

Subject:	Libtayo (cemiplimab-rwlc)		
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Overview

This document addresses the use of Libtayo (cemiplimab-rwlc). Libtayo (cemiplimab-rwlc) is a programmed death receptor-1 (PD-1) blocking antibody used to treat cutaneous squamous cell carcinoma (CSCC).

The FDA approved indications for Libtayo (cemiplimab-rwlc) is for the treatment of metastatic CSCC or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

Approval of Libtayo was based on two open-label multi-center, non-randomized, multicohort studies which demonstrated reduction in tumor size or complete disappearance of tumor after treatment. Libtayo marks the first drug FDA-approved specifically for advanced CSCC.

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

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 metastatic Cutaneous Squamous Cell Carcinoma (CSCC) (Label, NCCN 2A);

OR

- II. Individual has a diagnosis of locally advanced CSCC and are not candidates for curative surgery or radiation;

AND

- III. Individual has current ECOG performance status of 0-2; **AND**
IV. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
V. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Requests for Libtayo (cemiplimab-rwlc) may not be approved 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]
C9044	Injection, cemiplimab-rwlc, 1 mg used for Hospital Outpatient coding only [Libtayo]

ICD-10 Diagnosis

C44.0-C44.99	Other and unspecified malignant neoplasm of skin
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Document History

Revised: 08/16/2019

Document History:

- 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, C9044. Added ICD-10 C44.0-C44.99

References

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- NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 26, 2019.
 - Squamous Cell Skin Cancer. V2.2019. Revised October 10, 2018.

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

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