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.*

☐	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 ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐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)

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

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

_____

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

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ 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. **Drug meets the following utilization management criteria:**
    a. Patient has not received previous therapy with a programmed death (PD 1/PD L1) directed therapy: avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, dostarlimab, nivolumab/relatlimab-rmbw, etc.
3. 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:

N/A

Coverage Duration:

Approvals will be for 6 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:

N/A

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/876FBC/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/156E2E/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFAction

Id/evidencexpert.GoToDashboard?docId=932549&contentSetId=100&title=Cemiplimab-rwlc&servicesTitle=Cemiplimab-rwlc&brandName=Libtayo&UserMdxSearchTerm=libtayo&=null#