Evolent Clinical Guideline 3013 for Libtayo™ (cemiplimab-rwlc)

Guideline Number: Evolent_CG_3013	Applicable Codes	
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STATEMENT

Purpose

To define and describe the accepted indications for Libtayo (cemiplimab-rwlc) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Basal Cell Carcinoma

- Libtayo (cemiplimab-rwlc) may be used as a single agent, in members with locally advanced/recurrent/metastatic basal cell carcinoma, who are not candidates for surgery and/or radiation therapy.

Cutaneous Squamous Cell Carcinoma (CSCC)

- Libtayo (cemiplimab-rwlc) may be used as monotherapy for the adjuvant treatment of adult members with cutaneous squamous cell carcinoma (CSCC) at high risk of recurrence after surgery and radiation.
    - High risk of recurrence is defined as at least one of the following features:

- Nodal Features:
  - Extracapsular extension (ECE) with ≥1 node ≥20 mm, or
  - ≥3 involved lymph nodes regardless of ECE
- Non-Nodal Features:
  - In-transit metastases (skin or subcutaneous metastases > 2 cm from the primary lesion but not beyond the regional nodal basin),
  - Invasion of the skeleton or base of the skull (T4 Lesion),
  - Perineural Invasion, or
  - Locally recurrent tumor with ≥1 additional adverse feature listed below:
    - Multiple ipsilateral nodes
    - ≥T3 (≥4 cm diameter or bone erosion or invasion >6 mm)
    - Poorly differentiated histology and recurrent lesion ≥20 mm diameter

- Libtayo (cemiplimab-rwlc) may be used as monotherapy in adult members with unresectable locally advanced or metastatic cutaneous squamous cell carcinoma who are not candidates for curative surgery and/or curative radiation AND have not received prior therapy with another immune checkpoint inhibitor (e.g., pembrolizumab).

Non-Small Cell Lung Cancer (NSCLC)

- The member has locally advanced, recurrent, or metastatic NSCLC, negative for the following actionable molecular markers ALK, EGFR, and ROS-1 (ALK, EGFR, and ROS-1 not required for squamous histology), and has not experienced disease progression on prior Immune Checkpoint Inhibitor therapy, including Keytruda (pembrolizumab), Opdivo (nivolumab), OR Tecentriq (atezolizumab) AND the following criteria are met:
  - Libtayo (cemiplimab-rwlc) will be used as first line therapy as a single agent if PD-L1 is greater than or equal to 50%.
- Libtayo (cemiplimab-rwlc) may be used in combination with platinum-based chemotherapy for the first line treatment of adult members with non-small cell lung cancer (NSCLC) with no EGFR/ALK/ROS1 genomic aberrations (ALK, EGFR, and ROS-1 not required for squamous histology) in the following clinical scenarios:
  - Locally advanced Non-Small Cell Lung Cancer for which the members are not a candidate for surgical resection and also not a candidate for definitive chemoradiation OR,
  - Metastatic Non-Small Cell Lung Cancer

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Libtayo (cemiplimab-rwlc) is used after disease progression with the same regimen or prior treatment with an Immune Checkpoint Inhibitor therapy [e.g., Keytruda

(pembrolizumab), Opdivo (nivolumab), Tecentriq (atezolizumab)].

- Dosing exceeds single dose limit of Libtayo (cemiplimab-rwlc) 700 mg.
- Investigational use of Libtayo (cemiplimab-rwlc) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    - Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
    - That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

CODING AND STANDARDS

Codes

- J9119 - Injection, cemiplimab-rwlc, 1 mg

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
May 2026	• Updated maximum dose under exclusion criteria • Updated references
November 2025	• Updated CSCC indication section • Updated references
February 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1089 Libtayo (cemiplimab-rwlc)
February 2024	• Updated verbiage in single-agent use and in combination with platinum-based chemotherapy under NSCLC indication section

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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