



Libtayo® (cemiplimab-rwlc) (Intravenous)

Document Number: IC-0398

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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 Criteria ¹

Coverage is provided for the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ^{1,4,5}

- 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^{V600E}-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) † ^{1,2,4,5}

- Used as 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 Criteria ¹⁻⁵

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 with 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/Administration ¹

| 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

NDC:

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

VII. References

1. Libtayo [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals; June 2020. Accessed August 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cemiplimab-rwlc. 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 August 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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA): 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 |