORIGINAL EFFECTIVE DATE	01/01/2024
CURRENT VERSION NUMBER	2
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET*	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL *Policy applies to all markets where IFP, SG, or MA plans are offered

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

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POLICY/CRITERIA

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Imjudo (tremelimumab-actl) therapy.

POLICY

Prior Authorization and Medical Review is required.

Hepatocellular Carcinoma (HCC): Coverage for Imjudo will be provided for one dose only and may not be renewed.

Non-Small Cell Lung Cancer (NSCLC): Coverage will be provided for five doses only and may not be renewed.

- Max Units (per dose and over time):
  - HCC: 300mg one time only
  - NSCLC: 75mg x 4 doses every 21 days, followed by 75mg x 1 dose on day 112

Initial

A. Patient is 18 years of age or older, unless otherwise specified; **AND**

Hepatocellular Carcinoma (HCC)

A. Used as first-line therapy in combination with durvalumab; **AND**
B. Patient has Child-Pugh Class A hepatic impairment (i.e., excludes class B and C impairments); **AND**
   a. Patient has intermediate disease (i.e., multinodular, PS 0) and is not eligible for locoregional therapy, **OR**
   b. Patient has advanced disease (i.e., portal invasion, regional lymph node metastasis, distant metastasis, PS 1-2); **AND**

Non-Small Cell Lung Cancer (NSCLC)

A. Used in combination with durvalumab and platinum-based chemotherapy; **AND**
B. Used as first-line therapy for metastatic disease; **AND**
C. Patient had no EGFR mutations or ALK genomic tumor aberrations; **AND**
D. Patient has a performance status (PS) of 0-1

Renewal◊

A. Coverage may NOT be renewed.

◊Notes:
• Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of PD-directed therapy) are eligible to re-initiate checkpoint inhibitor therapy.
• 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.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. IMJUDO (tremelimumab) injection for intravenous use. Initial U.S Approval: 2022.
   a. IMJUDO (tremelimumab) injection solution is a clear to slightly opalescent, colorless to slightly yellow solution for intravenous infusion after dilution. It is supplied as

individually packaged single-dose vials. Discard partially used or empty vials of IMJUDO.

CODING

Applicable NDC Codes	
00310-4505-25	Imjudo 25mg/1.25mL solution for injection (single-dose vial)
00310-4535-30	Imjudo 300mg/15mL solution for injection (single-dose vial)

Applicable Procedure Code	
J9999	Not otherwise classified, antineoplastic drug

Applicable ICD-10 Codes

EVIDENCE BASED REFERENCES

1. Imjudo [package insert]. Wilmington, DE; AstraZeneca Pharm.; November 2022. Accessed November 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tremelimumab. National Comprehensive Cancer Network, 2022. 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 October 2022.

POLICY HISTORY

Original Effective Date	2/28/2023
Revised Date	
P&T Committee Endorsement	02/28/2023
Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan	01/01/2024

DISCLAIMER

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