

SPECIALTY GUIDELINE 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 Indication

1. **Cutaneous Squamous Cell Carcinoma (CSCC)**
Libtayo is indicated for the treatment of patients with metastatic 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 tumors 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 Uses

Inoperable or incompletely resected regional squamous cell skin cancer

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy.

III. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- 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.

Reference number(s)
2757-A

IV. CRITERIA FOR INITIAL APPROVAL

A. Cutaneous Squamous Cell Carcinoma (CSCC)

Authorization of 6 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)

Authorization of 6 months may be granted for treatment of locally advanced or metastatic basal cell carcinoma in members 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)

Authorization of 6 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, unless testing is not feasible due to insufficient tissue
4. The disease is either:
 - a. locally advanced where the member is not a candidate for surgical resection or definitive chemoradiation
 - b. metastatic

V. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

VI. REFERENCES

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