Reference number(s)
4202-A

Standard Medicare Part B Management Libtayo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Libtayo	cemiplimab-rwlc

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[1]

Cutaneous Squamous Cell Carcinoma (CSCC)

Libtayo is indicated for the treatment of adult patients with metastatic CSCC or locally advanced CSCC (laSCSS) 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

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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[2]

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

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

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

- 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.

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- Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) with ultra-hypermutated tumor mutational burden [TMB] (greater than 50 mutations/megabase [mut/Mb]) tumor status, where applicable.

Coverage Criteria

Cutaneous Squamous Cell Carcinoma (CSCC)[1,2]

Authorization of 12 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 12 months may be granted as single agent adjuvant treatment of CSCC at high risk of recurrence after surgery and radiation.

Authorization of 12 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 patient is not a candidate for curative surgery or curative radiation
- The requested medication will be used as a single agent

Basal Cell Carcinoma (BCC)[1,2]

Authorization of 12 months may be granted as single-agent neoadjuvant treatment of locally advanced basal cell carcinoma in members where radiation therapy or surgery is not feasible.

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:

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

Non-Small Cell Lung Cancer (NSCLC)[1,2]

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:

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- The requested medication will be used as first-line therapy and the tumor does not have EGFR exon 19 deletions or L858R mutations, or ALK, RET or ROS1 gene fusions (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, or ALK, RET or ROS1 gene fusions (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, or ALK , RET or ROS1 gene fusions (unless testing is not feasible due to insufficient tissue) in combination with platinum-based chemotherapy.

Vulvar Cancer[2]

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.

Cervical Cancer[2]

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.

Vaginal Cancer[2]

Authorization of 12 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[2]

Authorization of 12 months may be granted as subsequent therapy for locally recurrent, progressive, or metastatic anal carcinoma when the requested medication will be used as a single agent.

Small Bowel Adenocarcinoma[2]

Authorization of 12 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.

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Colon Cancer[2]

Authorization of 12 months may be granted as a single agent for neoadjuvant therapy or for 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 Neoplasms and Cancers[2]

Authorization of 12 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[2]

Authorization of 12 months may be granted as a single agent for neoadjuvant therapy or for 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

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

Basal Cell Carcinoma or Cutaneous Squamous Cell Carcinoma

Authorization for 12 months (up to 48 weeks 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:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used as adjuvant treatment of cutaneous squamous cell carcinoma
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease recurrence while on the current regimen

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:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat basal cell carcinoma or cutaneous squamous cell carcinoma (excluding adjuvant treatment)
- The member is receiving benefit from therapy. Benefit is defined as:

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  - No evidence of unacceptable toxicity while on the current regimen and
  - No evidence of disease progression while on the current regimen

All other indications

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

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
  - No evidence of unacceptable toxicity while on the current regimen and
  - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this document were created after examining the following resources:

- The prescribing information for Libtayo.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- NCCN Guideline: Squamous cell skin cancer
- NCCN Guideline: Basal cell skin cancer
- NCCN Guideline: Non-small cell lung cancer
- NCCN Guideline: Vulvar cancer
- NCCN Guideline: Cervical cancer
- NCCN Guideline: Vaginal cancer
- NCCN Guideline: Anal carcinoma
- NCCN Guideline: Small bowel adenocarcinoma
- NCCN Guideline: Colon cancer
- NCCN Guideline: Appendiceal neoplasms and cancers
- NCCN Guideline: Rectal cancer

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
- Recurrent basal cell carcinoma
- Additional non-small cell lung cancer scenarios that are not covered in the package insert
- Vulvar cancer
- Cervical cancer
- Vaginal cancer

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

Explanation of Rationale

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

Support for compendial uses 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).

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 December 4, 2025.

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