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P&T Date: 06/05/2025

Libtayo® (cemiplimab-rwlc)

HCPCS: J9119

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. Treatment must follow the Food and Drug Administration (FDA) approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation
      i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation
   b. Must be prescribed by, or in consultation with, an oncologist or hematologist
   c. No prior failure of a programmed death receptor-1 (PD-1 or PD-L1) inhibitor
   d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant
   e. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the WyoBlue Advantage 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:
      i. Metastatic non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy
      ii. All other indication: Treatment may be continued until unacceptable toxicity or disease progression

***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.

Background Information:

- Libtayo is a programmed death receptor-1 (PD-1) blocking antibody indicated for
    - The treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.
    - The treatment of patients with locally advanced BCC (laBCC) or metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
    - As a single agent for first-line treatment of patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK, or ROS1 aberrations, and is:
        - locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
        - metastatic
    - In combination with platinum-based chemotherapy for the first-line treatment of adult patients with NSCLC with no EGFR, ALK or ROS1 aberrations and is:
        - locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
        - metastatic
- The efficacy of Libtayo in patients with mCSCC or laCSCC who were not candidates for curative surgery or curative radiation was evaluated in two open-label, multi-center, non-randomized, multicohort studies: study 1423 and study 1540 (EMPOWER-CSCC-1). A total of 108 patients were included in the studies and received Libtayo monotherapy intravenously for up to 48 weeks in study 1423 and 96 weeks in study 1540. Treatment continued until progression of disease, unacceptable toxicity, or completion of planned therapy. Both studies excluded patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; history of solid organ transplant; prior treatment with anti–PD-1/PD-L1 blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B or hepatitis C; or patients with an ECOG score greater than or equal to 2. The study's primary endpoint was objective response rate, or the percentage of patients who experienced partial shrinkage or complete disappearance of their tumor(s) after treatment. Results showed that 47.2 percent of all patients treated with Libtayo had their tumors shrink or disappear.
- The efficacy of Libtayo in patients with laBCC or mBCC was evaluated in study 1620, an open-label, multi-center, non-randomized study of 112 patients with laBCC or mBCC who had progressed on hedgehog pathway inhibitor (HHI) therapy, had not had an objective response after 9 months on HHI therapy, or were intolerant of prior HHI therapy. Patients received Libtayo monotherapy for up to 93 weeks until disease progression, unacceptable toxicity, or completion of planned treatment. The study excluded patients with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; history of solid organ transplant; prior treatment with anti–PD-1/PD-L1 blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B or hepatitis C; or patients with an ECOG score greater than or equal to 2. The study's primary endpoints were objective response rate and duration of response. The objective response rate was 27%, including 21% of patients with mBCC and 29% of patients with locally advanced disease. Five patients in the locally advanced subgroup had

complete responses with Libtayo. Median duration of response has yet to be reached in the trial, overall or in the metastatic and locally advanced subgroups.

- The efficacy of Libtayo as a single agent in patients with NSCLC was evaluated in study 1624, a randomized, multicenter, open-label, active-controlled trial of 710 patients with locally advanced NSCLC who were not candidates for surgical resection or definitive chemoradiation, or with metastatic NSCLC. Patients received Libtayo monotherapy until RECIST 1.1-defined progressive disease, unacceptable toxicity, or up to 108 weeks. Only patient whose tumors had high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] were eligible for enrollment. The study excluded patients who had undergone prior systemic treatment; patients with EGFR, ALK or ROS1 genomic tumor aberrations; those with autoimmune disease that required systemic therapy with immunosuppressant agents within 5 years; prior treatment with anti–PD-1/PD-L1 blocking antibodies or other immune checkpoint inhibitor therapy; infection with HIV, hepatitis B or hepatitis C; or patients with an ECOG score greater than or equal to 1. The primary endpoints were overall survival and progression free survival. The trial demonstrated a statistically significant improvement in overall survival and progression free survival for patients randomized to Libtayo as compared with chemotherapy.

- The efficacy of LIBTAYO in combination with platinum-based chemotherapy was evaluated in study 16113, a randomized, multi-center, double-blind, active-controlled trial in 466 patients with locally advanced NSCLC who were not candidates for surgical resection or definitive chemoradiation or with metastatic NSCLC who had not previously received systemic treatment for metastatic NSCLC. Patients were eligible regardless of tumor PD-L1 expression status. Patients with EGFR, ALK or ROS1 genomic tumor aberrations; a medical condition that required systemic immunosuppression; or ongoing or recent autoimmune disease that required systemic therapy were ineligible. Subjects were randomized 2:1 to either 350 mg Libtayo plus platinum-based chemotherapy every 3 weeks or placebo plus platinum-based chemotherapy every 3 weeks. The primary endpoint was overall survival. The trial demonstrated a statistically significant improvement in OS for patients randomized to Libtayo in combination with chemotherapy compared with placebo in combination with chemotherapy.

References:

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3. National Comprehensive Cancer Network. Basal cell skin cancer (Version 2.2025). 2025 Feb 7. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed on April 14, 2025.
4. Migden MR, Rischin D, Schmults CD, et al. PD-1 blockade with cemiplimab in advanced cutaneous squamous cell carcinoma. NEJM. 2018 Jul 26; 379 (4): 341 - 51.
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7. Rischin D, Migden MR, Lim AM, et al. Phase 2 study of cemiplimab in patients with metastatic cutaneous squamous cell carcinoma: primary analysis of fixed-dosing, long-term outcome of weight-based dosing. J Immunother Cancer. 2020 Jun; 8 (1). pii: e000775.
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11. Clinicaltrials.gov. Combinations of cemiplimab (anti-PD-1 antibody) and platinum-based doublet chemotherapy in patients with lung cancer (NCT03409614). Available at: https://clinicaltrials.gov/ct2/show/NCT03409614?term=NCT03409614&draw=2&rank=1. Accessed on November 17, 2022.

Policy History		
#	Date	Change Description
1.0	Initial Effective Date: 01/01/2026	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.*