Medical Policy:

Libtayo (cemiplimab-rwlc) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.117	March 20, 2025	January 1st, 2019

Definitions

Libtayo® (Cemiplimab-rwlc) is a recombinant human IgG4 monoclonal antibody that binds to human programmed death receptor-1 (PD-1) and blocks its interaction with PD-1 ligands 1 and 2 (PD-L1 and PD-L2), which is the interaction responsible for the inhibition of T-cell proliferation and cytokine production, thus releasing the PD-1 pathway-mediated inhibition of immune response, including anti-tumor response.

Libtayo (cemiplimab-rwlc) is FDA approved 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.

Length of Authorization

Coverage will be provided for 6 months and may be renewed unless otherwise specified:

- Neoadjuvant therapy in Cutaneous Squamous Cell Carcinoma (cSCC) can be authorized up to a maximum of 4 doses and cannot be renewed.
- Treatment for metastatic, locally advanced, or recurrent cSCC, and Basal Cell Carcinoma (BCC) can be renewed up to a maximum of twenty-four (24) months of therapy (35 doses).

Dosing Limits [Medical Benefit]

Single dose limit 350 mg (350 billable units (350 mg) every 21 days)

Guideline

I. Initial Approval Criteria

Libtayo *may be considered medically necessary if the below condition is met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Cutaneous Squamous Cell Carcinoma (cSCC)**
    A. Patient must be ≥ 18 years of age; **AND**
        i. The patient has unresectable locally advanced or metastatic CSCC AND is not a candidate for curative surgery or curative radiation **OR**
        ii. Patient has very-high risk, locally advanced, unresectable, or regional disease AND Medication will be used as neoadjuvant therapy; **AND**
    B. Libtayo is being used as a single agent

2. **Basal Cell carcinoma (BCC)**
    A. Patient must have locally advanced or metastatic basal cell carcinoma (laBCC or mBCC); **AND**
    B. Patient must have been previously treated with a hedgehog pathway inhibitor (e.g., vismodegib, sonidegib, etc **) OR** for whom a hedgehog pathway inhibitor is not appropriate.

3. **Non-Small Cell Lung Cancer (NSCLC)**
    A. Patient has non-small cell lung cancer with no EGFR, ALK, or ROS1 aberrations; **AND**
    B. Patient must have locally advanced disease where patients are not candidates for surgical resection or definitive chemoradiation OR metastatic disease; **AND**
        i. Medication Is being used in combination with platinum-based chemotherapy for the first-line treatment; **OR**
        ii. Medication is being used as a single agent for the first-line treatment of adult patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test

Limitations/Exclusions

1. Libtayo (cemiplimab-rwlc) is not considered medically necessary when any of the following selection criteria are met:
    A. Libtayo (cemiplimab-rwlc) is being used after disease progression with the same regimen or prior treatment with a PD-1/PDL-1/BRAF inhibitor.
    B. Concurrent use or within 4 weeks prior to first dose of Libtayo (cemiplimab-rwlc) with other immune-modulating agents (e.g., immunosuppressive corticosteroid doses, therapeutic vaccines, cytokine treatments, or agents that target cytotoxic T-lymphocyte antigen 4 (CTLA-4), 4-1BB (CD137), or OX-40, etc.)
    C. Significant autoimmune disease that required treatment with systemic immunosuppressive treatments, active infection, history of pneumonitis or solid organ transplant.
    D. Dosing exceeds single dose limit of Libtayo (cemiplimab-rwlc) 350 mg.
    E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet the criteria in the INITIAL APPROVAL CRITERIA; **AND**
2. Patient does not experience unacceptable toxicity from this drug. Examples of unacceptable toxicity include the following: severe infusion reactions, severe immune-mediated adverse reactions such as pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, rash, encephalitis, etc.; **AND**
3. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread has been demonstrated.

Dosage/Administration

Indication	Dose
All Indications	350 mg IV infusion every 3 weeks until disease progression or unacceptable toxicity (Neoadjuvant therapy in Cutaneous Squamous Cell Carcinoma (cSCC) can be authorized up to a maximum of 4 doses and cannot be renewed. Treatment for metastatic, locally advanced, or recurrent cSCC, and Basal Cell Carcinoma (BCC) can be renewed up to a maximum of twenty-four (24) months of therapy (35 doses).)

Applicable Procedure Codes

Code	Description
J9119	Effective 10/1/19, Injection, cemiplimab-rwlc, 1 mg

Applicable NDCs

Code	Description
61755-0008-xx	Libtayo 350 mg/7 ml single use vial

ICD-10 Diagnoses

Code	Description
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung

C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C44.01	Basal cell carcinoma of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthusb
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canalb
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.310	Basal cell carcinoma of skin of unspecified parts of face
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
C44.320	Squamous cell carcinoma of skin of unspecified parts of faceb
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder
C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulderb
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip
C44.712	Basal cell carcinoma of skin of right lower limb, including hip
C44.719	Basal cell carcinoma of skin of left lower limb, including hip
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.81	Basal cell carcinoma of overlapping sites of skin
C44.82	Squamous cell carcinoma of skin of left lower limb, including hip
C44.91	Basal cell carcinoma of skin, unspecified
C44.92	Squamous cell carcinoma of overlapping sites of skin
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Revision History

<table>
<tr><th>Company(ies)</th><th>DATE</th><th>REVISION</th></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>3/20/2025</td><td>Annual Review: No criteria changes. Length of authorization: Added: “Treatment for metastatic, locally advanced, or recurrent cSCC, and Basal Cell Carcinoma (BCC) can be renewed up to a maximum of twenty-four (24) months of therapy (35 doses).” Updated dosing chart</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>2/5/2024</td><td>Annual Review: Removed NDC: 61755-0007-xx, Updated length of authorization, dosing limits and dosing chart.
Initial Criteria: Cutaneous Squamous Cell Carcinoma (CSCC)
Removed: “Cutaneous squamous cell carcinoma with nodal or distant metastatic disease; AND” Added: “Patient has very-high risk, locally advanced, unresectable, or regional disease AND Medication will be used as neoadjuvant therapy; AND”</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>06/08/2023</td><td>Annual Review: Added Basal Cell Carcinoma indication and Non-Small Cell Lung Cancer Indication
<u>Cutaneous Squamous Cell Carcinoma</u>: Initial Criteria- Removed:
“a. Patient has not received previous therapy with the following:
i. A programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, etc.) unless otherwise specified; OR
ii. A cytotoxic T-lymphocyte antigen 4 (CTLA-4) targeting agent (e.g., ipilimumab, etc.) within the previous 4 weeks prior to therapy; OR
iii. A BRAF-inhibitor (e.g., vemurafenib, dabrafenib, encorafenib, etc.); OR
iv. A small-molecule inhibitor (phosphtidylinositol-3 kinase inhibitor [PI3-K]) therapy (e.g., idelalisib, duvelisib, etc.)” Added “Libtayo is being used as a single agent”
Added codes:
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EmblemHealth & ConnectiCare	1/10/2023	Transferred to new template
EmblemHealth & ConnectiCare	7/7/2021	Removed C Code
EmblemHealth & ConnectiCare	8/15/2019	Removed J9999, Added New Code J9119, effective 10/1/19
EmblemHealth & ConnectiCare	3/29/2019	Added New Code C9044

References

1. Libtayo (cemiplimab-rwlc) PI prescribing information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. Revised November, 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.

3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018.