# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology (Injectable – Programmed Death Receptor-1) – Libtayo Prior Authorization Policy
- Libtayo® (cemiplimab-rwlc intravenous infusion – Regeneron/Sanofi Genzyme)

**REVIEW DATE:** 11/30/2022

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## OVERVIEW

Libtayo, a programmed death receptor-1 (PD-1) blocking antibody, is indicated for the treatment of the following conditions:[1]

- **Basal Cell Carcinoma**, for treatment of patients with locally advanced or metastatic disease previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate.
  This indication was approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit.
- **Cutaneous Squamous Cell Carcinoma**, for metastatic or locally advanced disease in patients who are not candidates for curative surgery or curative radiation.
- **Non-Small Cell Lung Cancer**, for first-line treatment, as a single agent, in patients with tumors that have high programmed death-ligand 1 (PD-L1) expression (tumor proportion score [TPS] ≥ 50%), as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or ROS1 aberrations. The disease can be locally advanced where patients are not candidates for surgical resection or definitive chemoradiation or for metastatic disease.
- **NSCLC**, for first-line treatment, in combination with platinum-based chemotherapy, for adults with NSCLC without EGFR, ALK, or ROS1 aberrations and with disease that is locally advanced where patients are not candidates for surgical resection or definitive chemoradiation, or for metastatic disease.

## GUIDELINES

Libtayo is addressed in National Comprehensive Cancer Network guidelines:

- **Basal Cell Carcinoma:** Guidelines (version 2.2022 – March 24, 2022) recommend Libtayo for locally advanced or metastatic disease previously treated with a hedgehog pathway inhibitor or for whom such a therapy is not appropriate (category 2A).[2,5]
- **Cutaneous Squamous Cell Carcinoma:** Guidelines (version 2.2022 – May 2, 2022) state the primary goals of treatment are the complete removal of the tumor and the maximal preservation of function and cosmesis.[3,5] Surgical excision offers the most effective and efficient means for curative therapy, but considerations of patient preference, preservation of function and cosmesis may lead to choosing radiation therapy as primary treatment to achieve optimal results. Libtayo is recommended as a preferred therapy (category 2A) for complicated cases of locally advanced or recurrent disease in which curative surgery and curative radiotherapy are not feasible; for regional disease if curative radiotherapy is not feasible; and also for regional recurrence or distant metastatic disease if surgery or radiotherapy are not feasible.
- **Non-Small Cell Lung Cancer:** Guidelines (version 5.2022 – September 26, 2022) recommend Libtayo as one of the preferred, category 1, treatment options for first-line therapy for PD-L1 ≥ 50% and negative for actionable molecular markers.[4,5]

## POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Libtayo. Because of the specialized skills required for evaluation and diagnosis of patients treated with Libtayo as well as the monitoring required for adverse events and long-term efficacy, approval requires Libtayo to be prescribed by, or in consultation with, a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Libtayo is recommended in those who meet one of the following criteria:

### FDA-Approved Indications

1. **Basal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has received previous treatment with at least one hedgehog pathway inhibitor; OR
       Note: Examples are Erivedge (vismodegib capsules), Odomzo (sonidegib capsules).
     - **ii.** Hedgehog pathway inhibitor is not an appropriate therapy for patient; AND
       Note: Not appropriate due to intolerance or lack of efficacy.
   - **D)** The medication is prescribed by or in consultation with an oncologist.

2. **Cutaneous Squamous Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced, recurrent, or metastatic disease; AND
   - **C)** Patient is not a candidate for curative surgery or curative radiation; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

3. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following criteria (i or ii):
     - **a)** Patient has locally advanced disease and is not eligible for surgical resection or chemoradiation; OR
     - **b)** Patient has metastatic disease; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets BOTH of the following (a and b):
       - **a)** The tumor proportion score (TPS) for programmed death ligand-1 (PD-L1) as determined by an approved test is ≥ 50%; AND
       - **b)** Libtayo will be used as a single agent; OR
     - **ii.** Libtayo will be used in combination with platinum-based chemotherapy; AND
       C) Note: Examples of platinum chemotherapy include cisplatin and carboplatin.
   - **D)** The tumor is negative for actionable mutations; AND
     Note: Examples include sensitizing epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *RET* rearrangement positive, *MET* exon 14 skipping, *NTRK* gene fusion positive, *BRAF V600E* mutation-positive, and *ROS1* rearrangement positive.

**E)** The medication is prescribed by or in consultation with an oncologist.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Libtayo is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Libtayo® intravenous infusion [prescribing information]. Tarrytown, NY and Bridgewater, NJ: Regeneron/Sanofi Genzyme; November 2022.
2. The NCCN Basal Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – March 24, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 23, 2022.
3. NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – May 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 239 2022.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 5.2022 – September 26, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed November 23, 2022.
5. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on November 23, 2022. Search term: cemiplimab.