SmartHealth Ascension

Cemiplimab-rwlc

(Libtayo®) J9119 (1mg)

Covered with prior authorization

Cemiplimab-rwlc (Libtayo®) may be authorized when the following criteria are met:

- Individual has a diagnosis of unresectable locally advanced, recurrent, or metastatic Basal Cell Carcinoma (BCC); **AND**
- Individual is using as single agent **AND**
- Individual has confirmed disease progression on a hedgehog pathway inhibitor, or ineligible for treatment with a hedgehog pathway inhibitor; **AND**
- Individual has a current ECOG performance status of 0-2; **AND**
- 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

- Individual has a diagnosis of Cutaneous Squamous Cell Carcinoma (CSCC); **AND**
- One of the following:
  - Individual is diagnosed with metastatic disease; **OR**
  - Individual is diagnosed with locally advanced or locally recurrent disease; **OR**
  - Individual is diagnosed with regional new or regional recurrent disease; **AND**
- Individual is using as single agent; **AND**
- Individual is not a candidate for curative surgery or radiation; **AND**
- Individual has current ECOG performance status of 0-2; **AND**
- 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

- Individual has a diagnosis of locally advanced Non-Small Cell Lung Cancer (NSCLC); **AND**
- Individual is using as single agent; **AND**
- Individual is not a candidate for surgical resection or chemoradiation; **AND**
- Individual has a tumor with PD-L1 gene expression with Tumor Proportion Score of greater than or equal to 50% (TPS ≥ 50%); **AND**
- Individual does not have presence of actionable molecular markers; **AND**

- 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.
    - ***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.*

OR

- Individual has a diagnosis of metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
- Individual is using as single agent; **AND**
- Individual has a tumor with PD-L1 gene expression with Tumor Proportion Score of greater than or equal to 50% (TPS ≥ 50%); **AND**
- Individual does not have presence of actionable molecular markers; **AND**
- Individual has a current ECOG performance status of 0-2; **AND**
- 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.
    - ***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.*

Exclusion criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization approval is up to 12 months.

Reauthorization approval is up to 12 months.

Reauthorization Criteria:

Cemiplimab-rwlc (Libtayo) is considered medically necessary for continued use when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Cemiplimab-rwlc (Libtayo®) is a programmed death receptor-1 (PD-1) blocking antibody indicated for:

- The treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.
- The treatment of patients with locally advanced BCC (laBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- The treatment of patients with metastatic BCC (mBCC) previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
- The first-line treatment of patients with NSCLC whose tumors have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations, and is:
    - locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or metastatic.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022.
3. Libtayo [Prescribing Information]. Tarrytown,NY: Regeneron Pharmaceuticals, Inc-Sanofi Aventis LLC.; 2021.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.