Drug Policy:
Libtayo™ (cemiplimab-rwlc)

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, the 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 ≥ 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 ≥ 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. 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 definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

4. Whether the experimental design, in light of 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
DOI:10.1056/NEJMoa1606774.
C. FDA press release, Silver Spring, MD: FDA; February 9, 2021.
J. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: