Libtayo® (cemiplimab-rwlc)
(Intravenous)

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I. Length of Authorization Δ [1,12,14,24]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
  - Neoadjuvant therapy for Cutaneous Squamous Cell Carcinoma (cSCC): Prior authorization validity may NOT be renewed.
  - Adjuvant therapy for cSCC: Prior authorization validity may be renewed up to a maximum of 48 weeks of therapy.
  - Metastatic, locally advanced, or recurrent cSCC OR unresectable or incompletely resected satellitosis/in-transit metastasis for cSCC, and Basal Cell Carcinoma (BCC): Prior authorization validity may be renewed up to a maximum of 24 months of therapy (35 doses).
  - Cervical Cancer, Vaginal Cancer and Vulvar Cancer: Prior authorization validity may be renewed up to a maximum of 96 weeks of therapy (32 doses).
  - Anal Carcinoma in combination with paclitaxel and carboplatin, then continued as a single agent: Prior authorization validity may be renewed up to a maximum of 12 months of therapy (17 total doses).

II. Dosing Limits

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

- cSCC: 700 billable units (700 mg) every 42 days
- All other indications: 350 billable units (350 mg) every 21 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided for the following conditions:

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

Universal Criteria [1]

- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified [Δ]; **AND**

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Anal Carcinoma ‡ [2,18]

- Member has squamous cell carcinoma; **AND**
  - Used as a single agent as subsequent therapy for metastatic disease; **OR**
  - Used in combination with paclitaxel and carboplatin, then continued as a single agent; **AND**
    - Used for the treatment of inguinal node recurrence; **OR**
    - Used as first-line treatment for metastatic disease

Cutaneous Squamous Cell Carcinoma (cSCC) † ‡ [1-5,8,12,22]

- Used as a single agent; **AND**
  - Member has metastatic, locally advanced, or recurrent disease OR unresectable or incompletely resected satellitosis/in-transit metastasis; **AND**
    - Member is not a candidate for curative surgery or curative radiation therapy; **OR**
  - Used as adjuvant therapy; **AND**
    - Disease has high risk of recurrence after surgery and radiation; **AND**
      - Member has nodal features (extracapsular extension with largest node ≥ 20 mm in diameter or ≥ 3 involved nodes); **OR**
      - Member has non-nodal features (in-transit metastases, T4 lesion [with bone invasion], perineural invasion, or locally recurrent tumor with ≥ 1 additional risk feature); **OR**
  - Used as neoadjuvant therapy; **AND**
    - Member has regional or satellitosis/in-transit metastatic disease; **AND**
      - Disease is operable, borderline resectable, unresectable, or surgery may carry a high morbidity; **OR**
    - Member has locally advanced disease; **AND**
      - Used if one of the following:
        - Tumor has very rapid growth
        - In-transit metastasis
        - Lymphovascular invasion
        - Borderline resectable
        - Surgery alone may not be curative or may result in significant functional limitation; **OR**
    - Member has very high-risk disease*; **AND**
      - Used if one of the following:
        - Tumor has non-reactive non-keratoacanthomatous rapid growth
        - In-transit metastasis
        - Borderline resectable
        - Surgery alone may not be curative or may result in significant functional limitation

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** Very High-Risk features include preoperative clinical tumor diameter >4 cm, poor differentiation, adenosquamous or sarcomatoid histologic subtypes in any portion of the tumor, thickness or level of invasion is >6 mm or invasion beyond subcutaneous fat, tumor cells within the nerve sheath of a nerve lying deeper than the dermis or measuring ≥0.1 mm, lymphatic or vascular involvement*

Cervical Cancer ‡ [2,14]

- Used as a single agent as subsequent therapy; **AND**
- Member has recurrent or metastatic disease

Basal Cell Carcinoma (BCC) † ‡ [1,2,6,9,13]

- Used as a single agent; **AND**
  - Member has locally advanced or metastatic disease; **OR**
  - Member has nodal disease and surgery is not feasible

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,7,10,11,15,16]

- Member has recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
  - Used in combination with platinum-based chemotherapy (e.g., paclitaxel and either carboplatin or cisplatin OR pemetrexed and either carboplatin or cisplatin); **AND**
    - Used as first-line therapy for one of the following:
      - Members who have tumors that are negative for actionable biomarkers*** ¥; OR**
      - Members who are positive for one of the following biomarkers: EGFR exon 20 insertion mutation, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, NRG1 gene fusion, or ERBB2 (HER2); **OR**
    - Used as subsequent therapy for one of the following:
      - Members who are positive for one of the following biomarkers and have received prior targeted therapy**§**: EGFR S768I, L861Q, and/or G719X; **OR**
      - Members who are positive for one of the following biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or ERBB2 (HER2); **OR**
  - Used in combination with pemetrexed; **AND**
    - Used as continuation maintenance therapy in members who have achieved a tumor response or stable disease after first-line therapy with cemiplimab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; **OR**
  - Used as a single agent; **AND**
    - Member has tumors that are negative for actionable biomarkers*** ¥** and high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 50%) as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA) compliant test❖; **AND**
      - Used as first-line therapy **†**; **OR**

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- Used as continuation maintenance therapy in members who achieved a tumor response or stable disease after first-line therapy with cemiplimab as monotherapy or as part of combination therapy; **OR**
- Member has tumors with PD-L1 expression <1% or ≥1%-49%; **AND**
  - Used as continuation maintenance therapy in members who have achieved a tumor response or stable disease following initial therapy with cemiplimab combination therapy

** Note: Actionable biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2). Complete biomarker testing including molecular assessment of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these members are treated as though they do not have driver oncogenes.*

¥ Note: May also be used for members with KRAS G12C mutation positive tumors.

§ Note: Genomic Aberration/Mutational Driver Targeted Therapies: Refer to guidelines for appropriate use.

Small Bowel Adenocarcinoma ‡ [2,17]

- Used as single agent treatment; **AND**
- Member has microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) disease OR polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Member has advanced or metastatic disease; **OR**
  - Member has locally unresectable or medically inoperable disease; **AND**
    - Used as primary treatment

Vaginal Cancer ‡ [2,14]

- Used as a single agent as subsequent therapy; **AND**
- Member has recurrent or metastatic disease

Vulvar Cancer ‡ [2,4,14]

- Used as a single agent as subsequent therapy; **AND**
- Member has advanced or recurrent/metastatic disease

Colon Cancer ‡ [2,19]

- Used as single agent treatment; **AND**
- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**

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- Used for locally unresectable, medically inoperable, advanced, or metastatic disease

Appendiceal Neoplasms and Cancers ‡ [2,23]

- Used as single agent treatment; **AND**
- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease

Rectal Cancer ‡ [2,20]

- Used as single agent treatment; **AND**
- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for locally unresectable, medically inoperable, advanced or metastatic disease

❖ *If confirmed using an FDA approved assay – http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria Δ [1,12]

Prior authorization validity may be renewed based on the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, etc.), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Δ **Notes**:

- Members responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Members previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.

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- Members who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Members whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ [1,12,14,17-21,24]

Indication	Dose
cSCC	Metastatic, locally advanced, or recurrent disease OR unresectable or incompletely resected satellitosis/in-transit metastasis: Administer 350 mg intravenously every 3 weeks for up to a maximum of 24 months in members without disease progression or unacceptable toxicity Adjuvant therapy: Administer 350 mg intravenously every 3 weeks for 12 weeks, followed by 700 mg every 6 weeks OR 350 mg every 3 weeks for up to a maximum of 48 weeks in members without disease recurrence or unacceptable toxicity Neoadjuvant therapy: Administer 350 mg intravenously every 3 weeks for up to 4 doses in members without disease progression or unacceptable toxicity
Cervical Cancer, Vaginal Cancer, and Vulvar Cancer	Administer 350 mg intravenously every 3 weeks up to a maximum of 96 weeks in members without disease progression or unacceptable toxicity
BCC	Administer 350 mg intravenously every 3 weeks up to a maximum of 24 months in members without disease progression or unacceptable toxicity
NSCLC, Small Bowel Adenocarcinoma, Colon Cancer, Rectal Cancer, and Appendiceal Neoplasms and Cancers	Administer 350 mg intravenously every 3 weeks until disease progression or unacceptable toxicity
Anal Carcinoma	Combination therapy: Administer 350 mg intravenously every 3 weeks until disease progression or unacceptable toxicity, or up to 12 months. *Note: when given in combination with carboplatin and paclitaxel, combination therapy may be administered for up to 24 weeks, followed by single agent maintenance therapy.* Single-agent therapy: Administer 350 mg intravenously every 3 weeks until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J9119 − Injection, cemiplimab-rwlc, 1 mg; 1 billable unit = 1 mg

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NDC:

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

VII. References

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung

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ICD-10	ICD-10 Description
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C44.01	Basal cell carcinoma of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.111	Basal cell carcinoma of skin of unspecified eyelid, including canthus
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus
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
C44.211	Basal cell carcinoma of skin of unspecified ear and external auricular canal
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal
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
C44.310	Basal cell carcinoma of skin of unspecified parts of face
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
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
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
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

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ICD-10	ICD-10 Description
C44.611	Basal cell carcinoma of skin of unspecified upper limb, including shoulder
C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder
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
C44.711	Basal cell carcinoma of skin of unspecified lower limb, including hip
C44.712	Basal cell carcinoma of skin of right lower limb, including hip
C44.719	Basal cell carcinoma of skin of left lower limb, including hip
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
C44.81	Basal cell carcinoma of overlapping sites of skin
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.91	Basal cell carcinoma of skin, unspecified
C44.92	Squamous cell carcinoma of skin, unspecified
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.8	Malignant neoplasm of overlapping sites of vulva
C51.9	Malignant neoplasm of vulva, unspecified
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
D37.3	Neoplasm of uncertain behavior of appendix
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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		
Jurisdictio	**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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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

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