

STANDARD MEDICARE PART B MANAGEMENT

LIBTAYO (cemiplimab-rwlc)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Libtayo is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

Compendial Uses

Inoperable or incompletely resected regional squamous cell skin cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Cutaneous squamous cell carcinoma

Authorization of 12 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:

- A. The disease is one of the following:
 - 1. Metastatic
 - 2. Locally advanced
 - 3. Regional and inoperable or incompletely resected
- B. The member is not a candidate for curative surgery or curative radiation

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- A. The member is currently receiving therapy with Libtayo
- B. Libtayo is being used to treat an indication enumerated in Section II
- C. The member is receiving benefit from therapy. Benefit is defined as:
 - 1. No evidence of unacceptable toxicity while on the current regimen or
 - 2. No evidence of disease progression while on the current regimen

Reference number(s)
4202-A

IV. REFERENCES

1. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed September 8, 2020.