IgG4 Monoclonal Antibodies
Libtayo (camiplimab-rwlc) J9119
Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ Patient has ONE of the following diagnoses:
- ☐ Unresectable, locally advanced, recurrent or metastatic Basel Cell Carcinoma (BCC)
- ☐ Cutaneous Squamous Cell Carcinoma (CSCC)
- ☐ Locally advanced Non-Small Cell Lung Cancer (NSCLC)
- ☐ Metastatic Non-Small Cell Lung Cancer (NSCLC)
- ☐ Individual has a current ECOG performance status of 0-2; AND

☐ Patient has not received treatment with another anti-PD-1 or anti-PD-L1 agent; AND

☐ Patient is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ **Continuation Requests: (Clinical documentation required for all requests**

☐ Patient had an adequate response or significant improvement while on this medication.
If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – IgG4 monoclonal antibody PA

Drug Name(s):
LIBTAYO **CEMIPLIMAB-RWLC**

Criteria for approval of Prior Authorization Drug:
1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
Oncologist or other cancer specialist

Coverage Duration:
New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months

FDA Indications:
Libtayo

- Basal cell carcinoma of skin, Metastatic or locally advanced, previously treated with a hedgehog pathway inhibitor or for whom a hedgehog pathway inhibitor is not appropriate
- Non-small cell lung cancer, Metastatic or locally advanced disease ineligible for surgical resection or definitive chemoradiation, high PD-L1 expression with no EGFR, ALK, or ROS1 aberrations, first-line, monotherapy
- Non-small cell lung cancer, Metastatic or locally advanced disease ineligible for surgical resection or definitive chemoradiation, with no EGFR, ALK, or ROS1 aberrations, first-line, in combination with platinum-based chemotherapy
- Squamous cell carcinoma of skin, Metastatic or locally advanced disease, in patients who are not candidates for curative surgery or curative radiation

Off-Label Uses:
N/A

Age Restrictions:
Safety and effectiveness have not been established in pediatric patients

Other Clinical Considerations:
Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/CE0226/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/674DD8/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932549&contentSetId=100&title=Cemiplimab-rwlc&servicesTitle=Cemiplimab-rwlc&brandName=Libtayo&UserMdxSearchTerm=Libtayo&=null#