

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	APPROVAL DATE April 14, 2021	EFFECTIVE DATE April 30, 2021	COMMITTEE APPROVAL DATES (latest version listed last) 10/10/18, 10/09/19, 12/11/19, 04/08/20, 09/09/20, 04/14/21	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	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.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, te [Preferred Drug Guidelines shall follow NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When available, generic alternatives are preferred over brand-name drugs.

B. Cutaneous Squamous Cell Carcinoma (CSCC)

1. **NOTE:** Per NCH Policy Libtayo (cemiplimab-rwlc) is the preferred agent for use in metastatic cutaneous squamous cell carcinoma, over Keytruda (pembrolizumab).
 - a. The member has unresectable locally advanced or metastatic Cutaneous Squamous Cell Carcinoma and is not a candidate for curative surgery or curative radiation **AND**
 - b. Libtayo (cemiplimab-rwlc) is being used as a single agent.

C. Basal Cell Carcinoma

1. Libtayo (cemiplimab-rwlc) may be used as a single agent, in a member with locally advanced/recurrent/metastatic basal cell carcinoma, who are not candidates for surgery or radiation therapy, and have failed prior therapy with/are intolerant to therapy with a Hedge Hog Pathway inhibitor (HHI). The preferred HHI per NCH Policy is Erivedge (vismodegib). *Please see UM ONC_1222 Erivedge (vismodegib) policy.*

D. Non-Small Cell Lung Cancer

1. **NOTE #1:** For recurrent/metastatic, NSCLC, with PD-L1 $\geq 50\%$, the recommended Immune Checkpoint Inhibitor per NCH Policy and NCH Pathway is Keytruda (pembrolizumab). This recommendation is based on the results of the KEYNOTE-024 trial, including the 5-year long term update of the latter trial, both referenced below. Furthermore there is no Level 1 evidence (randomized trial and/or meta-analysis) to support that Libtayo (cemiplimab) therapy results in superior outcomes compared to Keytruda (pembrolizumab) therapy in the above sub-group of patients with NSCLC.
2. Libtayo (cemiplimab) may be used as monotherapy in members with locally advanced, recurrent/metastatic NSCLC, with PD-L1 $\geq 50\%$, negative for actionable molecular markers (ALK, EGFR, or ROS-1), **AND** if there is a contraindication/intolerance to Keytruda (pembrolizumab). Libtayo (cemiplimab) use is not supported if the member has experienced disease progression on prior Immune Checkpoint Inhibitor therapy, including Imfinzi (durvalumab), Keytruda (pembrolizumab), Opdivo (nivolumab), **OR** Tecentriq (atezolizumab).

III. EXCLUSION CRITERIA

- A. Libtayo (cemiplimab-rwlc) use after disease progression with the same regimen or prior treatment with a PD-1/PDL-1 inhibitor.
- B. Dosing exceeds single dose limit of Libtayo (cemiplimab-rwlc) 350 mg.
- C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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. Brahmer et al, KEYNOTE-024 Updated Survival Results. *Annals of Oncology* 2020 (31(suppl_4): S1142-S1215. DOI:10/1016/annonc/annonc325.
- B. Reck, et al, KEYNOTE-024 trial, *N Engl J Med* 2016;375:1823-1833. DOI:10.1056/NEJMoa1606774.
- C. FDA press release, Silver Spring, MD: FDA; February 9, 2021.
- D. Libtayo (cemiplimab-rwlc) PI prescribing information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY 2021.
- E. *Clinical Pharmacology Elsevier Gold Standard* 2021.
- F. *Micromedex® Healthcare Series: Thomson Micromedex*, Greenwood Village, CO 2021.
- G. *National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium* 2021.
- H. *AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs*. Bethesda, MD 2021.