JOHNS HOPKINS MEDICINE
JOHNS HOPKINS HEALTHCARE

Opdivo

Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4**.**

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*

Drug Information:

*Strength/Measure*_____ *Units* ❑ ml ❑ Gm ❑ mg ❑ ea ❑ Un
*Directions(sig)*_____ *Route of administration*_____
*Dosing frequency*_____

Send completed form to: Priority Partners Fax: 1-866-212-4756

Criteria Questions:

1. What is the diagnosis?
   - ❑ Cutaneous melanoma
   - ❑ Non-small cell lung cancer (NSCLC)
   - ❑ Renal cell carcinoma
   - ❑ Classical Hodgkin lymphoma (cHL)
   - ❑ Squamous cell carcinoma of the head and neck (SCCHN)
   - ❑ 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
   - ❑ 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	
❑ Progressive disease	❑ Locally advanced disease	❑ Local recurrence

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❑ 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 N.*

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. Is the tumor negative for EGFR, ALK, and RET gene mutations? ACTION REQUIRED: Please attach documentation of EGFR, ALK or RET genomic aberrations, where applicable**.**
❑Yes, *If Yes, skip to #14* ❑ No, *If No, no further questions* ❑ Unknown

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

14. What is the patient's disease histology? ❑ Nonsquamous cell histology ❑ Squamous cell histology

15. Will the requested drug be used as a maintenance therapy? ❑ Yes ❑ No, *If no, skip to #17*

16. Is there tumor response or stable disease following first-line nivolumab and ipilimumab +/- chemotherapy?
❑ Yes ❑ No

17. Is tumor ROS1 rearrangement positive? ***ACTION REQUIRED: IF "Yes" Please attach documentation of ROS1 genomic aberration.*** ❑Yes ❑ No**,** *If no, no further questions* ❑ Unknown

18. Has the patient had a prior treatment with crizotinib, entrectinib, or ceritinib therapy? ❑ Yes ❑ No

Section C: Renal cell carcinoma

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

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

Section D: Classical Hodgkin Lymphoma

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

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

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

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

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

Section E: Squamous Cell Carcinoma of the Head and Neck

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

Section F: Bladder Cancer

27. *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*

28. *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 _____

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

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

30. *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 H: Colorectal Cancer

31. 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

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

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

33. 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

Section J: Gestational Trophoblastic Neoplasia

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

35. 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 _____

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

Section K: Esophageal and esophagogastric junction carcinoma

37. Will the requested medication be used as postoperative therapy following preoperative chemoradiation and complete tumor resection? *If Yes, skip to #39* ❑ Yes ❑ No

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

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

Section L: Small bowel adenocarcinoma, including advanced ampullary cancer

40. 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

Section M: Endometrial Carcinoma

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

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Section N: Vulvar Squamous Cell Carcinoma

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

Section O: Continuation of Therapy

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

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

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

46. *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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