



## 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.

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](mailto: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**

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062  
Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • [www.caremark.com](http://www.caremark.com)

**Clinical Criteria Questions:**

1. What is the ICD-10 code? \_\_\_\_\_
2. 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 *If No, skip to #6*
3. Is the requested drug prescribed as second-line or subsequent treatment for metastatic or unresectable melanoma?  Yes  No
4. Will the requested drug be used in combination with ipilimumab following disease progression on single agent anti-PD-1 immunotherapy?  Yes  No
5. Is this request for initiation or continuation of treatment with the requested medication?  
 Initiation *No further questions*  Continuation *Skip to section NN*
6. 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, MSI-H CNS cancer  Yes, TMB-H CNS cancer  No
7. Is the patient currently receiving treatment with the requested medication?  
*If Yes, skip to section NN*  Yes  No
8. Does the patient have a solid tumor that meets any of the following criteria? **Action required: If 'Yes', please 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) ( $\geq 10$  mutations/megabase) solid tumor  
 None of the above *Skip to #13*
9. Will the requested drug be used as a single agent?  Yes  No *If No, skip to #13*
10. What is the clinical setting in which the requested drug will be used?  
 Unresectable disease  
 Metastatic disease  
 Other *Skip to #13*
11. Has the patient experienced disease progression following prior treatment?  Yes  No *If No, skip to #13*
12. Are there other satisfactory alternative treatment options available for the patient?  
 Yes  No *If No, no further questions*
13. What is the diagnosis? *Continue to diagnosis section after answering*

<input type="checkbox"/> Cutaneous melanoma	<input type="checkbox"/> Non-small cell lung cancer
<input type="checkbox"/> Cutaneous squamous cell carcinoma	<input type="checkbox"/> Head and neck squamous cell cancer
<input type="checkbox"/> Classical Hodgkin lymphoma	<input type="checkbox"/> Urothelial carcinoma - Bladder cancer
<input type="checkbox"/> Primary carcinoma of the urethra	<input type="checkbox"/> Adrenocortical carcinoma
<input type="checkbox"/> Anaplastic thyroid carcinoma	<input type="checkbox"/> Follicular, hürthle cell, or papillary thyroid carcinoma
<input type="checkbox"/> Medullary thyroid carcinoma	<input type="checkbox"/> Colorectal cancer (including appendiceal carcinoma)
<input type="checkbox"/> Small Bowel Adenocarcinoma, including advanced ampullary cancer	<input type="checkbox"/> Merkel Cell Carcinoma
<input type="checkbox"/> Malignant Pleural Mesothelioma	<input type="checkbox"/> Esophagogastric junction cancer
<input type="checkbox"/> Gastric cancer	<input type="checkbox"/> Cervical cancer
<input type="checkbox"/> Esophageal cancer	<input type="checkbox"/> Testicular cancer
<input type="checkbox"/> Uveal melanoma	<input type="checkbox"/> Anal carcinoma
<input type="checkbox"/> Endometrial carcinoma	<input type="checkbox"/> Pancreatic adenocarcinoma
<input type="checkbox"/> Primary mediastinal large B-cell lymphoma	<input type="checkbox"/> Vulvar cancer
<input type="checkbox"/> Hepatocellular carcinoma	<input type="checkbox"/> Thymic carcinoma
<input type="checkbox"/> Renal cell carcinoma	<input type="checkbox"/> Extranodal NK/T-cell lymphoma, nasal type
<input type="checkbox"/> Mycosis fungoides or Sezary syndrome	<input type="checkbox"/> Soft Tissue Sarcomas
<input type="checkbox"/> Gestational trophoblastic neoplasia	

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

- Tumor mutational burden-high solid tumor
- Triple-Negative Breast Cancer (TNBC), locally recurrent unresectable or metastatic
- Triple-Negative Breast Cancer (TNBC), high-risk early-stage disease
- Microsatellite instability-high or mismatch repair deficient solid tumor
- Upper genitourinary tract tumor or urothelial carcinoma of the prostate
- Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
- Poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma
- Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer
- Hepatobiliary cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer)
- Other \_\_\_\_\_

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

Section A: Cutaneous Melanoma.

14. Will the requested drug be used as a single agent?  Yes  No
15. What is the clinical setting in which the requested drug will be used?
- Adjuvant treatment
  - Unresectable disease *No further questions*
  - Metastatic disease *No further questions*
  - Other
16. 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

17. Will the requested drug be used for the treatment of recurrent, advanced, or metastatic disease?  Yes  No
18. Will the requested drug be used as a single agent?  Yes  No *If No, skip to #24*
19. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Tumor Proportion Score (TPS) of  $\geq 1\%$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**
- Yes  No
20. Is the patient's disease EGFR positive?  Yes  No  Unknown *If No or Unknown, skip to #22*
21. Has the patient received prior EGFR-targeted therapy?  Yes  No
22. Is the patient's disease ALK positive?  Yes  No  Unknown *If No or Unknown, no further questions.*
23. Has the patient received prior ALK targeted therapy?  Yes  No *No further questions*
24. Does the disease express squamous or nonsquamous histology?
- Squamous
  - Nonsquamous *Skip to #26*
25. Will the requested drug be used as part of any of the following regimens? *No further questions*
- Carboplatin and paclitaxel
  - Carboplatin and paclitaxel protein-bound
  - Other
26. Will the requested drug be used as part of any of the following regimens?
- In combination with pemetrexed and cisplatin
  - In combination with pemetrexed and carboplatin
  - Other
27. Is the patient's disease EGFR positive?  Yes  No  Unknown *If No or Unknown, skip to #29*
28. Has the patient received prior EGFR-targeted therapy?  Yes  No
29. Is the patient's disease ALK positive?  Yes  No  Unknown *If No or Unknown, no further questions.*

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062  
 Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

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

Section C: Cutaneous Squamous Cell Carcinoma

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

32. What is the clinical setting in which the requested drug will be used?  
 Recurrent disease  Metastatic disease  Other

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

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

34. What is the clinical setting in which the requested drug will be used?  
 Very advanced disease  Other

35. Will the requested drug be used as a single agent?  Yes  No *If No, skip to #39*

36. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  
 Subsequent treatment *No further questions*

37. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 1$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  
 Yes  No *No further questions*

38. 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: Classical Hodgkin Lymphoma

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

40. What is the clinical setting in which the requested drug will be used?  
 Refractory disease  Relapsed disease  Other

Section F: Urothelial Carcinoma - Bladder Cancer

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

42. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  
 Subsequent treatment *Skip to #52*

43. Is the patient eligible for any platinum-containing chemotherapy?  Yes  No *If No, skip to #47*

44. Is the patient eligible for cisplatin chemotherapy?  Yes  No

45. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 10$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  Yes  No

46. What is the clinical setting in which the requested drug will be used?  
 Stage II disease  
 Stage IIIA disease  
 Locally advanced disease *No further questions*  
 Metastatic disease *No further questions*  
 Post-cystectomy *Skip to #50*  
 Preserved bladder *Skip to #51*  
 Other

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

48. Is tumor present following reassessment 2-3 months after primary treatment?  Yes  No *No further questions*

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

49. What is the clinical setting in which the requested drug will be used following cystectomy? *No further questions*  
 Metastatic disease  Local recurrence  Other
50. What is the clinical setting in which the requested drug will be used in a preserved bladder? *No further questions*  
 Muscle invasive local recurrence  
 Muscle invasive persistent disease  
 Other
51. Is the requested drug prescribed for the treatment of high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)? *If Yes, skip to #57*  Yes  No
52. Has the patient previously received platinum-containing chemotherapy?  Yes  No
53. What is the clinical setting in which the requested drug will be used?  
 Locally advanced disease *No further questions*  
 Metastatic disease *No further questions*  
 Post-cystectomy  
 Preserved bladder *Skip to #56*  
 Other
54. What is the clinical setting in which the requested drug will be used following cystectomy? *No further questions*  
 Metastatic disease  Local recurrence  Other
55. What is the clinical setting in which the requested drug will be used in a preserved bladder? *No further questions*  
 Muscle invasive local recurrence  
 Muscle invasive persistent disease  
 Other
56. Is the disease responsive to Bacillus Calmette-Guerin (BCG)?  Yes  No
57. Is the patient eligible for cystectomy?  Yes  No *If No, no further questions*
58. Has the patient elected not to undergo cystectomy?  Yes  No

**Section G: Primary Carcinoma of the Urethra**

59. Will the requested drug be used as a single agent?  Yes  No
60. What is the clinical setting in which the requested drug will be used?  
 Recurrent disease  
 Locally advanced disease  
 Metastatic disease  
 Other
61. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  
 Subsequent treatment *Skip to #66*
62. Is the patient eligible for any platinum-containing chemotherapy?  Yes  No *If No, no further questions*
63. Is the patient eligible for cisplatin chemotherapy?  Yes  No
64. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 10$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  
 Yes  No *No further questions*
65. Has the patient previously received platinum-containing chemotherapy?  Yes  No

**Section H: Upper Genitourinary Tract Tumor, Urothelial Carcinoma of the Prostate**

66. Will the requested drug be used as a single agent?  Yes  No
67. What is the clinical setting in which the requested drug will be used?  
 Locally advanced disease  Metastatic disease  Other

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

**CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062  
 Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com**

68. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  
 Subsequent treatment *Skip to #73*
69. Is the patient eligible for any platinum-containing chemotherapy?  Yes  No *If No, no further questions*
70. Is the patient eligible for cisplatin chemotherapy?  Yes  No
71. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 10$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  
 Yes  No *No further questions*
72. Has the patient previously received platinum-containing chemotherapy?  Yes  No

**Section I: Colorectal Cancer**

73. Will the requested drug be used as a single agent?  Yes  No
74. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status**  Yes  No
75. What is the clinical setting in which the requested drug will be used?  
 Unresectable disease  Advanced disease  Metastatic disease  Other

**Section J: Malignant Pleural Mesothelioma**

76. Will the requested drug be used as a single agent?  Yes  No
77. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  
 Subsequent treatment

**Section K: Merkel Cell Carcinoma**

78. What is the clinical setting in which the requested drug will be used?  
 Recurrent locally advanced disease  Metastatic disease  Other

**Section L: Gastric Cancer**

79. What is the clinical setting in which the requested drug will be used?  
 Locally advanced disease *Skip to #82*  
 Recurrent disease *Skip to #82*  
 Metastatic disease *Skip to #82*  
 Other
80. Is the patient a surgical candidate?  Yes  No
81. Will the requested drug be used as part of any of the following regimens?  
 Single agent  
 In combination with trastuzumab, fluoropyrimidine-(e.g., fluorouracil, capecitabine) and platinum-containing (e.g., cisplatin, oxaliplatin) chemotherapy *Skip to #87*  
 Other
82. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No *If No, skip to #85*
83. What is the place in therapy in which the requested drug will be used? *No further questions*  
 First-line treatment  Second-line or subsequent treatment
84. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 1$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  
 Yes  No

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062  
 Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

85. What is the place in therapy in which the requested drug will be used? *No further questions*  
 First-line treatment  Second-line treatment  Third-line or subsequent treatment
86. What is the patient's histology?  Adenocarcinoma  Other
87. Is the patient's disease HER2-positive? **Action required: If 'Yes' please attach supporting documentation of laboratory report confirming HER2 status**  Yes  No  Unknown
88. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment

Section M: Esophageal Cancer

89. What is the clinical setting in which the requested drug will be used?  
 Locally advanced disease *Skip to #92*  
 Recurrent disease *Skip to #92*  
 Metastatic disease *Skip to #92*  
 Other
90. Is the patient a surgical candidate?  Yes  No
91. Will the requested drug be used in combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy? *If Yes, no further questions*  Yes  No
92. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No *If No, skip to #96*
93. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment
94. Will the requested drug be used as a single agent?  Yes  No *No further questions*
95. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 10$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  
 Yes  No *If No, skip to #99*
96. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment
97. Does the patient's disease express squamous or nonsquamous histology?  
 Squamous *No further questions*  
 Nonsquamous *Skip to #100*
98. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 1$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  Yes  No
99. Will the requested drug be used as a single agent?  Yes  No
100. What is the place in therapy in which the requested drug will be used? *No further questions*  
 First-line treatment  Second-line treatment  Third-line or subsequent treatment

Section N: Cervical Cancer

101. Will the requested drug be used as a single agent?  Yes  No
102. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment
103. What is the clinical setting in which the requested drug will be used?  
 Recurrent disease  Metastatic disease  Other

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062  
 Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

104. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.** *If Yes, no further questions*  Yes  No
105. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 1$ ? **Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.**  Yes  No
106. Has the patient experienced disease progression on or after chemotherapy?  Yes  No

Section O: Epithelial Ovarian cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer

107. Will the requested drug be used as a single agent?  Yes  No
108. What is the clinical setting in which the requested drug will be used?  
 Recurrent disease  Persistent disease  Other
109. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No

Section P: Uveal Melanoma

110. Will the requested drug be used as a single agent?  Yes  No
111. What is the clinical setting in which the requested drug will be used?  
 Distant metastatic disease  Other

Section Q: Testicular Cancer

112. Will the requested drug be used as a single agent?  Yes  No
113. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line treatment  Third-line or subsequent treatment
114. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No

Section R: Endometrial Carcinoma

115. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No *If No, skip to #119*
116. What is the clinical setting in which the requested drug will be used?  
 Recurrent disease  Metastatic disease  High-risk disease  Other
117. Has the disease progressed following prior systemic therapy?  Yes  No *No further questions*
118. What is the clinical setting in which the requested drug will be used?  
 Advanced disease  Other
119. Has the disease progressed following prior systemic therapy?  Yes  No
120. Is the patient a candidate for curative surgery or radiation?  Yes  No
121. Will the requested drug be used in combination with lenvatinib?  Yes  No

Section S: Anal Carcinoma

122. Will the requested drug be used as a single agent?  Yes  No
123. What is the clinical setting in which the requested drug will be used?  
 Metastatic disease  Other
124. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062  
 Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com



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

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

126. What type of underlying cancer does the patient have?

- Melanoma *No further questions*
- Non-small cell lung cancer
- Other

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

Section U: Primary Mediastinal Large B-cell Lymphoma

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

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

- Relapsed disease
- Refractory disease
- Other

Section V: Pancreatic Adenocarcinoma

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

131. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No

132. Does the patient have poor performance status?  Yes  No *If No, skip to #136*

133. What is the place in therapy in which the requested drug will be used?

- First-line treatment
- Subsequent treatment

134. What is the clinical setting in which the requested drug will be used? *No further questions*

- Metastatic disease
- Other

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

- Locally advanced disease
- Metastatic disease
- Local recurrence in the pancreatic operative bed after resection *No further questions*
- Other

136. What is the place in therapy in which the requested drug will be used?

- First-line treatment
- Subsequent treatment

Section W: Hepatobiliary Cancers

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

138. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? **Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No

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

- Unresectable disease
- Metastatic disease
- Other

Section X: Hepatocellular Carcinoma

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

Section Y: Vulvar Cancer

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

142. What is the place in therapy in which the requested drug will be used?

- First-line treatment
- Subsequent treatment

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

- Advanced disease
- Recurrent disease
- Metastatic disease
- Other

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

**CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062**

**Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com**

144. Does the disease express squamous or nonsquamous histology?  Squamous  Nonsquamous
145. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? *Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status. If Yes, no further questions*  Yes  No
146. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 1$ ? *Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.*  Yes  No
147. Has the patient experienced disease progression on or after chemotherapy?  Yes  No

Section Z: Renal Cell Carcinoma

148. Will the requested drug be used in combination with axitinib?  Yes  No
149. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  
 Subsequent treatment *Skip to #152*
150. What is the clinical setting in which the requested drug will be used? *No further questions*  
 Advanced disease  Recurrent disease  Stage IV disease  Other
151. What is the clinical setting in which the requested drug will be used? *No further questions*  
 Relapsed disease  Stage IV disease  Other
152. Does the tumor express clear cell histology?  Yes  No

Section AA: Thymic Carcinoma

153. Will the requested drug be used as a single agent?  Yes  No
154. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment
155. What is the clinical setting in which the requested drug will be used?  
 Unresectable disease  Locally advanced disease  Metastatic disease  Other

Section BB: Extranodal NK/T-Cell Lymphoma, Nasal Type

156. Does the patient have nasal type disease?  Yes  No
157. What is the clinical setting in which the requested drug will be used?  
 Relapsed disease  Refractory disease  Other

Section CC: Gestational Trophoblastic Neoplasia

158. Will the requested drug be used as a single agent?  Yes  No
159. Is the disease resistant to multi-agent chemotherapy?  Yes  No
160. What type of disease does the patient have?  
 Intermediate trophoblastic tumor  
 High-risk disease *No further questions*  
 Other

161. What is the clinical setting in which the requested drug will be used?  
 Recurrent disease  Progressive disease  Other

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

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

163. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? *Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status. If Yes, skip to #166*  Yes  No

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

164. Does the disease have tumor mutational burden-high tumors (greater than or equal to 10 mutations per megabase)?  
**Action required: If 'Yes', please attach laboratory report confirming tumor mutational burden-high tumor status.**  Yes  No

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

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

Section EE: Soft Tissue Sarcoma (alveolar soft part sarcoma (ASPS), cutaneous angiosarcoma, myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), undifferentiated sarcoma)

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

168. Which of the following type of soft tissue sarcoma applies to the patient?

- Alveolar soft part sarcoma (ASPS)
- Cutaneous angiosarcoma
- Myxofibrosarcoma
- Undifferentiated pleomorphic sarcoma (UPS)
- Undifferentiated sarcoma
- Other

Section FF: Occult Primary Cancer

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

170. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?

**ACTION REQUIRED: If Yes, please attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**  Yes  No

Section GG: Adrenocortical Carcinoma

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

- Metastatic disease
- Other

Section HH: Anaplastic Thyroid Carcinoma

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

173. Does the disease have tumor mutational burden-high tumors (greater than or equal to 10 mutations per megabase)?

**Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high tumor status**  
 Yes  No

174. What is the clinical setting in which the requested drug will be used?  Metastatic disease  Other

Section II: Follicular, Hürthle cell, or Papillary Thyroid Carcinoma

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

- Unresectable disease
- Metastatic disease *Skip to #178*
- Other

176. Does the disease have tumor mutational burden-high tumors (greater than or equal to 10 mutations per megabase)?

**Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high tumor status**  
 Yes  No

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

Section JJ: Medullary Thyroid Carcinoma

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

- Unresectable disease
- Recurrent disease
- Metastatic disease
- Other

179. Does the disease have tumor mutational burden-high tumors (greater than or equal to 10 mutations per megabase)?

**Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high tumor status**  
 Yes  No

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

Section KK: Small Bowel Adenocarcinoma, including Advanced Ampullary Cancer

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

- Advanced disease  Metastatic disease  Other

181. 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 LL: Triple-Negative Breast Cancer (TNBC)

182. 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  Unknown

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

- Locally recurrent unresectable disease  
 Metastatic disease  
 High-risk early-stage disease *Skip to #187*  
 Other

184. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 10$ ? **Action required: If 'Yes', attach supporting chart note(s) for PD-L1 expression.**

Yes  No  Unknown

185. Will the requested drug be used in combination with chemotherapy?  Yes  No *No further questions*

186. What is the place in therapy in which the requested drug will be used?

- Neoadjuvant treatment  
 Continued adjuvant treatment after surgery *Skip to #189*  
 Other

187. Will the requested drug be used in combination with chemotherapy?  Yes  No *No further questions*

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

Section MM: Esophagogastric Junction Cancer

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

- Locally advanced disease *Skip to #192*  
 Recurrent disease *Skip to #192*  
 Metastatic disease *Skip to #192*  
 Other

190. Is the patient a surgical candidate?  Yes  No

191. Will the requested drug be used in either of the following regimens?

- In combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy *No further questions*  
 In combination with trastuzumab, fluoropyrimidine-(e.g., fluorouracil, capecitabine) and platinum-(e.g., cisplatin, oxaliplatin) containing chemotherapy  
 Other *Skip to #196*

192. What is the patient's histology?  Adenocarcinoma  Other

193. Is the patient's disease HER2-positive? **ACTION REQUIRED: If 'Yes' attach supporting documentation of laboratory report confirming HER2 status.**  Yes  No

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

194. What is the place in therapy in which the requested drug will be used? *No further questions*  
 First-line treatment  Second-line or subsequent treatment
195. 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 *If No, skip to #199*
196. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment
197. Will the requested drug be used as a single agent?  Yes  No *No further questions*
198. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 10$ ? ***Action required: If 'Yes' attach supporting chart note(s) for PD-L1 expression.***  
 Yes  No *If No, skip to #202*
199. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line or subsequent treatment
200. Does the patient's disease express squamous or nonsquamous histology?  
 Squamous *No further questions*  
 Nonsquamous *Skip to #203*
201. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of  $\geq 1$ ? ***Action required: If 'Yes' attach supporting chart note(s) for PD-L1 expression.***  Yes  No
202. Will the requested drug be used as a single agent?  Yes  No
203. What is the place in therapy in which the requested drug will be used?  
 First-line treatment  Second-line treatment  Third-line or subsequent treatment

**Section NN: Continuation of Therapy**

204. What is the diagnosis?  
 Cutaneous melanoma *Skip to #208*  
 Non-small cell lung cancer  
 Cutaneous squamous cell carcinoma  
 Head and neck squamous cell cancer  
 Classical Hodgkin lymphoma  
 Bladder cancer *Skip to #213*  
 Primary carcinoma of the urethra  
 Upper genitourinary tract tumor or urothelial carcinoma of the prostate  
 Colorectal cancer (including appendiceal carcinoma)  
 Malignant Pleural Mesothelioma *Skip to #211*  
 Merkel Cell Carcinoma  
 Gastric cancer  
 Esophageal cancer  
 Cervical cancer  
 Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer  
 Uveal melanoma *Skip to #211*  
 Testicular cancer  
 Endometrial carcinoma  
 Anal carcinoma *Skip to #211*  
 Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer *Skip to #211*  
 Primary mediastinal large B-cell lymphoma  
 Pancreatic adenocarcinoma  
 Hepatobiliary cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer)  
 Hepatocellular carcinoma

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062

Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com

- Vulvar cancer *Skip to #212*
- Renal cell carcinoma
- Thymic carcinoma *Skip to #211*
- Mycosis fungoides or Sezary syndrome *Skip to #211*
- Extranodal NK/T-cell lymphoma *Skip to #211*
- Gestational trophoblastic neoplasia *Skip to #211*
- Poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma
- Adrenocortical carcinoma *Skip to #211*
- Anaplastic thyroid carcinoma
- Follicular, hürthle cell, or papillary thyroid carcinoma
- Medullary thyroid carcinoma
- Small bowel adenocarcinoma, including advanced ampullary cancer
- Soft tissue sarcomas (alveolar soft part sarcoma (ASPS), cutaneous angiosarcoma, myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), undifferentiated sarcoma) *Skip to #211*
- Occult primary cancer
- Microsatellite instability-high or mismatch repair deficient solid tumor
- Tumor mutational burden-high solid tumor
- Triple-Negative Breast Cancer (TNBC), locally recurrent unresectable or metastatic
- Triple-Negative Breast Cancer (TNBC), high-risk early-stage disease *Skip to #208*
- Esophagogastric junction cancer
- Other

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

206. How many continuous months of treatment has the patient received with the requested drug? \_\_\_\_\_ months  
*No further questions*

207. Is the requested drug prescribed for the adjuvant treatment of melanoma or high-risk early-stage TNBC?  
 Yes  No *If No, skip to #211*

208. Is there evidence of disease recurrence or unacceptable toxicity on the current regimen?  Yes  No

209. How many months of treatment has the patient received with the requested drug? \_\_\_\_\_ months  
*No further questions*

210. Is there evidence of disease progression or unacceptable toxicity on the current regimen?  Yes  No  
*No further questions*

211. 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 *Skip to #215*  
 PD-L1 expression with CPS score greater than or equal to 1 *Go back to #211*

212. Is the requested drug prescribed for the treatment of high-risk BCG-unresponsive non-muscle invasive bladder cancer?  Yes  No *If No, skip to #215*

213. Is the disease persistent or recurrent?  Yes  No

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

215. 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)**

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Keytruda SGM – 09/2021.

**CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062  
Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com**