



Libtayo® (cemiplimab-rwlc) (Intravenous)

Document Number: IC-0398

Last Review Date: 03/03/2020

Date of Origin: 10/30/2018

Dates Reviewed: 11/2018, 03/2019, 06/2019, 09/2019, 12/2019, 03/2020

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Libtayo 350 mg/7 mL single-use vial: 1 vial per 21 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 350 billable units every 21 days

III. Initial Approval Criteria¹⁻⁵

- Patient must be 18 years of age or older; **AND**

Universal Criteria

Coverage is provided for the following conditions:

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, etc.), unless otherwise specified; **AND**
- Patient has not received previous therapy with a BRAF-inhibitor (e.g., vemurafenib, dabrafenib, encorafenib, etc.); **AND**
- Patient has not received previous therapy with a cytotoxic T-lymphocyte antigen 4 (CTLA-4) targeting agent (e.g., ipilimumab, etc.) within the 4 weeks prior to therapy; **AND**

Cutaneous Squamous Cell Carcinoma (CSCC) †

- Used as a single-agent therapy; **AND**
- Patient has nodal or distant metastatic disease, locally advanced disease, inoperable or incompletely resected regional disease, or regional recurrence; **AND**
- Patient is not a candidate for curative surgery or curative radiation therapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria¹⁻⁵

Authorizations can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, skin reactions, etc.), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration¹

Indication	Dose
CSCC	Administer 350 mg as an intravenous infusion every 3 weeks, until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- J9119 – Injection, cemiplimab-rwlc, 1 mg; 1 billable units = 1 mg (*Effective 10/1/19*)

NDC:

- Libtayo 350 mg/7 mL single-use vial: 61755-0008-xx

VII. References

1. Libtayo [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals; March 2019. Accessed February 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cemiplimab. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2020.
3. Falchook GS, Leidner R, Stankevich E, et al. Responses of metastatic basal cell and cutaneous squamous cell carcinomas to anti-PD1 monoclonal antibody REGN2810. *J Immunother Cancer*. 2016 Nov 15;4:70. doi: 10.1186/s40425-016-0176-3. eCollection 2016.
4. Migden MR, Rischin D, Schmults CD, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. *N Engl J Med*. 2018 Jul 26;379(4):341-351. doi: 10.1056/NEJMoa1805131. Epub 2018 Jun 4.

5. Migden MR, Khushalani NI, Chang ALS, et al. Cemiplimab in locally advanced cutaneous squamous cell carcinoma: results from an open-label, phase 2, single-arm trial. *Lancet Oncol.* 2020 Feb;21(2):294-305. doi: 10.1016/S1470-2045(19)30728-4. Epub 2020 Jan 14.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C44.02	Squamous cell carcinoma of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified
Z85.828	Personal history of other malignant neoplasm of skin

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC