Policy Title:	Libtayo (cemiplimab-rwlc) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	6/7/19, 12/20/2019		
Revision Date:	6/7/19, 12/20/2019		

Purpose: To support safe, effective and appropriate use of Libtayo (cemiplimab-rwlc).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Libtayo (cemiplimab-rwlc) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Libtayo (cemiplimab-rwlc) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient must be 18 years of age or older; AND
- 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 small-molecule inhibitor (phosphtidylinositol-3 kinase inhibitor [PI3-K]) therapy (e.g., idelalisib, duvelisib, 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 previous 4 weeks prior to therapy; AND

Cutaneous Squamous Cell Carcinoma (CSCC) *

- Used as a single-agent therapy; AND
  - Patient has locally advanced disease and not a candidate for curative surgery or radiation therapy; OR
  - Patient has nodal or distant metastatic disease

* FDA Approved Indication(s)

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria; AND
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; AND
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, rash, etc.),

Coverage durations:

- Initial & Renewal coverage = 6 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	Dose (1 billable unit = 1mg)
CSCC	350 mg intravenously every 21 days

Dosing Limits:

Maximum Units (per dose and over time): 350 billable units every 21 days

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J9119	Injection, cemiplimab-rwlc, 1mg

References:

1. Libtayo [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals; October 2018. Accessed March 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cemiplimab. National Comprehensive Cancer Network, 2018. 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 October 2018.
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.