Keytruda

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.

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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*

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Clinical Criteria Questions:

1. What is the diagnosis? *List continues on following page.*
   - ❑ Cutaneous melanoma
   - ❑ Non-small cell lung cancer
   - ❑ Cutaneous squamous cell carcinoma
   - ❑ Head and neck squamous cell cancer
   - ❑ Classical Hodgkin lymphoma
   - ❑ Urothelial carcinoma - Bladder cancer
   - ❑ Primary carcinoma of the urethra
   - ❑ Upper genitourinary tract tumor or urothelial carcinoma of the prostate
   - ❑ Adrenocortical carcinoma
   - ❑ Anaplastic thyroid carcinoma
   - ❑ Follicular, hürthle cell, or papillary thyroid carcinoma
   - ❑ Medullary thyroid carcinoma
   - ❑ Colorectal cancer (including appendiceal carcinoma)
   - ❑ Small Bowel Adenocarcinoma
   - ❑ Malignant Pleural Mesothelioma
   - ❑ Merkel Cell Carcinoma
   - ❑ Gastric or esophagogastric junction cancer
   - ❑ Esophageal cancer
   - ❑ Cervical cancer
   - ❑ Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
   - ❑ Uveal melanoma
   - ❑ Testicular cancer
   - ❑ Endometrial carcinoma
   - ❑ Anal carcinoma
   - ❑ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer
   - ❑ Primary mediastinal large B-cell lymphoma
   - ❑ Pancreatic adenocarcinoma
   - ❑ Hepatobiliary cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer)
   - ❑ Hepatocellular carcinoma
   - ❑ Vulvar cancer
   - ❑ Renal cell carcinoma
   - ❑ Thymic carcinoma
   - ❑ Mycosis fungoides or Sezary syndrome
   - ❑ Extranodal NK/T-cell lymphoma, nasal type
   - ❑ Gestational trophoblastic neoplasia
   - ❑ Small cell lung cancer
   - ❑ Poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma
   - ❑ Soft Tissue Sarcomas (alveolar soft part sarcoma (ASPS), cutaneous angiosarcoma, myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), undifferentiated sarcoma)
   - ❑ Triple-Negative Breast Cancer (TNBC)
   - ❑ Occult primary cancer
   - ❑ Microsatellite instability-high or mismatch repair deficient solid tumor
   - ❑ Tumor mutational burden-high solid tumor
   - ❑ Other _____

2. What is the ICD-10 code? _____

3. 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., Opdivo, Imfinzi)? ❑ Yes ❑ No

4. Is the requested drug prescribed for a pediatric patient with microsatellite instability-high (MSI-H) or tumor mutational burden-high (TMB-H) central nervous system (CNS) cancer? ❑ Yes ❑ No

5. Is the patient currently receiving treatment with the requested medication?
❑ Yes ❑ No *If yes, skip to #66*

6. Does the patient have a solid tumor that meets any of the following criteria? ***Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high tumor status, microsatellite instability-high tumor status, or mismatch repair deficient tumor status.***
❑ Microsatellite instability-high (MSI-H) solid tumor
❑ Mismatch repair deficient (dMMR) solid tumor
❑ Tumor mutational burden-high (TMB-H) (≥10 mutations/megabase) solid tumor
❑ None of the above *Skip to #9*

7. Has the patient experienced disease progression following prior treatment? ❑ Yes ❑ No *If No, skip to #9*

8. Are there other satisfactory alternative treatment options available for the patient? ❑ Yes ❑ No *If No, no further questions*

9. Will the requested drug be used as a single agent? ❑ Yes ❑ No

10. What is the clinical setting in which the requested drug will be used? ***Indicate ALL that apply.***

❑ Adjuvant treatment	❑ Unresectable disease	❑ Metastatic disease	❑ Distant metastatic disease
❑ Recurrent disease	❑ High-risk disease	❑ Advanced disease	❑ Very Advanced disease
❑ Refractory disease	❑ Persistent disease	❑ Local recurrence	❑ Relapsed disease
❑ Stage II disease	❑ Stage IIIA disease	❑ Stage IV disease	❑ Preserved bladder
❑ Locally advanced disease	❑ Post-cystectomy	❑ Recurrent locally advanced disease	
❑ Locally recurrent unresectable disease		❑ Primary progressive disease	

❑ Other _____

11. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Tumor Proportion Score (TPS) of greater than or equal to 1%? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) for PD-L1 expression.***
❑ Yes ❑ No ❑ Not applicable for diagnosis

12. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of greater than or equal to either 1 or 10? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) for PD-L1 expression.*** ❑ Yes - 1 ❑ Yes - 10 ❑ No ❑ Not applicable for diagnosis

13. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
ACTION REQUIRED: If Yes or No, attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status. ❑ Yes ❑ No ❑ Not applicable for diagnosis

14. What is the place in therapy in which the requested drug will be used?
❑ First-line treatment ❑ Second-line treatment ❑ Third-line
❑ Subsequent treatment

Complete the following section based on the patient's diagnosis

Section A: Cutaneous Melanoma

15. *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

16. Will the requested drug be used as part of any of the following regimens?
❑ Carboplatin and paclitaxel ❑ Carboplatin and paclitaxel protein-bound
❑ Pemetrexed and cisplatin ❑ Pemetrexed and carboplatin
❑ Other _____

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17. Does the disease express squamous or nonsquamous histology? ❑ Squamous ❑ Nonsquamous

18. Is the patient's disease EGFR positive? ❑ Yes ❑ No ❑ Unknown *If No or Unknown, skip to #20*

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

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

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

Section C: Cutaneous Squamous Cell Carcinoma

22. Is the disease curable by surgery or radiation? ❑ Yes ❑ No

Section D: Head and Neck Squamous Cell Cancer (HNSCC)

23. Will the requested drug be used as part of any of the following regimens?
    ❑ In combination with fluorouracil and carboplatin
    ❑ In combination with fluorouracil and cisplatin
    ❑ Other _____

Section E: Urothelial Carcinoma - Bladder Cancer

24. Is the patient eligible for any platinum-containing chemotherapy? ❑ Yes ❑ No *If No, skip to #28 for post-cystectomy or #29 for preserved bladder*

25. Is the patient eligible for cisplatin chemotherapy? ❑ Yes ❑ No

26. Has the patient received primary treatment with concurrent chemoradiotherapy? ❑ Yes ❑ No

27. Is tumor present following reassessment 2-3 months after primary treatment? ❑ Yes ❑ No

28. What is the clinical setting in which the requested drug will be used following cystectomy?
    ❑ Metastatic disease ❑ Local recurrence ❑ Other _____

29. 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 _____

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

31. Is the requested drug prescribed for the treatment of high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)? ❑ Yes ❑ No *If No, no further questions*

32. Is the disease responsive to Bacillus Calmette-Guerin (BCG)? ❑ Yes ❑ No

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

34. Has the patient elected not to undergo cystectomy? ❑ Yes ❑ No

Section F: Primary Carcinoma of the Urethra and Upper Genitourinary Tract Tumor, Urothelial Carcinoma of the Prostate

35. Is the patient eligible for any platinum-containing chemotherapy? ❑ Yes ❑ No

36. Is the patient eligible for cisplatin chemotherapy? ❑ Yes ❑ No

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

Section G: Gastric Cancer or Esophagogastric Junction Cancer

38. Is the patient a surgical candidate? ❑ Yes ❑ No

Section H: Esophageal Cancer

39. Is the patient a surgical candidate? ❑ Yes ❑ No

40. Does the patient's disease express squamous or nonsquamous histology? ❑ Squamous ❑ Nonsquamous

Section I: Cervical Cancer

41. Has the patient experienced disease progression on or after chemotherapy? ❑ Yes ❑ No

Section J: Endometrial Carcinoma

42. Has the disease progressed following prior systemic therapy? ❑ Yes ❑ No

43. Is the patient a candidate for curative surgery or radiation? ❑ Yes ❑ No

44. Will the requested drug be used in combination with lenvatinib? ❑ Yes ❑ No

Section K: Central Nervous System (CNS) Brain Metastases in Patients with Melanoma or Non-Small Cell Lung Cancer

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

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

Section L: Pancreatic Adenocarcinoma

47. Does the patient have poor performance status? ❑ Yes ❑ No

Section M: Hepatocellular Carcinoma

48. Has the patient previously been treated with sorafenib? ❑ Yes ❑ No

Section N: Vulvar Cancer

49. Does the disease express squamous or nonsquamous histology? ❑ Squamous ❑ Nonsquamous

50. Has the patient experienced disease progression on or after chemotherapy? ❑ Yes ❑ No

Section O: Renal Cell Carcinoma

51. Will the requested drug be used in combination with axitinib? ❑ Yes ❑ No

52. Does the tumor express clear cell histology? ❑ Yes ❑ No

Section P: Extranodal NK/T-Cell Lymphoma, nasal type

53. Does the patient have nasal type disease? ❑ Yes ❑ No

Section Q: Gestational Trophoblastic Neoplasia

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

55. What type of disease does the patient have?
❑ Intermediate trophoblastic tumor
❑ High-risk disease
❑ Other _____

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

Section R: Small Cell Lung Cancer

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

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

Section S: Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma

59. Has the patient experienced disease progression following prior treatment? ❑ Yes ❑ No

60. Are there other satisfactory alternative treatment options available for the patient? ❑ Yes ❑ No

Section T: Follicular, Hürthle cell, or Papillary thyroid carcinoma

61. Is the disease amenable to radioactive iodine therapy? ❑ Yes ❑ No

Section U: Small Bowel Adenocarcinoma

62. Has the patient had prior adjuvant oxaliplatin exposure? ❑ Yes ❑ No

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

Section V: Triple-Negative Breast Cancer (TNBC)

64. Is the patient's diagnosis confirmed by the breast cancer cells testing negative for ALL of the following receptors? ***ACTION REQUIRED**: **If yes, please submit test results confirming cancer cells are negative for human epidermal growth factor receptor 2 (HER-2), estrogen, and progesterone receptors.***
    - Human epidermal growth factor receptor 2 (HER-2)
    - Estrogen
    - Progesterone

    ❑ Yes ❑ No

65. Will the requested drug be used in combination with chemotherapy? ❑ Yes ❑ No

Continuation of Therapy

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

67. How many continuous months of treatment has the patient received with the requested drug? _____ months

Complete the following section based on the patient's diagnosis

Section W: Cutaneous Melanoma

68. Is the requested drug prescribed for the adjuvant treatment of melanoma? ❑ Yes ❑ No

Section X: Vulvar cancer

69. Is the tumor microsatellite instability-high or mismatch repair deficient or does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of greater than or equal to 1?
    ❑ Microsatellite instability-high or mismatch repair deficient
    ❑ PD-L1 expression with CPS score greater than or equal to 1

Section Y: Bladder cancer

70. Is the requested drug prescribed for the treatment of high-risk BCG-unresponsive non-muscle invasive bladder cancer? ❑ Yes ❑ No *If No, no further questions*

71. Is the disease persistent or recurrent? ❑ 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)**

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