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)
   - ❑ Squamous cell carcinoma of the head and neck (SCCHN)
   - ❑ Bladder cancer
   - ❑ Primary carcinoma of the urethra
   - ❑ Upper genitourinary tract tumor or urothelial carcinoma of the prostate
   - ❑ Colorectal cancer (including appendiceal carcinoma)
   - ❑ Small bowel adenocarcinoma
   - ❑ Small cell lung 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 squamous cell carcinoma
   - ❑ Extranodal NK/T-cell lymphoma, nasal type
   - ❑ 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
   - ❑ In combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy
   - ❑ In combination with brentuximab vedotin

   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 #6*

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

6. Is the patient currently receiving treatment with the requested medication? ❑ Yes ❑ No *If No, skip to #11*

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

8. Is the requested drug prescribed for the adjuvant treatment of melanoma? ❑ Yes ❑ No *If No, skip to #10*

9. How many months of adjuvant treatment has the patient received with the requested drug? _____ months *No further questions*

10. *If the diagnosis is Non-small cell lung cancer,* how many continuous months of treatment has the patient received with the requested drug? _____months. *No further questions*

11. 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
❑ Poor risk	❑ Intermediate risk	❑ Favorable risk
❑ Unresectable disease	❑ Unresectable advanced disease	❑ Stage IV disease
❑ Second primary disease	❑ Primary progressive disease	❑ Locally advanced disease
❑ Local recurrence	❑ Disseminated, metastatic disease	❑ Adjuvant treatment

❑ Post-cystectomy ❑ Unresectable metachronous metastases ❑ Preserved bladder
❑ Disease with tumor mutational burden (TMB) ❑ Progressive disease
❑ Very advanced disease ❑ Other _____

12. 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 _____

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

Section A: Cutaneous Melanoma

13. *If adjuvant treatment*, has the patient had a complete lymph node surgical resection or complete resection of metastatic disease? ❑ Yes ❑ No

Section B: Non-small cell lung cancer

14. Is the patient's disease EGFR positive? ❑Yes ❑ No ❑ Unknown *If No or unknown, skip to #16*

15. Has the patient received prior EGFR targeted therapy? ❑Yes ❑ No

16. Is the patient's disease ALK positive? ❑Yes ❑ No ❑ Unknown *If No or unknown, no further questions*

17. Has the patient received prior ALK targeted therapy? ❑Yes ❑ No

Section C: Renal cell carcinoma

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

Section D: Classical Hodgkin Lymphoma

19. Is the patient eligible for transplant? ❑ Yes ❑ No

20. Has the patient received 2 or more prior lines of therapy? ❑ Yes ❑ No

21. Has the patient received a hematopoietic stem cell transplant? ❑ Yes ❑ No

Section E: Squamous Cell Carcinoma of the Head and Neck

22. Has the patient experienced disease progression on or after platinum-containing chemotherapy? ❑ Yes ❑ No

Section F: Bladder Cancer

23. Has the patient previously received platinum-containing chemotherapy? ❑ Yes ❑ No

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 recurrent
❑ Muscle invasive persistent disease
❑ Other _____

Section G: Primary Carcinoma of the Urethra, Upper Genitourinary Tract Tumor, or Urothelial Carcinoma of the Prostate

25. Has the patient previously received platinum-containing chemotherapy? ❑ Yes ❑ No

Section H: Colorectal Cancer

26. 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

27. Which of the following treatments has the patient received within the past 12 months?
❑ Adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin)
❑ Adjuvant CapeOX (capecitabine and oxaliplatin)
❑ Not applicable

28. Is the patient a candidate for intensive therapy? ❑ Yes ❑ No

29. Which of the following treatments has the patient previously received?
    - ❑ Oxaliplatin-based therapy
    - ❑ Irinotecan-based therapy
    - ❑ Fluoropyrimidine-based therapy
    - ❑ Other _____

Section I: Small Cell Lung Cancer

30. Has the disease relapsed within 6 months following complete or partial response or stable disease with initial treatment? ❑ Yes ❑ No

31. Has the disease progressed after platinum-based chemotherapy and at least one other line of therapy? ❑ Yes ❑ No

Section J: 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

33. Is the patient's disease positive for programmed death ligand 1 (PD-L1)? ❑ Yes ❑ No

Section K: 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
    - ❑ High-risk disease *No further questions*
    - ❑ Other _____

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

Section L: Small bowel adenocarcinoma

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

38. Has the patient previously received adjuvant oxaliplatin? ❑ Yes *If Yes, no further questions* ❑ No

39. Does the patient have a contraindication to oxaliplatin? ❑ Yes ❑ No

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