Reference number(s)
2757-A

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 Indications
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)
   a. Libtayo, as a single agent, is indicated for the first-line treatment of adult 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:
      i. locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
      ii. metastatic
   b. Libtayo, in combination with platinum-based chemotherapy, is indicated for the first-line treatment of adult patients with NSCLC with no EGFR, ALK, or ROS1 aberrations and is:
      i. locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
      ii. metastatic

B. Compendial Uses
1. Squamous cell skin cancer
2. Basal cell skin cancer
3. Non-small cell lung 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, ROS1, BRAF, NTRK, MET, or RET genomic tumor aberrations, where applicable.

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. Recurrent
    d. Regional and inoperable or incompletely resected
2. The member is not a candidate for curative surgery or curative radiation
3. The requested medication will be used as a single agent

B. Basal Cell Carcinoma (BCC)

Authorization of 6 months may be granted for single-agent treatment of advanced, recurrent, 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 recurrent, advanced, or metastatic non-small cell lung cancer (NSCLC) when any of the following criteria are met:
1. The requested medication will be used as first-line therapy and the tumor does not have EGFR exon 19 deletions or L858R mutations, ALK rearrangements, or ROS1 aberrations (unless testing is not feasible due to insufficient tissue) as either:
    a. A single agent for tumors with a high PD-L1 expression [Tumor Proportion Score (TPS) $\geq$ 50%], or
    b. In combination with platinum-based chemotherapy

2. The requested medication will be used as maintenance therapy following first-line cemiplimab-rwlc therapy and the tumor does not have EGFR exon 19 deletions or L858R mutations, ALK rearrangements, or ROS1 aberrations (unless testing is not feasible due to insufficient tissue) as either:
    a. A single agent, or
    b. In combination with pemetrexed

3. The requested medication will be used as subsequent therapy in combination with platinum-based chemotherapy for any of the following biomarkers:
    a. BRAF V600E mutation, NTRK 1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement
    b. A sensitizing EGFR mutation (e.g., exon 19 deletion, exon 21 L858R, S768I, L861Q, G719X mutation) and the member has received prior therapy with an EGFR inhibitor (e.g., erlotinib, afatinib, gefitinib, osimertinib, dacomitinib)
    c. An ALK rearrangement and the member has received prior therapy with an ALK inhibitor (e.g., crizotinib, ceritinib, alectinib, brigatinib, lorlatinib)

d. The member has a ROS1 rearrangement and has received prior therapy with crizotinib, entrecitinib, or ceritinib

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.; November 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed April 5, 2023.