Reference number(s)
4202-A

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 Indications
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)
   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) ≥ 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
4. Vulvar cancer
5. Cervical 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, KRAS, ALK, ROS1, BRAF, NTRK, MET, or RET genomic tumor aberrations, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Cutaneous Squamous Cell Carcinoma (CSCC)

1. Authorization of 12 months may be granted as single-agent neoadjuvant treatment of cutaneous squamous cell carcinoma that is borderline resectable, unresectable, or if surgery may carry a high morbidity.
2. Authorization of 12 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:
   a. The disease is one of the following:
      1. Metastatic
      2. Locally advanced
      3. Recurrent
   b. The member is not a candidate for curative surgery or curative radiation
   c. The requested medication will be used as a single agent

B. Basal Cell Carcinoma (BCC)

Authorization of 12 months may be granted for single-agent treatment of 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 and when any of the following criteria are met:
1. Member has locally advanced disease
2. Member has nodal disease and surgery is not feasible
3. Member has metastatic disease

C. Non-Small Cell Lung Cancer (NSCLC)

Authorization of 12 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

D. Vulvar Cancer
Authorization of 12 months may be granted as subsequent therapy for advanced or recurrent/metastatic vulvar cancer when the requested medication will be used as a single agent.

E. Cervical Cancer
Authorization of 12 months may be granted as subsequent therapy for recurrent or metastatic cervical cancer when the requested medication will be used as a single agent.

IV. CONTINUATION OF THERAPY

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

A. Basal Cell Carcinoma or Cutaneous Squamous Cell Carcinoma
Authorization for 12 months (up to 24 months total) may be granted for all members (including new members) who are continuing with the requested medication when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication
2. The requested medication is being used to treat basal cell carcinoma or cutaneous squamous cell carcinoma
3. The member is receiving benefit from therapy. Benefit is defined as:
   a. No evidence of unacceptable toxicity while on the current regimen and
   b. No evidence of disease progression while on the current regimen

B. All other indications
Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication
2. The requested medication is being used to treat an indication enumerated in Section III
3. The member is receiving benefit from therapy. Benefit is defined as:
   a. No evidence of unacceptable toxicity while on the current regimen and
   b. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Libtayo.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: Squamous cell skin cancer
4. NCCN Guideline: Basal cell skin cancer
5. NCCN Guideline: Non-small cell lung cancer
6. NCCN Guideline: Vulvar cancer

7. NCCN Guideline: Cervical cancer

A. After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Libtayo are covered in addition to the following:Recurrent or regional cutaneous squamous cell carcinoma
B. Recurrent basal cell carcinoma
C. Additional non-small cell lung cancer scenarios that are not covered in the package insert
D. Vulvar cancer
E. Cervical cancer

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for recurrent or regional cutaneous squamous cell carcinoma, recurrent basal cell carcinoma, non-small cell lung cancer, vulvar cancer, and cervical cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VII. REFERENCES

1. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed November 6, 2023.