

Policy: MBP 186.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Libtayo (cemiplimab-rwlc)

I. Policy:

Libtayo (cemiplimab-rwlc)

II. Purpose/Objective:

To provide a policy of coverage regarding Libtayo (cemiplimab-rwlc)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Libtayo (cemiplimab-rwlc) is a recombinant human IgG4 monoclonal antibody that inhibits programmed death-1 (PD-1) activity by binding to PD-1 and blocking the interactions with the ligands PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of immune response, including anti-tumor response. PD-1 ligand upregulation may occur in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Blocking PD-1 activity has resulted in decreased tumor growth.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Libtayo (cemiplimab-rwlc) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Cutaneous Squamous Cell Carcinoma (cSCC)

- Prescription written by a hematologist or oncologist **AND**
- Documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of metastatic cutaneous squamous cell carcinoma (cSCC) or locally advanced cSCC **AND**
- Medical record documentation that the patient is not a candidate for curative surgery or curative radiation

Basal Cell Carcinoma

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of a diagnosis of one of the following:
 - Documentation of a diagnosis of locally advanced BCC (laBCC) **OR**
 - Documentation of a diagnosis of metastatic BCC (mBCC)**AND**
- Medical record documentation of previous treatment with a hedgehog pathway inhibitor or documentation that a hedgehog pathway inhibitor is not appropriate

Non-Small Cell Lung Cancer (NSCLC)

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation that the patient is 18 years of age or older **AND**
- Medical record documentation of non-small cell lung cancer (NSCLC) **AND** medical record documentation of one of the following:
 - Documentation of locally advanced disease **AND** the patient is not a candidate for surgical resection or definitive chemoradiation **OR**
 - Documentation of metastatic disease**AND**
- Medical record documentation of no EGFR, ALK, or ROS1 genomic tumor aberrations **AND**
- Medical record documentation that Libtayo is being used as first-line treatment **AND**
- Medical record documentation of one of the following situations being met:
 - Libtayo is being used as a single agent **AND**
 - High PD-L1 expression [Tumor Proportion Score (TPS) \geq 50%] as determined by an FDA-approved test**OR**
- Libtayo is being used in combination with platinum-based chemotherapy

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 11/20/18

Revised: 4/29/21 (NSCLC, BCC), 12/23/22 (LOB Carve out, Medicaid business segment, NSCLC in combo w/ platinum chemo)

Reviewed: 9/30/19, 8/26/20, 3/23/22 (Medicaid PARP statement), 12/18/23

MA UM Committee approval: 12/31/23