Wellmark Advantage Health Plan

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Effective Date: 04/14/2022

**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. FDA approved age
   b. Prescribed by or in consultation with an oncologist or dermatologist
   c. Diagnosis of cutaneous squamous cell carcinoma (CSCC)
      i. Patient is not a candidate for curative surgery or curative radiation
   d. Diagnosis of basal cell carcinoma (BCC)
      i. Must have unresectable locally advanced or metastatic disease
      ii. Must have had prior treatment with a hedgehog pathway inhibitor or not be a candidate for a hedgehog pathway inhibitor
   e. Diagnosis of non-small cell lung cancer (NSCLC)
      i. Must have locally advanced disease where patient is not a candidate for surgical resection or definitive chemoradiation or metastatic disease
      ii. Must have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] with no EGFR, ALK, or ROS1 aberrations
   f. Must be used as a single agent
   g. Cannot be used after treatment failure has occurred with Libtayo or another PD-L1 inhibitor
   h. Patient is not receiving therapy for a chronic condition, such as autoimmune disease, that requires treatment with a systemic immunosuppressant
   i. ECOG status of 0 - 2

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 up to 6 months at a time
   c. Renewal Criteria: Treatment continued until unacceptable toxicity or disease progression

***Note: Coverage 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 isnot appropriate.
    - 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
- 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: study1423 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 wereintolerant 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; historyof 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 patientswith locally advanced disease. Five patients in the locally advanced subgroup had complete responses withLibtayo. 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 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 forsurgical 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 eligiblefor 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

**References:**


1. Libtayo [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2021.
2. National Comprehensive Cancer Network. Squamous cell skin cancer (Version 1.2022). 2021 Nov 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf. Accessed on February 17, 2022.
3. National Comprehensive Cancer Network. Basal cell skin cancer (Version 1.2022). 2021 Nov 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed on February 17, 2022.
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.
5. Falchook GS, Leidner R, Stankevich E, et al. Responses of metastatic basal cell and cutaneous squamous cell carcinomas to anti-PD1 monoclonal antibody REGN2810. J Immunother Cancer. 2016 Nov 15; 4: 70.
6. Migden MR, Khushalani NI, Chang ALS, et al. Cemiplimab in locally advanced cutaneous squamous cell carcinoma: results from an open-label, phase 2, single-arm trial. Lancet Oncol. 2020 Feb; 21 (2): 294 -305.
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.
8. Clinicaltrials.gov. A phase 2 study of REGN2810, a fully human monoclonal antibody to programmed death-1, in patients with advanced basal cell carcinoma who experienced progression of disease on hedgehog pathway inhibitor therapy, or were intolerant of prior hedgehog pathway inhibitor therapy (NCT03132636). Available at: https://clinicaltrials.gov/ct2/show/NCT03132636. Accessed on February 11, 2021.
9. Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. Lancet. 2021 Feb 13; 397 (10274): 592 - 604.
10. National Comprehensive Cancer Network. Non-small cell lung cancer (Version 1.2022). 2021 Dec 7. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed on February 17, 2022.


| Policy History | | |
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| # | Date | Change Description |
| 1.1 | Effective Date: 04/16/2022 | Updated approval length to allow for FDA recommended dosing or up to 6 months at a time |
| 1.0 | Effective Date: 01/01/2022 | Effective as of date of 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.*