Drug Policy:

Libtayo™ (cemiplimab-rwlc)

POLICY NUMBER UM ONC_1089	SUBJECT Libtayo™ (cemiplimab-rwlc)		DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 10/10/18, 10/09/19, 12/11/19, 04/08/20, 09/09/20, 04/14/21, 11/15/21, 04/13/22, 05/11/22, 11/09/22, 12/14/22, 06/14/23, 09/13/23, 02/14/24	APPROVAL DATE February 14, 2024	EFFECTIVE DATE February 23, 2024	COMMITTEE APPROVAL DATES 10/10/18, 10/09/19, 12/11/19, 04/08/20, 09/09/20, 04/14/21, 11/15/21, 04/13/22, 05/11/22, 11/09/22, 12/14/22, 06/14/23, 09/13/23, 02/14/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. 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.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Basal Cell Carcinoma

1. 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.

C. Cutaneous Squamous Cell Carcinoma (CSCC)

1. The member has unresectable locally advanced or metastatic Cutaneous Squamous Cell Carcinoma and is not a candidate for curative surgery and/or curative radiation AND
2. Libtayo (cemiplimab-rwlc) is being used as a single agent AND
3. The member has not received prior therapy with another immune checkpoint inhibitor (e.g., pembrolizumab).

D. Non-Small Cell Lung Cancer (NSCLC)

1. 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:
    a. Libtayo (cemiplimab-rwlc) will be used as first line therapy as a single agent if PD-L1 is greater than or equal to 50%.
2. 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:
    a. 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,
    b. Metastatic Non-Small Cell Lung Cancer

III. EXCLUSION CRITERIA

A. 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)].

B. Dosing exceeds single dose limit of Libtayo (cemiplimab-rwlc) 350 mg.

C. 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:
    1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    3. 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.
    4. 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).
    5. 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.

6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. 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.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Gogishvili M, et al. EMPOWER-Lung 3 Clinical Trial. Cemiplimab plus chemotherapy versus chemotherapy alone in non-small cell lung cancer: a randomized, controlled, double-blind phase 3 trial. Nat Med. 2022 Nov;28(11):2374-2380.

B. Sezer et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomized, controlled trial. The Lancet. Vol 397, Issue 10274,P592-604, February 13, 2021

C. Migden MR, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 Jul 26;379(4):341-351.

D. Libtayo (cemiplimab-rwlc) prescribing information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY 2021.

E. Clinical Pharmacology Elsevier Gold Standard 2023.

F. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

I. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

J. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.