Libtayo (cemiplimab-rwlc)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Libtayo (cemiplimab-rwlc)

APPROVAL CRITERIA

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 Basal 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. Individual is diagnosed with regional new or regional recurrent disease;

   AND
   B. Individual is using as single agent; **AND**
   C. Individual is not a candidate for curative surgery or radiation; **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

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**

B. Individual is not a candidate for surgical resection or chemoradiation; **AND**
C. Individual has a tumor with PD-L1 gene expression with Tumor Proportion Score of greater than or equal to 50% (TPS ≥ 50%); **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**
G. 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**
B. Individual does not have presence of actionable molecular markers*; **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

V. Individual has a diagnosis of NSCLC; **AND**
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. Individual is using in combination with pemetrexed (NCCN 2A) or platinum-based chemotherapy (Label); **AND**
C. Individual is using for first-line therapy (Label) or maintenance (NCCN 2A); **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**
G. 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 (NCCN 1, 2A).

Libtayo (cemiplimab-rwlc) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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. Accessed: April 5, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. 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. Accessed on April 5, 2023.
    a. Basal Cell Skin Cancer. V1.2023. Revised March 10, 2023.
    b. Non-Small Cell Lung Cancer. V2.2023. Revised February 17, 2023.
    c. Squamous Cell Skin Cancer. V1.2023. Revised March 10, 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.