

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Libtayo (cemiplimab-rwlc)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Libtayo (cemiplimab-rwlc)

APPROVAL CRITERIA

Requests for Libtayo (cemiplimab-rwlc) injection may be approved if the following criteria are met:

- I. Individual has a diagnosis of metastatic Cutaneous Squamous Cell Carcinoma (CSCC);
OR
- II. Individual has a diagnosis of locally advanced CSCC and are not candidates for curative surgery or radiation;

AND

- III. Individual has current ECOG performance status of 0-2; **AND**
- IV. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- V. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Libtayo (cemiplimab-rwlc) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 15, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 15, 2020.
 - a. Squamous Cell Skin Cancer. V1.2020. Revised October 2, 2019.

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Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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