

STANDARD MEDICARE PART B MANAGEMENT

LIBTAYO (cemiplimab-rwlc)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications¹

1. **Cutaneous Squamous Cell Carcinoma (CSCC)**
Libtayo is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.
2. **Basal Cell Carcinoma (BCC)**
 - a. Libtayo is indicated for the treatment of patients with locally advanced BCC previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
 - b. Libtayo is indicated for the treatment of patients with metastatic BCC previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
3. **Non-Small Cell Lung Cancer (NSCLC)**
Libtayo is indicated for the first-line treatment of patients with non-small cell lung cancer (NSCLC) whose tumor have high PD-L1 expression [Tumor Proportion Score (TPS) \geq 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is:
 - a. locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
 - b. metastatic

B. Compendial Uses²

Inoperable or incompletely resected regional squamous cell skin cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
- B. Documentation of molecular testing for EGFR, ALK, and ROS1 genomic tumor aberrations, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. **Cutaneous Squamous Cell Carcinoma (CSCC)**^{1,2}

Reference number(s)
4202-A

Authorization of 12 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:

1. The disease is one of the following:
 - a. Metastatic
 - b. Locally advanced
 - c. Regional and inoperable or incompletely resected
2. The member is not a candidate for curative surgery or curative radiation

B. Basal Cell Carcinoma (BCC)¹

Authorization of 12 months may be granted for treatment of locally advanced or metastatic basal cell carcinoma in patients who have received a hedgehog pathway inhibitor (e.g., vismodegib [Erivedge], sonidegib [Odomzo]) or for whom a hedgehog pathway inhibitor is not appropriate.

C. Non-Small Cell Lung Cancer (NSCLC)¹

Authorization of 12 months may be granted for treatment of non-small cell lung cancer when all of the following criteria are met:

1. Libtayo will be used as first-line treatment
2. The tumor has high PD-L1 expression [Tumor Proportion Score (TPS) \geq 50%]
3. The tumor does not have EGFR, ALK or ROS1 aberrations
4. The disease is either:
 - a. locally advanced where the member is not a candidate for surgical resection or definitive chemoradiation
 - b. metastatic

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Libtayo
- B. Libtayo is being used to treat an indication enumerated in Section III
- C. The member is receiving benefit from therapy. Benefit is defined as:
 1. No evidence of unacceptable toxicity while on the current regimen or
 2. No evidence of disease progression while on the current regimen

V. REFERENCES

1. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; February 2021.
2. The NCCN Drugs & Biologics Compendium[®] © 2020 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed February 22, 2021.