POLICY NUMBER UM_1089	**SUBJECT** Libtayo™ (cemiplimab-rwlc)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 10/10/18, 10/09/19	**APPROVAL DATE** October 9, 2019	**EFFECTIVE DATE** October 9, 2019	**COMMITTEE APPROVAL DATES** (latest version listed last) 10/10/18, 10/09/19	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1		**NCQA STANDARDS**	**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Oncology	

I. PURPOSE

To define and describe the accepted indications for Libtayo (cemiplimab-rwlc) usage in the treatment of cancer.

II. DEFINITIONS

Libtayo (cemiplimab-rwlc): a recombinant human IgG4 monoclonal antibody that binds to human programmed death receptor-1 (PD-1) and blocks its interaction with PD-1 ligands 1 and 2 (PD-L1 and PD-L2), which is the interaction responsible for the inhibition of T-cell proliferation and cytokine production, thus releasing the PD-1 pathway-mediated inhibition of immune response, including anti-tumor response.

Libtayo (cemiplimab-rwlc) is FDA approved 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.

Libtayo (cemiplimab-rwlc) is available in a single dose vial: 350 mg/7mL.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century Health may be deemed as not approvable and therefore not reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Libtayo (cemiplimab-rwlc) may be considered medically necessary when any of the following selection criteria are met:

1. Cutaneous Squamous Cell Carcinoma (CSCC)
    a. The member has unresectable locally advanced or metastatic CSCC and is not a candidate for curative surgery or curative radiation **AND**
    b. Libtayo (cemiplimab-rwlc) is being used as a single in members with ECOG performance score (PS) ≤ 1.

Exclusion Criteria: Libtayo (cemiplimab-rwlc) is not considered medically necessary when any of the following selection criteria are met:

1. Libtayo (cemiplimab-rwlc) is being used after disease progression with the same regimen or prior treatment with a PD-1/PDL-1/BRAF inhibitor.
2. Concurrent use or within 4 weeks prior to first dose of Libtayo (cemiplimab-rwlc) with other immune-modulating agents (e.g., immunosuppressive corticosteroid doses, therapeutic vaccines, cytokine treatments, or agents that target cytotoxic T-lymphocyte antigen 4 (CTLA-4), 4-1BB (CD137), or OX-40, etc.)

3. Significant autoimmune disease that required treatment with systemic immunosuppressive treatments, active infection, history of pneumonitis or solid organ transplant.
4. Dosing exceeds single dose limit of Libtayo (cemiplimab-rwlc) 350 mg.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Libtayo (cemiplimab-rwlc) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration:** 350 mg IV infusion over 30 minutes every 3 weeks until disease progression or unacceptable toxicity.
2. **Dosage Adjustments:** Dosage reductions are not recommended
    a. Colitis (Grades 2 or 3): Withhold therapy and administer corticosteroids (1 to 2 mg/kg/day predniSONE or equivalent) or other appropriate therapy, followed by a corticosteroid taper over 1 month; resume with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.
    b. Colitis (Grade 4): Permanently discontinue.
    c. Endocrinopathies (Grades 2, 3, or 4): Withhold if clinically necessary; institute hormone replacement therapy as warranted.
    d. Hepatitis (AST or ALT increases to more than 3 to 10 times ULN or if total bilirubin increases up to 3 times ULN): Withhold therapy and administer corticosteroids (1 to 2 mg/kg/day predniSONE or equivalent) or other appropriate therapy, followed by a corticosteroid taper over 1 month; resume with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.
    e. Hepatitis (AST or ALT increases to more than 10 times ULN or total bilirubin increases to more than 3 times ULN): Permanently discontinue.
    f. Immune-mediated adverse reactions (other) involving a major organ (Grade 3): Withhold therapy and administer corticosteroids (1 to 2 mg/kg/day predniSONE or equivalent) or other appropriate therapy, followed by a corticosteroid taper over 1 month; resume with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.
    g. Immune-mediated adverse reactions (other) involving a major organ (Grade 4): Permanently discontinue.
    h. Immune-mediated adverse reactions, recurrent or persistent (recurrent Grade 3 or 4, Grade 2 or 3 persistent for 12 weeks or longer after last cemiplimab-rwlc dose, requirement of prednisone 10 mg/day or greater or equivalent lasting 12 weeks or longer after last cemiplimab-rwlc dose): Permanently discontinue.
    i. Infusion-related reactions (Grades 1 or 2): Interrupt or slow the infusion rate.
    j. Infusion-related reactions (Grades 3 or 4): Permanently discontinue.
    k. Pneumonitis (Grade 2): Withhold therapy and administer corticosteroids (1 to 2 mg/kg/day predniSONE or equivalent) or other appropriate therapy, followed by a corticosteroid taper over 1 month; resume with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.
    l. Pneumonitis (Grades 3 or 4): Permanently discontinue.

3. **Monitoring**
    a. Evidence of disease response or stabilization is indicative of efficacy.
    b. Pregnancy test: Prior to initiation verify pregnancy status in women of reproductive potential.
    c. Signs and symptoms of infusion-related reactions.
    d. Signs and symptoms of immune-mediated adverse reactions: Including pneumonitis, colitis, hepatitis, endocrinopathies, dermatologic adverse reactions, and nephritis and renal dysfunction; evaluate clinical chemistries, including liver and thyroid function, at baseline and periodically during treatment.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Libtayo (cemiplimab-rwlc) PI prescribing information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.