Clinical Policy Title:	cemiplimab-rwlc
Policy Number:	RxA.611
Drug(s) Applied:	Libtayo®
Original Policy Date:	03/06/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Cemiplimab-rwlc (Libtayo®) is a programmed death receptor-1 (PD-1) blocking antibody.
It is indicated :

- For treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.
- For treatment of patients with metastatic basal cell carcinoma (mBCC) or locally advanced basal cell carcinoma (laBCC) who were previously treated with a hedgehog pathway inhibitor or for whom hedgehog pathway inhibitor is not appropriate.
- For first-line treatment of patients with non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (Tumor Proportion Score (TPS) ≥50%) as determined by an FDA-approved test, with no EGFR, ALK, or ROS1 aberrations, and locally advanced or metastatic disease.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
cemiplimab-rwlc (Libtayo®)	CSCC	350 mg IV over 30 minutes every 3 weeks	See dosing regimen

Dosage Forms

- Single-dose vial for injection: 350 mg/7 mL (50 mg/mL) solution

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Cutaneous Squamous Cell Carcinoma (must meet all)**:**

1. Diagnosis of CSCC;
2. Disease is metastatic or locally advanced;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;

5. Member is not a candidate for curative surgery or curative radiation;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 350 mg (1 vial) every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

B. Basal Cell Carcinoma (must meet all):
1. Diagnosis of locally advanced basal cell carcinoma or metastatic basal cell carcinoma
2. Prescribed by or in consultation with an oncologist;
3. Member is 18 years of age or older;
4. Drug is being prescribed as a single-agent and has failed previous treatment with a hedgehog inhibitor(such as Daurismo, Odomzo, Erivedge etc) or it is not appropriate or if the member is not a candidate for surgery;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 350 mg (1 vial) every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

C. Non-Small Cell Lung Cancer (must meet all):
1. Diagnosis of recurrent, advanced, or metastatic NSCLC
2. Prescribed by or in consultation with an oncologist;
3. Member is 18 years of age or older;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 350 mg (1 vial) every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Cutaneous Squamous Cell Carcinoma, Basal Cell Carcinoma, Non-Small Cell Lung Cancer (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 350 mg (1 vial) every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 6 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CSCC: cutaneous squamous cell carcinoma
mCSCC: metastatic cutaneous squamous cell carcinoma
laCSCC: locally advanced cutaneous squamous cell carcinoma
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
NSCLC: Non-Small Cell Lung Cancer
PD-1: programmed death receptor-1

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported
- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue and usually occur during treatment; however, they can also occur after discontinuation.

References

1. Libtayo® Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; June 2020. Available at: https://www.libtayohcp.com/. Accessed September 24, 2020.
2. National Comprehensive Cancer Network. Squamous Cell Skin Cancer (Version 2.2020). Available at: https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf . Accessed September 24, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title updated 2. Line of business policy applies to was updated to All lines of business 3. I.B and I.C were added. 4. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..." 5. Updated Appendix A to add CSCC, m-CSCC, and laCSCC 6. Added Appendix D general information. 7. Reference reviewed and updated.	05/03/2021	06/10/2021