Libtayo

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical*	❑ *Home*	❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital*	❑ *Office*	❑ *Pharmacy*

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

 Standard Oncology SOC Libtayo SGM 2757-A – 08/2023.

Site of Service Questions (SOS):

A. Indicate the site of service requested:
- ❑ On Campus Outpatient Hospital
- ❑ Off Campus Outpatient Hospital
- ❑ Home infusion, *skip to Criteria Questions*
- ❑ Physician office, *skip to Criteria Questions*
- ❑ Ambulatory surgical, *skip to Criteria Questions*
- ❑ Pharmacy, *skip to Criteria Questions.*

B. Is the patient less than 14 years of age? *If Yes, skip to Clinical Criteria Questions* ❑ Yes ❑ No

C. Is the patient receiving provider-administered combination oncology therapy or other provider-administered drug therapies at the same visit? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation***.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

D. Is this request to continue previously established treatment with the requested regimen?
- ❑ No – This is a new therapy request (patient has not received 6 months or more of requested regimen). *Skip to Clinical Criteria Questions*
- ❑ Yes – This is a continuation of existing treatment (patient has received requested regimen for 6 months). *Skip to Clinical Criteria Questions*
- ❑ Yes – This is a continuation of an existing treatment (patient has received requested regimen for 7 months or greater – initial 6 months plus 45 days grace period).

E. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, or other pre- medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Has the patient experienced 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, or conduction abnormalities)? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. Does the patient have severe venous access issues that require the use of a special intervention only available in the outpatient hospital setting? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

I. 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?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation. ❑ Yes ❑ No

Criteria Questions:

What is the ICD-10 code? _____

1. What is the diagnosis?

❒ Cutaneous squamous cell carcinoma (CSCC) (*If checked, go to 2*)

❒ Basal cell carcinoma (BCC) (*If checked, go to 2*)

❒ Non-small cell lung cancer (NSCLC) (*If checked, go to 2*)

❒ Other, please specify. _____ (*If checked, go to 2*)

2. Has the patient experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy?

❒ Yes, *No Further Questions*

❒ No, *Continue to 3*

3. Is the patient currently receiving the requested medication?

❒ Yes, *Continue to 4*

❒ No, *Continue to 5*

4. Has the patient experienced disease progression or an unacceptable toxicity while on the current regimen?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

5. What is the diagnosis?

❒ Cutaneous squamous cell carcinoma (CSCC) (*If checked, go to 6*)

❒ Basal cell carcinoma (BCC) (*If checked, go to 10*)

❒ Non-small cell lung cancer (NSCLC) (*If checked, go to 14*)

6. What is the clinical setting in which the requested medication will be used?

❒ Metastatic disease (*If checked, go to 8*)

❒ Locally advanced disease (*If checked, go to 8*)

❒ Recurrent disease (*If checked, go to 8*)

❒ Regional disease (*If checked, go to 7*)

❒ Other, please specify. _____ (*If checked, no further questions*)

7. Is the disease inoperable or incompletely resected?

❒ Yes, *Continue to 8*

❒ No, *Continue to 8*

8. Is the patient a candidate for curative surgery or curative radiation?

❒ Yes, *Continue to 9*

❒ No, *Continue to 9*

9. Will the requested medication be used as a single agent?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

10. Will the requested medication be used as a single agent?

❒ Yes, *Continue to 11*

❒ No, *Continue to 11*

11. What is the clinical setting in which the requested medication will be used?

❒ Metastatic disease (*If checked, go to 12*)

❒ Advanced disease (*If checked, go to 12*)

❒ Recurrent disease (*If checked, go to 12*)

❒ Other, please specify. _____ (*If checked, go to 12*)

12. Has the patient received a hedgehog pathway inhibitor (e.g., vismodegib [Erivedge], sonidegib [Odomzo])?
❒ Yes, *No Further Questions*
❒ No, *Continue to 13*

13. Is a hedgehog pathway inhibitor appropriate for the patient?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

14. What is the clinical setting in which the requested medication will be used?

❒ Metastatic disease (*If checked, go to 15*)

❒ Advanced disease (*If checked, go to 15*)

❒ Recurrent disease (*If checked, go to 15*)

❒ Other, please specify. _____ (*If checked, go to 15*)

15. Is the tumor negative for EGFR mutations (e.g., exon 19 deletions or L858R), ALK rearrangements, and ROS1 aberrations? ***ACTION REQUIRED***: Please attach chart note(s) or test results of EGFR mutations, ALK rearrangements and ROS1 aberrations.

❒ Yes, ***ACTION REQUIRED***: Submit supporting documentation (*If checked, go to 17)*

❒ No, ***ACTION REQUIRED***: Submit supporting documentation (*If checked, go to 22*)

❒ Unknown (*If checked, go to 16*)

16. Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?
❒ Yes, *Continue to 17*
❒ No, *Continue to 17*

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

❒ First-line treatment (*If checked, go to 18*)

❒ Maintenance therapy (*If checked, go to 20*)

❒ Other, please specify. _____ (*If checked, no further questions*)

18. What is the requested regimen?

❒ Single agent (*If checked, go to 19*)
❒ In combination with platinum-based chemotherapy (e.g., cisplatin, carboplatin) (*If checked, no further questions*)

❒ Other, please specify. _____ (*If checked, no further questions*)

19. Does the tumor have high PD-L1 expression [Tumor Proportion Score (TPS) greater than or equal to 50%]? ***ACTION REQUIRED***: If yes, please attach chart note(s) or test results of programmed death ligand 1 (PD-L1) tumor expression.

❒ Yes, ***ACTION REQUIRED***: Submit supporting documentation (*If checked, no further questions*)

❒ No (*If checked, no further questions*)

❒ Unknown (*If checked, no further questions*)

20. Is there tumor response or stable disease following first-line cemiplimab-rwlc therapy?
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

21. What is the requested regimen?

❒ Single agent (*If checked, no further questions*)

❒ In combination with pemetrexed (*If checked, no further questions*)

❒ Other, please specify. _____ (*If checked, no further questions*)

22. Which of the following biomarkers apply to the patient's disease? ***ACTION REQUIRED***: Please attach chart notes or test results of biomarker testing.

❒ BRAF V600E mutation, NTRK 1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement (*If checked, go to 26*)

❒ A sensitizing EGFR mutation (e.g., exon 19 deletion, exon 21 L858R, S768I, L861Q or G719X) (*If checked, go to 23*)

❒ An ALK rearrangement (*If checked, go to 24*)

❒ A ROS1 rearrangement (*If checked, go to 25*)

❒ None of the above (*If checked, no further questions*)

23. Has the patient been previously treated with an EGFR inhibitor (e.g., erlotinib, afatinib, gefitinib, osimertinib, dacomitinib)?

❒ Yes, *Continue to 26*

❒ No, *Continue to 26*

24. Has the patient been previously treated with an ALK inhibitor (e.g., crizotinib, ceritinib, alectinib, brigatinib, lorlatinib)?

❒ Yes, *Continue to 26*

❒ No, *Continue to 26*

25. Has the patient been previously treated with crizotinib, entrecitinib, or ceritinib?

❒ Yes, *Continue to 26*

❒ No, *Continue to 26*

26. Will the requested drug be used as subsequent therapy?

❒ Yes, *Continue to 27*

❒ No, *Continue to 27*

27. What is the requested regimen?

❒ In combination with platinum-based chemotherapy (*If checked, no further questions*)

❒ Other, please specify. _____ (*If checked, no further questions*)

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720