Cemiplimab-rwlc (Libtayo®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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.

FDA-Approved Indications

Cutaneous Squamous Cell Carcinoma (CSCC)
Libtayo is indicated for the treatment of adult patients with metastatic CSCC or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

Libtayo is indicated for the adjuvant treatment of adult patients with CSCC at high risk of recurrence after surgery and radiation.

Basal Cell Carcinoma (BCC)
Libtayo is indicated for the treatment of adult patients with locally advanced or metastatic BCC who have been previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.

Non-Small Cell Lung Cancer (NSCLC)

- 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:
  - locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
  - metastatic
- 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:
  - locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or
  - metastatic

Compendial Uses

- Squamous cell skin cancer
- Basal cell skin cancer
- Non-small cell lung cancer
- Vulvar Cancer
- Cervical Cancer
- Vaginal Cancer

- Anal carcinoma
- Small bowel adenocarcinoma
- Colon adenocarcinoma
- Appendiceal neoplasms and cancers
- Rectal adenocarcinoma

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

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.

DOCUMENTATION

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

- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
- Documentation of molecular testing for EGFR, ALK, ROS1, BRAF, NTRK, MET, or RET genomic tumor aberrations, where applicable.
- Documentation of laboratory report confirming MSI-H, mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.

COVERAGE CRITERIA

Cutaneous Squamous Cell Carcinoma (CSCC)

Authorization of 6 months may be granted as single-agent neoadjuvant treatment of very high risk, locally advanced, borderline resectable, unresectable, in-transit metastatic, or regional cutaneous squamous cell carcinoma.

Authorization of 6 months may be granted as single agent adjuvant treatment of CSCC at high risk of recurrence after surgery and radiation.

Authorization of 6 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:

- The disease is one of the following:
  - Metastatic
  - Locally advanced
  - Recurrent
  - Satellitosis/in-transit metastatic
- The member is not a candidate for curative surgery or curative radiation
- The requested medication will be used as a single agent

Basal Cell Carcinoma (BCC)

Authorization of 6 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:

- Member has locally advanced disease
- Member has nodal disease and surgery is not feasible

- Member has metastatic disease

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:

- 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, RET or ROS1 aberrations (unless testing is not feasible due to insufficient tissue) as either:
  - A single agent for tumors with a high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%], or
  - In combination with platinum-based chemotherapy
- 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, RET or ROS1 aberrations (unless testing is not feasible due to insufficient tissue) as either:
  - A single agent, or
  - In combination with pemetrexed
- The requested medication will be used as subsequent therapy and the tumor does not have EGFR exon 19 deletions or L858R mutations, ALK rearrangements, RET or ROS1 aberrations (unless testing is not feasible due to insufficient tissue) in combination with platinum-based chemotherapy.

Vulvar Cancer

Authorization of 6 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.

Cervical Cancer

Authorization of 6 months may be granted as subsequent therapy for recurrent or metastatic cervical cancer when the requested medication will be used as a single agent.

Vaginal Cancer

Authorization of 6 months may be granted as subsequent therapy for recurrent or metastatic vaginal cancer when the requested medication will be used as a single agent.

Anal Carcinoma

Authorization of 6 months may be granted as subsequent therapy for metastatic anal carcinoma when the requested medication will be used as a single agent.

Small Bowel Adenocarcinoma

Authorization of 6 months may be granted as a single agent for treatment of advanced, locally unresectable, medically inoperable, or metastatic deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., tumor mutational burden [TMB] greater than 50 mut/Mb) small bowel adenocarcinoma.

Colon Cancer

Authorization of 6 months may be granted as a single agent for neoadjuvant therapy or treatment of unresectable, inoperable, or metastatic colon adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair

deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Appendiceal Cancer

Authorization of 6 months may be granted as a single agent for treatment of appendiceal neoplasms and cancers for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Rectal Cancer

Authorization of 6 months may be granted as a single agent for neoadjuvant therapy or treatment of recurrent or metastatic rectal adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

CONTINUATION OF THERAPY

Basal Cell Carcinoma or Cutaneous Squamous Cell Carcinoma

Authorization of 6 months may be granted (up to 48 weeks total) for continued treatment in members requesting reauthorization for adjuvant treatment of cutaneous squamous cell carcinoma who have not experienced disease recurrence or an unacceptable toxicity.

Authorization of 6 months may be granted (up to 24 months total) for continued treatment in members requesting reauthorization for treatment of basal cell carcinoma or cutaneous squamous cell carcinoma (excluding adjuvant treatment) who have not experienced disease progression or an unacceptable toxicity.

All Other Indications

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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed November 11, 2025.

EFFECTIVE DATE 7/31/2026

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