Libtayo® (cemiplimab-rwlc) Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021 **(TTY:** 711**)**
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Please indicate: ☐ Start of treatment: Start date ____/____/____
☐ Continuation of therapy: Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:	DOB:	
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	Email:
Patient Current Weight: ____ lbs or ____ kgs Patient Height: ____ inches or ____ cms		Allergies:	

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured: _____

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured: _____

Medicare: ☐ Yes ☐ No If yes, provide ID #: _____ **Medicaid**: ☐ Yes ☐ No If yes, provide ID #: _____

C. PRESCRIBER INFORMATION

First Name:	Last Name: *(Check One):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.				
Address:	City:	State:	ZIP:		
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider Email:	Office Contact Name:	Phone:			

Specialty *(Check one):* ☐ **Oncologist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for Libtayo (cemiplimab-rwlc): Dose: _____ **Frequency:** _____

F. DIAGNOSIS INFORMATION – Please indicate primary ICD Code and specify any other where applicable.

Primary ICD Code: _____ Secondary ICD Code: _____ Other ICD Code: _____

G. CLINICAL INFORMATION – Required clinical information must be completed in its entirety for all precertification requests.

For ALL Requests (clinical documentation required for all requests):

☐ Yes ☐ No Has the patient experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy before? (e.g., Bavencio (avelumab), Imfinzi (durvalumab), Keytruda (pembrolizumab), Opdivo (nivolumab), and Tecentriq (atezolizumab))?

For Initiation Requests (clinical documentation required for all requests):

Basal Cell Carcinoma (BCC)

☐ Yes ☐ No Will the requested drug be used as a single agent?
Please indicate the clinical setting in which the requested drug will be used:
☐ Metastatic disease ☐ Locally advanced disease ☐ Nodal disease and surgery is not feasible ☐ Other
☐ Yes ☐ No Has the patient received a hedgehog pathway inhibitor (e.g., vismodegib [Erivedge], sonidegib [Odomzo])?
→ ☐ Yes ☐ No Is a hedgehog pathway inhibitor appropriate for the patient?

Cervical cancer

Please indicate the place in therapy in which the requested drug will be used: ☐ First line therapy ☐ Subsequent therapy
Please indicate the clinical setting in which the requested drug will be used: ☐ Recurrent disease ☐ Metastatic disease ☐ Other
☐ Yes ☐ No Will the requested drug be used as a single agent?

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G. CLINICAL INFORMATION ***(continued)*** – Required clinical information must be completed in its entirety for all precertification requests.

Cutaneous Squamous Cell Carcinoma (CSCC)

☐ Yes ☐ No Will the requested drug be used as a single agent?

☐ Yes ☐ No Will the requested drug be used as neoadjuvant treatment?

→ ☐ Yes ☐ No Is the patient a candidate for curative surgery or curative radiation?

Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Locally advanced disease ☐ Recurrent disease ☐ Other

Please indicate the clinical setting in which the requested drug will be used: ☐ Very high risk disease ☐ Locally advanced disease ☐ Unresectable disease ☐ Regional disease ☐ Other

Non-Small Cell Lung Cancer

Please indicate the clinical setting in which the requested drug will be used:

☐ Metastatic disease ☐ Advanced disease ☐ Recurrent disease ☐ Other

For tumors *negative* for EGFR mutations (e.g., exon 19 deletions or L858R), ALK rearrangements, and ROS1 aberrations only:

☐ Yes ☐ No ☐ Unknown Is the tumor negative for EGFR mutations (e.g., exon 19 deletions or L858R), ALK rearrangements, or ROS1 aberrations?

→ ☐ Yes ☐ No Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?

What is the clinical setting in which the requested drug will be used?

☐ First-line treatment

What is the requested regimen?

☐ In combination with platinum-based chemotherapy (e.g., cisplatin, carboplatin)

☐ The requested drug will be used as a single agent

→ ☐ Yes ☐ No ☐ Unknown Does the tumor have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%]?

☐ Other

☐ Maintenance therapy

☐ Yes ☐ No Is there tumor response or stable disease following first-line cemiplimab-rwlc therapy?

What is the requested regimen?

☐ In combination with pemetrexed

☐ The requested drug will be used as a single agent

☐ Other

☐ Other clinical setting

For tumors *positive* for EGFR mutations (e.g., exon 19 deletions or L858R), ALK rearrangements, and ROS1 aberrations only:

What is the requested regimen? ☐ In combination with platinum-based chemotherapy ☐ Other

Please indicate the place in therapy in which the requested drug will be used: ☐ First line therapy ☐ Subsequent therapy

Vulvar cancer

Please indicate the place in therapy in which the requested drug will be used: ☐ First line therapy ☐ Subsequent therapy

Please indicate the clinical setting in which the requested drug will be used: ☐ Advanced disease ☐ Recurrent/metastatic disease ☐ Other

☐ Yes ☐ No Will the requested drug be used as a single agent?

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G. CLINICAL INFORMATION ***(continued)*** – Required clinical information must be completed in its entirety for all precertification requests.

For Continuation Requests (clinical documentation required for all requests):

Please provide the start date of the requested medication: ____/____/____

☐ Yes ☐ No Is there evidence of disease progression or unacceptable toxicity while on the current regimen?

☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?

→ ☐ Yes ☐ No Is the patient continuing on a maintenance regimen that includes provider administered combination chemotherapy?

→ Please provide the regimen: _____

☐ Yes ☐ No Is the patient experiencing severe toxicity requiring continuous monitoring (e.g., Grade 2-4 bullous dermatitis, transaminitis, pneumonitis, Stevens-Johnson syndrome, acute pancreatitis, primary adrenal insufficiency aseptic meningitis, encephalitis, transverse myelitis, myocarditis, pericarditis, arrhythmias, impaired ventricular function, conduction abnormalities)?

→ Please explain: _____

☐ Yes ☐ No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?

→ Please explain: _____

☐ Yes ☐ No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?

→ Please explain: _____

☐ Yes ☐ No Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?

→ Please explain: _____

☐ Yes ☐ No Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the patient's ability to tolerate a large volume or load or predispose the patient to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?

→ Please provide a description of the condition:

- ☐ Cardiopulmonary: _____
- ☐ Respiratory: _____
- ☐ Renal: _____
- ☐ Other: _____

☐ Yes ☐ No Is the patient within the initial 6 months of starting therapy?

→ Please indicate how many continuous months of treatment the patient has received with the requested drug: _____

For continued treatment of basal cell carcinoma or cutaneous squamous cell carcinoma: Please indicate how many continuous months of treatment has the patient received with the requested medication: _____

H. ACKNOWLEDGEMENT

Request Completed 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.

The plan may request additional information or clarification, if needed, to evaluate requests.