Opdivo

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*

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

Criteria Questions:

1. What is the diagnosis?
   - ❑ Cutaneous melanoma
   - ❑ Non-small cell lung cancer (NSCLC)
   - ❑ Renal cell carcinoma
   - ❑ Classical Hodgkin lymphoma (cHL)
   - ❑ Cervical cancer
   - ❑ Squamous cell carcinoma of the head and neck (SCCHN)
   - ❑ Nasopharyngeal Carcinoma (NPC)
   - ❑ Urothelial carcinoma - Bladder cancer
   - ❑ Urothelial carcinoma - Primary carcinoma of the urethra
   - ❑ Urothelial carcinoma - Upper genitourinary tract tumor or urothelial carcinoma of the prostate
   - ❑ Colorectal cancer (including appendiceal carcinoma and anal adenocarcinoma)
   - ❑ Small bowel adenocarcinoma (including advanced ampullary cancer)
   - ❑ Hepatocellular carcinoma
   - ❑ Uveal melanoma
   - ❑ Anal carcinoma
   - ❑ Merkel cell carcinoma
   - ❑ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer
   - ❑ Gestational trophoblastic neoplasia
   - ❑ Malignant pleural mesothelioma
   - ❑ Esophageal and esophagogastric junction carcinoma
   - ❑ Extranodal NK/T-cell lymphoma, nasal type
   - ❑ Endometrial carcinoma
   - ❑ Vulvar squamous cell carcinoma
   - ❑ Gastric cancer
   - ❑ Small cell lung cancer
   - ❑ Other _____

2. What is the ICD-10 code? _____

3. Will the requested drug be used in any of the following regimens?
   - ❑ Single agent
   - ❑ In combination with ipilimumab and pemetrexed plus carboplatin or cisplatin
   - ❑ In combination with ipilimumab, paclitaxel, and carboplatin
   - ❑ In combination with ipilimumab only
   - ❑ In combination with brentuximab vedotin
   - ❑ In combination with cabozantinib
   - ❑ In combination with chemotherapy
   - ❑ In combination with cisplatin and gemcitabine
   - ❑ In a regimen containing ipilimumab
   - ❑ Other _____

4. Has the patient experienced disease progression while receiving another programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor (e.g., Keytruda, Imfinzi)? ❑ Yes ❑ No *If No, skip to #7*

5. Is the requested drug prescribed as second-line or subsequent treatment for metastatic or unresectable melanoma? ❑ Yes ❑ No

6. Will the requested drug be used in combination with ipilimumab following disease progression on single agent anti-PD-1 immunotherapy? ❑ Yes ❑ No

7. What is the clinical setting in which the requested drug will be used? ***Indicate ALL that apply.***
   - ❑ Recurrent disease
   - ❑ Relapsed disease
   - ❑ Refractory disease
   - ❑ Advanced disease
   - ❑ Metastatic disease
   - ❑ Distant metastatic disease
   - ❑ Progressed disease
   - ❑ Stage II or IIIA disease
   - ❑ High-Risk disease
   - ❑ Unresectable disease
   - ❑ Favorable risk

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❑ Progressive disease ❑ Locally advanced disease ❑ Local recurrence
❑ Stage IV disease ❑ Recurrent disseminated disease ❑ Adjuvant treatment
❑ Post-cystectomy ❑ Unresectable locally advanced disease ❑ Preserved bladder
❑ Very advanced disease ❑ Patient is not a surgical candidate ❑ Inoperable disease
❑ Postoperative therapy for completely resected disease
❑ High risk of recurrence after undergoing radical resection
❑ Other _____

8. What is the place in therapy in which the requested drug will be used?
❑ Initial treatment ❑ First-line treatment ❑ Subsequent treatment ❑ Second-line treatment
❑ Other _____

9. Is the patient currently receiving treatment with the requested medication? ❑ Yes ❑ No *If Yes, skip to Section Q.*

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Cutaneous Melanoma

10. *If adjuvant treatment*, what is the clinical setting in which the requested drug will be used?
❑ Stage III disease ❑ Stage IV disease ❑ Other _____

11. *If adjuvant treatment*, has the patient had a complete resection or no evidence of disease? ❑ Yes ❑ No

Section B: Non-small cell lung cancer

12. Are there no EGFR exon 19 deletions or L858R mutations or ALK rearrangements? ***ACTION REQUIRED: Please attach documentation of EGFR exon 19 deletions or L858R mutations or ALK rearrangements, where applicable.*** *If Yes or No, no further questions* ❑Yes ❑ No ❑ Unknown

13. Is testing for these genomic tumor aberrations not feasible due to insufficient tissue? ❑ Yes ❑ No

Section C: Renal cell carcinoma

14. Which of the following describes the risk?
❑ Poor risk ❑ Intermediate risk ❑ Favorable risk ❑ Other _____

15. What is the histology? ❑ Clear cell ❑ Non-clear cell

Section D: Classical Hodgkin Lymphoma

16. Has the patient received 2 or more prior lines of therapy? *If Yes, no further questions* ❑ Yes ❑ No

17. Has the patient received a hematopoietic stem cell transplant? *If Yes, no further questions* ❑ Yes ❑ No

18. Is the patient eligible for transplant? ❑ Yes ❑ No *If No, no further questions*

19. Has the patient been heavily pretreated? *If Yes, no further questions* ❑ Yes ❑ No

20. Did the patient experience a decrease in cardiac function? ❑ Yes ❑ No

Section E: Cervical Cancer

21. Is the patient's disease positive for programmed death ligand 1 (PD-L1) (combined positive score [CPS] ≥1)?
Action Required: If 'Yes', attach supporting chart note(s) for PD-L1 expression. ❑ Yes ❑ No

Section F: Squamous Cell Carcinoma of the Head and Neck

22. Has the patient experienced disease progression on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin)? ❑ Yes ❑ No

Section G: Bladder Cancer

23. *If the patient has high risk of recurrence after undergoing radical resection,* will the requested drug be used as adjuvant treatment? ❑ Yes ❑ No *No further questions*

24. *If the patient has a preserved bladder*, what is the clinical setting in which the requested drug will be used in a preserved bladder?
❑ Muscle invasive local recurrence
❑ Muscle invasive persistent disease

❑ Other _____

25. *If the clinical setting is Stage II or IIIA disease*, is the tumor present following primary bladder preserving chemoradiation? ❑ Yes ❑ No

Section H: Primary Carcinoma of the Urethra and Upper genitourinary tract tumor or urethelial carcinoma of the prostate

26. *If the patient has high risk of recurrence after undergoing radical resection,* will the requested drug be used as adjuvant treatment? ❑ Yes ❑ No *No further questions*

Section I: Colorectal Cancer

27. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? ***ACTION REQUIRED: If Yes, attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.*** ❑ Yes ❑ No ❑ Unknown

Section J: Merkel Cell Carcinoma

28. Will the requested drug be used as neoadjuvant treatment? ❑ Yes ❑ No

Section K: Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer

29. What type of underlying cancer does the patient have?
❑ Melanoma *If Melanoma, no further questions* ❑ Non-small cell lung cancer ❑ Other

30. Is the patient's disease positive for programmed death ligand 1 (PD-L1)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s) for PD-L1 expression****?* ❑ Yes ❑ No ❑ Unknown

Section L: Gestational Trophoblastic Neoplasia

31. Is the disease resistant to multi-agent chemotherapy? ❑ Yes ❑ No

32. What type of disease does the patient have?
❑ Intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor)
❑ High-risk disease *No further questions*
❑ Other _____

33. Has the patient previously received treatment with a platinum/etoposide-containing regimen?
❑ Yes ❑ No

Section M: Esophageal and esophagogastric junction carcinoma

34. Will the requested medication be used as postoperative therapy following preoperative chemoradiation and complete tumor resection? *If Yes, skip to #36* ❑ Yes ❑ No

35. What is the patient's histology?
❑ Squamous cell carcinoma, *no further questions* ❑ Adenocarcinoma, *no further questions*

36. Does the patient have residual pathologic disease? ❑ Yes ❑ No

Section N: Small bowel adenocarcinoma, including advanced ampullary cancer

37. Is the tumor microsatellite-instability high (MSI-H) or mismatch repair deficient (dMMR)? ***ACTION REQUIRED: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.*** ❑ Yes ❑ No ❑ Unknown

Section O: Endometrial Carcinoma

38. Is the tumor mismatch repair deficient (dMMR)? ***ACTION REQUIRED: If 'yes', attach laboratory report confirming mismatch repair deficient tumor status.*** ❑ Yes ❑ No ❑ Unknown

Section P: Vulvar Squamous Cell Carcinoma

39. Is the disease HPV-related? ❑ Yes ❑ No

Section Q: Continuation of Therapy

40. Is there evidence of disease progression or unacceptable toxicity on the current regimen? ❑ Yes ❑ No

41. *For adjuvant Treatment of Melanoma or Urothelial Carcinoma*, is the requested drug prescribed for the adjuvant treatment of melanoma or urothelial carcinoma? ❑ Yes ❑ No

42. *For Renal Cell Carcinoma,* how many continuous months of treatment has the patient received with the requested drug in combination with cabozantinib?_____ months

43. *For all indications except Renal cell Carcinoma,* how many continuous months of treatment has the patient received with the requested drug? _____ months

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)**

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