Medical Drug Clinical Criteria

Subject:	Libtayo (cemiplimab-rwlc)		
Document #:	CC-0145	**Publish Date:**	~~06/20/2023~~07/01/2024
Status:	Revised	**Last Review Date:**	~~05/19/2023~~05/17/2024

Table of Contents

Overview

This document addresses the use of Libtayo (cemiplimab). Libtayo (cemiplimab) is a programmed death receptor-1 (PD-1) blocking antibody used to treat cutaneous squamous cell carcinoma (CSCC), basal cell carcinoma, and non-small cell lung cancer.

The FDA approved indications for Libtayo (cemiplimab):

- Metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation
- Locally advanced or metastatic basal cell carcinoma (BCC) in those previously treated with a hedgehog pathway inhibitor, or for whom a hedgehog pathway inhibitor is not appropriate
- Unresectable locally advanced, or metastatic non-small cell lung cancer (NSCLC) as first line treatment in those with high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] with no EGFR, ALK, or ROS1 mutations
- In combination with platinum-based chemotherapy for the first-line treatment of adults with NSCLC with no EGFR, ALK or ROS1 aberrations, and is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.

The indication for metastatic BCC was approved under the FDA accelerated approval program, and continued approval is contingent upon verification of clinical benefit in confirmatory trials.
NCCN panel recommends that individuals with NSCLC be tested for actionable molecular markers, such as EGFR, ALK, ROS1, BRAF, NTRK, MET and RET mutations, before initiating first line therapy to help guide treatment. If there is insufficient tissue to allow testing for all of these markers, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.

Definitions and Measures

ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

Hegdehog pathway inhibitor: FDA-approved examples include vismodegib (Erivedge) and sonidegib (Odomzo)

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Libtayo (cemiplimab-rwlc) injection

Requests for Libtayo (cemiplimab-rwlc) injection may be approved if the following criteria are met:

I. Individual has a diagnosis of unresectable locally advanced, recurrent, or metastatic Basel Cell Carcinoma (BCC) (Label, NCCN 2A); **AND**
   A. Individual is using as single agent for subsequent therapy; **AND**
   B. Individual has confirmed disease progression on a hedgehog pathway inhibitor, or ineligible for treatment with a hedgehog pathway inhibitor; ~~**AND**~~
   ~~C. Individual has a current ECOG performance status of 0-2; **AND**~~
   ~~D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**~~
   ~~E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;~~

OR

II. Individual has a diagnosis of Cutaneous Squamous Cell Carcinoma (CSCC) (Label, NCCN 2A); **AND**
   A. One of the following:
      1. Individual is diagnosed with metastatic disease; **OR**
      2. Individual is diagnosed with locally advanced or locally recurrent disease; **OR**

   ~~3.~~B. Individual is diagnosed with regional new or regional recurrent disease; **AND**

   ~~B.~~C. Individual is using as single agent; ~~**AND**~~
   ~~C. Individual is not a candidate for curative surgery or radiation; **AND**~~
   ~~D. Individual has current ECOG performance status of 0-2; **AND**~~
   ~~E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**~~
   ~~F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;~~

~~**OR**~~

~~III. Individual has a diagnosis of locally advanced Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 1); **AND**~~
   ~~A. Individual is using as single agent; **AND**~~
   ~~A. Individual is not a candidate for surgical resection or chemoradiation; **AND**~~
   ~~B. Individual has a tumor with PD-L1 gene expression with Tumor Proportion Score of greater than or equal to 50% (TPS ≥ 50%); **AND**~~
   ~~C. Individual does not have presence of actionable molecular markers*; **AND**~~
   ~~D. Individual has a current ECOG performance status of 0-2; **AND**~~
   ~~E. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**~~
   ~~F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;~~

~~**OR**~~

~~IV. Individual has a diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 1); **AND**~~
   ~~A. Individual is using as single agent or in combination therapy; **AND**~~
   ~~A. Individual does not have presence of actionable molecular markers*; **AND**~~
   ~~B. Individual has a current ECOG performance status of 0-2; **AND**~~
   ~~C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**~~
   ~~D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;~~

OR

~~V.~~III. Individual has a diagnosis of recurrent, advanced, or metastatic disease NSCLC; **AND**

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~~A. One of the following:~~
~~1. Individual has recurrent, metastatic or locally advance disease where individual is not a candidate for surgical resection or definitive chemoradiation; **OR**~~
~~2. Individual has recurrent, advanced, or metastatic disease; **AND**~~
~~B.~~A. Individual is using in combination with pemetrexed (NCCN 2A) or platinum-based chemotherapy (Label); ~~**AND**~~**OR**
~~C.~~ Individual is using as a single agent;~~Individual is using for first-line (Label) or maintenance (NCCN 2A) therapy; **AND**~~
~~D. Individual does not have presence of actionable molecular markers*; **AND**~~
~~E. Individual has a current ECOG performance status of 0-2; **AND**~~
~~F. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**~~
~~Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant~~

OR

IV. Individual has a diagnosis of cervical or vulvar cancer (NCCN 2A); **AND**
A. Individual has advanced, recurrent, or metastatic disease; **AND**
~~C.~~B. Individual is using as second-line or subsequent therapy.

~~***Note:** Actionable molecular markers include EGFR, ALK, ROS1, BRAF, NTRK, MET and RET mutations. The NCCN panel recommends testing prior to initiating therapy to help guide appropriate treatment. If there is insufficient tissue to allow testing for all of these markers, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes (NCCN 1, 2A).~~

Requests for Libtayo (cemiplimab-rwlc) may not be approved for the following:

I. All other indications not included above; **OR**
II. Individual has received treatment with another anti-PD-1 or anti-PD-L1 agent; **OR**
III. Individual is receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

~~when the above criteria are not met and for all other indications.~~

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9119	Injection, cemiplimab-rwlc, 1 mg [Libtayo]

ICD-10 Diagnosis

C34.90-C34.92	Malignant neoplasm of unspecified part of bronchus or lung
C44.00-C44.99	Other and unspecified malignant neoplasm of skin
C51.0-C51.9	Malignant neoplasm of vulva
C53.0-C53.9	Malignant neoplasm of cervix uteri

Document History

Revised: 05/17/2024
Document History:

- 05/17/2024 – Annual Review: update cutaneous squamous cell carcinoma remove requirements needing curative surgery or radiation, add cervical and vulvar cancer criteria, update non-small cell lung cancer to include recurrent/advanced and actionable mutations, wording and formatting. Coding

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Reviewed: Added ICD-10-CM C51.0-C51.9, C53.0-C53.9. Expanded ICD-10-CM Code range to C34.00-C34.92.

- 05/19/2023 – Annual Review: update NSCLC criteria for recurrent/metastatic and for PDL-1<1% and actionable mutations present, add pemetrexed combination. Coding Reviewed: No changes.
- 12/12/2022 – Select Review: Add FDA approved use for combination use with platinum-based chemotherapy in first-line therapy for NSCLC, either locally advanced disease or metastatic disease. Coding Reviewed: No changes.
- 05/20/2022 – Annual Review: Add CSCC local recurrence, regional new, recurrent disease. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: Update BCC criteria to specify use in unresectable locally advanced disease. Update NSCLC criteria to specify any actionable molecular marker with a note to further expand on definition and marker testing. Wording, formatting, and reference updates. Coding Reviewed: No changes.
- 03/15/2021 – Select Review: Update criteria to add indications for basal cell carcinoma and non-small cell lung cancer per label. Clarify use as single agent in cutaneous squamous cell carcinoma per NCCN and clinical trials. Retire quantity limits. Wording and formatting changes. Coding Reviewed: Added ICD-10-CM C34.90-C34.92.
- 05/15/2020 – Annual Review: Wording and formatting changes. Coding review: No changes
- 08/16/2019 – Annual Review: Add new quantity limit per FDA label. Update criteria to add ECOG status, prior use of other anti-PD-1/PD-L1 agents, and history of immunosuppression for consistency. Coding Review: Added HCPCS J9119. Added ICD-10 C44.00-C44.99

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 19, 2024.
    a. Basal Cell Skin Cancer. V3.2024. Revised March 1, 2024.
    b. Cervical Cancer. V2.2024. Revised February 23, 2024.
    c. Non-Small Cell Lung Cancer. V3.2024. Revised March 12, 2024.
    d. Squamous Cell Skin Cancer. V1.2024. Revised November 9, 2023.
    e. Vaginal Cancer. V1.2025. Revised March 26, 2024
    f. Vulvar Cancer. V3.2024. Revised December 21, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.