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. 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

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 RR*

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 RR* ❑ 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) (≥10 mutations/megabase [mut/Mb]) solid tumor
   ❑ None of the above *Skip to #13*

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?
    ❑ Unresectable disease
    ❑ Metastatic disease
    ❑ Other

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

12. Are there other satisfactory alternative treatment options available for the patient? ❑ Yes ❑ No *No further questions*

13. What is the diagnosis? *Continue to diagnosis section after answering*
    ❑ Cutaneous melanoma
    ❑ Salivary gland tumors
    ❑ Head and neck squamous cell cancer
    ❑ Urothelial carcinoma - Bladder cancer
    ❑ Anaplastic thyroid carcinoma
    ❑ Medullary thyroid carcinoma
    ❑ Non-small cell lung cancer
    ❑ Cutaneous squamous cell carcinoma
    ❑ Classical Hodgkin lymphoma
    ❑ Primary carcinoma of the urethra
    ❑ Follicular, hürthle cell, or papillary thyroid carcinoma
    ❑ Colorectal cancer (including appendiceal carcinoma)
    ❑ Small Bowel Adenocarcinoma, including advanced ampullary cancer
    ❑ Malignant Pleural Mesothelioma
    ❑ Merkel Cell Carcinoma
    ❑ Esophageal cancer and Esophagogastric Junction Cancer
    ❑ Gastric cancer
    ❑ Uveal melanoma
    ❑ Endometrial carcinoma
    ❑ Primary mediastinal large B-cell lymphoma
    ❑ Hepatocellular carcinoma
    ❑ Renal cell carcinoma
    ❑ Mycosis fungoides or Sezary syndrome
    ❑ Gestational trophoblastic neoplasia
    ❑ Cervical cancer
    ❑ Testicular cancer
    ❑ Anal carcinoma
    ❑ Pancreatic adenocarcinoma
    ❑ Vulvar cancer
    ❑ Thymic carcinoma
    ❑ Extranodal NK/T-cell lymphoma, nasal type
    ❑ Neuroendocrine and Adrenal Tumors

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- ❑ Soft Tissue Sarcomas
- ❑ Tumor mutational burden-high solid tumor
- ❑ Prostate Cancer
- ❑ Uterine Sarcoma
- ❑ Breast Cancer
- ❑ Occult primary cancer
- ❑ Penile cancer
- ❑ Small cell lung cancer
- ❑ Bone cancer (Chondrosarcoma, Ewing Sarcoma, Osteosarcoma, Chordoma)
- ❑ Upper genitourinary tract tumor or urothelial carcinoma of the prostate
- ❑ Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential with invasive implants)
- ❑ 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. What is the clinical setting in which the requested drug will be used?
    - ❑ Adjuvant treatment
    - ❑ Unresectable disease *Skip to #16*
    - ❑ Metastatic disease *Skip to #16*
    - ❑ Subsequent therapy *Skip to #17*
    - ❑ Other
15. Has the patient had a complete lymph node surgical resection or complete resection of stage IIB, IIC, III or metastatic disease? ❑ Yes ❑ No
16. Will the requested drug be used as a single agent? ❑ Yes ❑ No *No further questions*
17. Will the requested drug be used for disease progression of metastatic or unresectable tumors? ❑ Yes ❑ No
18. Will the requested drug be used in any of the following regimens?
    ❑ Single agent ❑ In combination with ipilimumab ❑ Other

Section B: Non-Small Cell Lung Cancer

19. Is the tumor negative for EGFR, ALK, and RET gene mutations? ***ACTION REQUIRED: Please attach documentation of EGFR, ALK or RET genomic aberration, where applicable***
    - ❑ Yes *Skip to #23*
    - ❑ No *Skip to #21*
    - ❑ Unknown
20. Is testing for these genomic tumor aberrations not feasible due to insufficient tissue? ❑ Yes ❑ No
21. Will the requested drug be used as a single agent? ❑ Yes ❑ No
22. What is the place in therapy in which the requested drug will be used?
    ❑ Initial treatment ❑ Subsequent treatment *Either answer, skip to #28*
23. Will the requested drug be used in any of the following regimens?
    - ❑ Single agent
    - ❑ In combination with pemetrexed plus carboplatin or cisplatin *Skip to #30*
    - ❑ In combination with carboplatin plus paclitaxel or albumin-bound paclitaxel *Skip to #31*
    - ❑ In combination with pemetrexed only *Skip to #36*
    - ❑ Other
24. Will the requested drug be used as maintenance therapy? ❑ Yes ❑ No *If No, skip to #26*
25. Is there tumor response or stable disease following first-line monotherapy or pembrolizumab and carboplatin plus paclitaxel or albumin-bound paclitaxel regimen? ❑ Yes ❑ No *No further questions*

26. What is the place in therapy in which the requested drug will be used?
❑ Initial treatment ❑ Subsequent treatment *If Subsequent, skip to #28*

27. Does the tumor express programmed death ligand 1 (PD-L1) of ≥50%? ***Action required: If 'Yes', attach supporting chart note(s) for PD-L1 expression*** ❑ Yes ❑ No ❑ Unknown *Any answer, skip to #29*

28. Does the tumor express programmed death ligand 1 (PD-L1) of ≥ 1%? ***Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.*** ❑ Yes ❑ No

29. What is the clinical setting in which the requested drug will be used?
❑ Recurrent disease ❑ Advanced disease ❑ Metastatic disease ❑ Other *Any answer, No further questions*

30. What is the patient's disease histology?
❑ Nonsquamous cell histology ❑ Squamous cell histology *Either answer, skip to #32*

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

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

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

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

35. Has the patient had a prior treatment with crizotinib, entrectinib, or ceritinib therapy?
If Yes or No, no further questions ❑ Yes ❑ No

36. Is there tumor response or stable disease following first-line pembrolizumab and pemetrexed plus cisplatin or carboplatin regimen? ❑ Yes ❑ No

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

38. Will the requested drug be used as maintenance therapy? ❑ Yes ❑ No

Section C: Prostate Cancer

39. Will the requested drug be used for treatment of castration-resistant distant metastatic prostate cancer?
❑ Yes ❑ No

40. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb])? ***Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high, mismatch repair deficient tumor or tumor mutational burden-high (TMB-H) ≥10 mutations/megabase status*** ❑ Yes ❑ No

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

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

Section D: Salivary gland tumors

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

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

45. Does the disease have tumor mutational burden-high tumors (TMB-H) (greater than or equal to 10 mutations per megabase [mut/Mb])? ***Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high tumor status.*** ❑ Yes ❑ No

Section E: Cutaneous Squamous Cell Carcinoma

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

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

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

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

49. Will the requested drug be used as a single agent? ❑ Yes ❑ No *If No, skip to #52*

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

51. Does the disease have tumor mutational burden-high tumors (TMB-H) (greater than or equal to 10 mutations per megabase [mut/Mb])? ***Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high tumor status.*** ❑ Yes ❑ No *No further questions*

52. 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 G: Classical Hodgkin Lymphoma

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

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

Section H: Urothelial Carcinoma - Bladder Cancer

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

56. What is the place in therapy in which the requested drug will be used?
❑ First-line treatment
❑ Subsequent treatment *Skip to #66*

57. Is the patient eligible for any platinum-containing chemotherapy? ❑ Yes ❑ No *If No, skip to #59*

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

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

60. 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 #63*
❑ Preserved bladder *Skip to #64*
❑ Stage IIIB disease *Skip to #65*
❑ Other

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

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

63. What is the clinical setting in which the requested drug will be used following cystectomy? *No further questions*
❑ Metastatic disease ❑ Local recurrence ❑ Other

64. 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

65. Will the requested drug be used as downstaging systemic therapy or following partial response or progression after primary treatment with concurrent chemoradiotherapy? ❑ Yes ❑ No *No further questions*

66. 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 #72* ❑ Yes ❑ No

67. 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 #69*
    ❑ Stage II disease *Skip to #70*
    ❑ Stage IIIA disease *Skip to #70*
    ❑ Stage IIIB disease *Skip to #71*
    ❑ Other

68. What is the clinical setting in which the requested drug will be used following cystectomy? *No further questions*
    ❑ Metastatic disease ❑ Local recurrence ❑ Other

69. 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

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

71. Is there partial response or progression after primary treatment with concurrent chemoradiotherapy?
    ❑ Yes ❑ No *No further questions*

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

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

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

Section I: Primary Carcinoma of the Urethra

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

76. What is the place in therapy in which the requested drug will be used?
    ❑ First-line treatment
    ❑ Subsequent treatment *Skip to #81*

77. What is the clinical setting in which the requested drug will be used?
    ❑ Recurrent disease
    ❑ Locally advanced disease
    ❑ Metastatic disease
    ❑ Other

78. Is the patient eligible for any platinum-containing chemotherapy? ❑ Yes ❑ No *If No, no further questions*

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

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

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

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

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

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

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

85. Is the patient eligible for any platinum-containing chemotherapy? ❑ Yes ❑ No *If No, no further questions*

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

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

Seciont K: Small Cell Lung Cancer

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

89. What is the clinical setting in which the requested drug will be used?
❑ Relapsed disease ❑ Progressive disease ❑ Other

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

Section L: Colorectal Cancer (including appendiceal carcinoma)

91. Will the requested drug be used as a single agent? ❑ 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

93. What is the clinical setting in which the requested drug will be used?
❑ Inoperable disease ❑ Advanced disease ❑ Metastatic disease ❑ Other

Section M: Malignant Pleural Mesothelioma

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

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

Section N: Merkel Cell Carcinoma

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

Section O: Gastric Cancer

97. What is the clinical setting in which the requested drug will be used?
❑ Unresectable locally advanced disease *Skip to #99*
❑ Recurrent disease *Skip to #99*
❑ Metastatic disease *Skip to #99*
❑ Other

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

99. 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 #104*
❑ Other

100. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb))? ***Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high, mismatch repair deficient tumor or high tumor mutational burden (≥10 mutations/megabase [mut/Mb]) status.*** ❑ Yes ❑ No *If No, skip to #102*

101. 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

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

103. 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

104. What is the patient's histology? ❑ Adenocarcinoma ❑ Other

105. Is the patient's disease HER2-positive? ***Action required: If 'Yes' please attach supporting documentation of laboratory report confirming HER2 status*** ❑ Yes ❑ No ❑ Unknown

Section P: Esophageal Cancer, including esophagogastric junction (EGJ) cancer

106. What is the clinical setting in which the requested drug will be used?
❑ Unresectable locally advanced disease *Skip to #108*
❑ Recurrent disease *Skip to #108*
❑ Metastatic disease *Skip to #108*
❑ Other

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

108. Will the requested drug be used in any of the following regimens?
❑ Combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy
❑ Combination with trastuzumab, platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy *Skip to #110*
❑ No *Skip to #111*

109. Is the tumor HER2 overexpression negative? ***Action required: If 'Yes', attach laboratory report confirming HER2 overexpression negative.*** ❑ Yes ❑ No *No further questions*

110. Is the tumor HER2 overexpression positive? ***Action required: If 'Yes', attach laboratory report confirming HER2 overexpression positive.*** ❑ Yes ❑ No *No further questions*

111. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb))? ***Action required: If 'Yes', please attach laboratory report confirming microsatellite instability-high, mismatch repair deficient or mutational burden (TMB) high (≥10 mutations/megabase) tumor status.*** ❑ Yes ❑ No *If No, skip to #114*

112. What is the place in therapy in which the requested drug will be used?
❑ First-line treatment ❑ Second-line or subsequent treatment

113. Will the requested drug be used as a single agent? ❑ Yes ❑ No *No further questions*

114. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of ≥ 10? ***Action required: If 'Yes', please attach supporting chart note(s) for PD-L1 expression.***
❑ Yes ❑ No *If No, skip to #117*

115. What is the place in therapy in which the requested drug will be used?
❑ First-line treatment ❑ Second-line or subsequent treatment

116. Does the patient's disease express squamous or nonsquamous histology?
❑ Squamous *No further questions*
❑ Nonsquamous *Skip to #118*

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

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

119. 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 Q: Cervical Cancer

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

121. Does the patient's disease meet any of the following? ***Action required: attach laboratory report confirming programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1, microsatellite instability-high tumor status, mismatch repair deficient tumor status, or tissue tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]).***
❑ Tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
❑ Tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1 *Skip to #123*
❑ Tissue tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) *Skip to #126*
❑ None of the above

122. Will the requested drug be used as a single agent? ❑ Yes ❑ No *Skip to #125*

123. Will the requested drug be used as part of any of the following regimens?
❑ As a single agent
❑ In combination with chemotherapy *Skip to #125*
❑ Other

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

125. What is the clinical setting in which the requested drug will be used?
❑ Persistent disease ❑ Recurrent disease ❑ Metastatic disease ❑ Other *No further questions*

126. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

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

Section R: Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential with invasive implants)

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

130. What is the clinical setting in which the requested drug will be used?
❑ Recurrent disease ❑ Persistent disease ❑ Other

131. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H) (tumors ≥10 mutations/megabase [mut/Mb])? ***Action required: If 'Yes', please attach laboratory report confirming tumor mutational burden-high tumor status, microsatellite instability-high or mismatch repair deficient tumor status.*** ❑ Yes ❑ No

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

Section S: Uveal Melanoma

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

134. What is the clinical setting in which the requested drug will be used?
❑ Distant metastatic disease ❑ Other

Section T: Testicular Cancer

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

136. 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

137. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H) (tumors ≥10 mutations/megabase [mut/Mb])? ***Action required: If 'Yes', please attach laboratory report confirming tumor mutational burden-high tumor status, microsatellite instability-high or mismatch repair deficient tumor status.*** ❑ Yes ❑ No

Section U: Endometrial Carcinoma

138. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (tumors ≥10 mutations/megabase [mut/Mb])? ***Action required: Attach laboratory report confirming tumor mutational burden-high (TMB-H), microsatellite instability-high or mismatch repair deficient tumor status for both 'Yes' and 'No' options.***
    ❑ Yes, the tumor microsatellite instability-high (MSI-H)
    ❑ Yes, mismatch repair deficient (dMMR)
    ❑ Yes, tumor mutational burden-high (TMB-H)(tumors ≥10 mutations/megabase [mut/Mb]) *Skip to #145*
    ❑ No *Skip to #141*

139. What is the clinical setting in which the requested drug will be used?
    ❑ Recurrent disease ❑ Metastatic disease ❑ High-risk disease ❑ Other

140. Has the disease progressed following prior systemic therapy? ❑ Yes ❑ No *No further questions*

141. What is the clinical setting in which the requested drug will be used?
    ❑ Advanced disease ❑ Recurrent disease ❑ Other

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

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

144. Will the requested drug be used in combination with lenvatinib? ❑ Yes ❑ No *No further questions*

145. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

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

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

Section V: Anal Carcinoma

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

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

151. What is the place in therapy in which the requested drug will be used?
    ❑ First-line treatment ❑ Second-line or subsequent treatment

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

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

153. What type of underlying cancer does the patient have?
    ❑ Melanoma *No further questions*
    ❑ Non-small cell lung cancer
    ❑ Other

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

Section X: Primary Mediastinal Large B-cell Lymphoma

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

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

Section Y: Pancreatic Adenocarcinoma

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

158. 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

159. Does the patient have poor performance status? ❑ Yes ❑ No *If No, skip to #162*

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

161. What is the clinical setting in which the requested drug will be used? *No further questions*
❑ Metastatic disease ❑ Other

162. 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*
❑ Recurrent metastatic disease *No further questions*
❑ Other

163. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

Section Z: Hepatobiliary Cancers, including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer

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

166. 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

167. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

Section AA: Hepatocellular Carcinoma

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

Section BB: Vulvar Cancer

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

171. What is the place in therapy in which the requested drug will be used?
❑ First-line treatment ❑ Second-line or subsequent treatment

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

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

174. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb])? ***Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high (TMB-H), microsatellite instability-high or mismatch repair deficient tumor status***.
❑ Yes, tumor microsatellite instability-high (MSI-H) *No further questions*
❑ Yes, mismatch repair deficient (dMMR) *No further questions*
❑ Yes, tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) Skip *to #177*
❑ No

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

176. Has the patient experienced disease progression on or after chemotherapy? ❑ Yes ❑ No *No further questions*

177. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

Section CC: Renal Cell Carcinoma

179. Will the requested drug be used as part of any of the following regiments?
- ❑ As a single agent
- ❑ In combination with axitinib *Skip to #182*
- ❑ In combination with Lenvatinib *Skip to #182*
- ❑ Other *Skip to #186*

180. What is the clinical setting in which the requested drug will be used?
❑ Relapsed disease ❑ Stage IV disease ❑ Other

181. Does the tumor express non-clear cell histology? ❑ Yes ❑ No *No further questions*

182. What is the place in therapy in which the requested drug will be used?
- ❑ First-line treatment
- ❑ Subsequent treatment *Skip to #184*

183. What is the clinical setting in which the requested drug will be used? *No further questions*
❑ Advanced disease ❑ Recurrent disease ❑ Stage IV disease ❑ Other

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

185. What is the clinical setting in which the requested drug will be used? *No further questions*
❑ Relapsed disease ❑ Stage IV disease ❑ Other

186. Will the requested drug be used as adjuvant treatment? ❑ Yes ❑ No

187. What is the clinical setting in which the requested drug will be used for adjuvant treatment?
- ❑ Intermediate-high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions
- ❑ High risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions
- ❑ Other

Section DD: Thymic Carcinoma

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

189. What is the clinical setting in which the requested drug will be used?
❑ Unresectable disease ❑ Locally advanced disease ❑ Metastatic disease ❑ Other

190. Will the requested drug be used as postoperative therapy for residual tumor in member who cannot tolerate first-line combination regimens? ❑ Yes ❑ No

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

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

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

Section FF: Gestational Trophoblastic Neoplasia

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

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

195. What type of disease does the patient have?
- ❑ Intermediate trophoblastic tumor
- ❑ High-risk disease *No further questions*
- ❑ Other

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

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

Section GG: Neuroendocrine and Adrenal Tumors

198. What is the clinical setting in which the requested drug will be used?
- ❑ Poorly differentiated large or small cell carcinoma
- ❑ Well differentiated grade 3 neuroendocrine tumors *Skip to #200*
- ❑ Adrenocortical carcinoma *Skip to #204*
- ❑ Other

199. 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 #202* ❑ Yes ❑ No *If No, skip to #201*

200. What is the clinical setting in which the requested drug will be used*?*
❑ Locally advanced disease ❑ Metastatic disease ❑ Other

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

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

203. Are there other satisfactory alternative treatment options available for the patient?
❑ Yes ❑ No *No further questions*

204. What is the clinical setting in which the requested drug will be used?
- ❑ Unresectable disease
- ❑ Metastatic disease
- ❑ Other

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

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

206. 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 II: Occult Primary Cancer

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

208. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb])? ***Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high microsatellite instability-high or mismatch repair.*** ❑ Yes ❑ No

Section JJ: Anaplastic Thyroid Carcinoma

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

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

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

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

212. What is the clinical setting in which the requested drug will be used?
❑ Unresectable disease
❑ Metastatic disease *Skip to #214*
❑ Other

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

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

Section LL: Medullary Thyroid Carcinoma

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

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

Section MM: Small Bowel Adenocarcinoma, including Advanced Ampullary Cancer

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

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

219. 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 NN: Breast Cancer

220. 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 *If No, skip to #227* ❑ Unknown

221. 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 #224*
❑ Other

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

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

224. What is the place in therapy in which the requested drug will be used?
❑ Neoadjuvant treatment
❑ Continued adjuvant treatment after surgery *Skip to #226*
❑ Other

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

226. Will the requested drug be used as a single agent? ❑ Yes ❑ No *No further questions*

227. Are the tumors microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tissue tumor mutation burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb])? ***Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high (TMB-H), microsatellite instability-high or mismatch repair deficient tumor status.*** ❑ Yes ❑ No

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

229. Hare the disease progressed following prior treatment? ❑ Yes ❑ No

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

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

Section OO: Bone cancer (Chondrosarcoma, Ewing Sarcoma, Osteosarcoma, Chordoma)

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

233. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

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

236. Are the tumors microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tissue tumor mutation burden-high (TMB-H) (≥10 mutations/megabase (mut/Mb))? ***Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high (TMB-H), microsatellite instability-high or mismatch repair deficient tumor status***. ❑ Yes ❑ No

Section PP: Penile Cancer

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

238. 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

239. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

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

Section QQ: Uterine Sarcoma

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

243. Is the tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)]? Action required: If 'Yes', attach laboratory report confirming tumor mutational burden-high (TMB-H) tumor status. ❑ Yes ❑ No

244. Has the disease progressed following prior treatment? ❑ Yes ❑ No

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

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

Section RR: Continuation of Therapy

247. What is the diagnosis? *List continues on next page*

- ❑ Cutaneous melanoma *Skip to #251*
- ❑ Non-small cell lung cancer
- ❑ Cutaneous squamous cell carcinoma
- ❑ Head and neck squamous cell cancer
- ❑ Classical Hodgkin lymphoma
- ❑ Bladder cancer *Skip to #256*
- ❑ 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 #254*
- ❑ Merkel Cell Carcinoma
- ❑ Gastric cancer
- ❑ Esophageal cancer
- ❑ Cervical cancer
- ❑ Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma, mucinous carcinoma, grade 1 endometrioid carcinoma, low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential with invasive implants)
- ❑ Uveal melanoma *Skip to #254*
- ❑ Testicular cancer
- ❑ Endometrial carcinoma
- ❑ Anal carcinoma *Skip to #254*
- ❑ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer *Skip to #254*
- ❑ Primary mediastinal large B-cell lymphoma
- ❑ Pancreatic adenocarcinoma
- ❑ Hepatobiliary cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer)
- ❑ Hepatocellular carcinoma
- ❑ Vulvar cancer *Skip to #255*
- ❑ Renal cell carcinoma *Skip to #250*
- ❑ Thymic carcinoma *Skip to #254*
- ❑ Mycosis fungoides or Sezary syndrome *Skip to #254*
- ❑ Extranodal NK/T-cell lymphoma *Skip to #254*
- ❑ Gestational trophoblastic neoplasia *Skip to #254*
- ❑ Neuroendocrine tumors
- ❑ Adrenal tumors *Skip to #254*
- ❑ Salivary gland tumors
- ❑ 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 #254*
- ❑ 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 #251*
- ❑ Breast cancer
- ❑ Esophagogastric junction cancer
- ❑ Prostate cancer
- ❑ Bone cancer (Chondrosarcoma, Ewing Sarcoma, Osteosarcoma, Chordoma)

❑ Penile cancer
❑ Uterine sarcoma
❑ Small cell lung cancer *Skip to #254*
❑ Other

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

249. How many continuous months of treatment has the patient received with the requested drug? _____ months
No further questions

250. Is the request for the adjuvant treatment of renal cell carcinoma? ❑ Yes ❑ No *If No, skip to #258*

251. Is the requested drug prescribed for the treatment of adjuvant melanoma or adjuvant high-risk early-stage TNBC?
❑ Yes ❑ No *If No, skip to #254*

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

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

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

255. 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 #258*
❑ PD-L1 expression with CPS score greater than or equal to 1 *Go back to #254*

256. Is the requested drug prescribed for the treatment of high-risk BCG-unresponsive non-muscle invasive bladder cancer? ❑ Yes ❑ No *If No, skip to #258*

257. Is the disease persistent or recurrent? ❑ Yes ❑ No

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

259. 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