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*

Site of Service Questions (SOS):

A. Indicate the site of service requested:
- ❑ On Campus Outpatient Hospital
- ❑ Off Campus Outpatient Hospital
- ❑ Home infusion, *skip to Criteria Questions*
- ❑ Physician office, *skip to Criteria Questions*
- ❑ Ambulatory surgical, *skip to Criteria Questions*
- ❑ Pharmacy, *skip to Criteria Questions.*

B. Is the patient less than 14 years of age? *If Yes, skip to Clinical Criteria Questions* ❑ Yes ❑ No

C. Is the patient receiving provider-administered combination oncology therapy or other provider-administered drug therapies at the same visit? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation***.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

D. Is this request to continue previously established treatment with the requested regimen?

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

❑ No – This is a new therapy request (patient has not received 6 months or more of requested regimen). *Skip to Clinical Criteria Questions*
❑ Yes – This is a continuation of existing treatment (patient has received requested regimen for 6 months). *Skip to Clinical Criteria Questions*
❑ Yes – This is a continuation of an existing treatment (patient has received requested regimen for 7 months or greater – initial 6 months plus 45 days grace period).

E. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, or other pre- medications or slowing of the infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Has the patient experienced severe toxicity requiring continuous monitoring (e.g. Grade 2-4 bullous dermatitis, transaminitis, pneumonitis, Stevens-Johnson syndrome, acute pancreatitis, primary adrenal insufficiency aseptic meningitis, encephalitis, transverse myelitis, myocarditis, pericarditis, arrhythmias, impaired ventricular function, or conduction abnormalities)? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation***.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

H. Does the patient have severe venous access issues that require the use of a special intervention only available in the outpatient hospital setting? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

I. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation. ❑ Yes ❑ No

Clinical Criteria Questions:

1. 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, *Continue to #2*

❒ No, *Continue to #5*

2. Is the requested drug prescribed as second-line or subsequent treatment for metastatic or unresectable melanoma?

❒ Yes, *Continue to #3*

❒ No, *Continue to #3*

3. Will the requested drug be used in combination with ipilimumab following disease progression on single agent anti-PD-1 immunotherapy?

❒ Yes, *Continue to #4*

❒ No, *Continue to #4*

4. Is this request for initiation or continuation of treatment with the requested medication?

❒ Initiation, *No Further Questions*

❒ Continuation, *Continue to #900*

5. 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, *Continue to #6*

❒ Yes, TMB-H CNS cancer, *Continue to #6*

❒ No, *Continue to #6*

6. Is the patient currently receiving treatment with the requested medication?

❒ Yes, *Continue to #900*

❒ No, *Continue to #7*

7. Does the patient have a solid tumor [including salivary gland tumors, endometrial carcinoma, vulvar cancer, poorly differentiated large or small cell carcinoma, well differentiated grade 3 neuroendocrine tumors, myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), cutaneous angiosarcoma, undifferentiated sarcoma, breast cancer, bone cancer (chondrosarcoma, chordoma, Ewing sarcoma, osteosarcoma), penile cancer or uterine sarcoma] that meets any of the following criteria? ***Action required***: If 'Yes', attach chart note(s) or test results 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, *Continue to #8*

❒ Mismatch repair deficient (dMMR) solid tumor, *Continue to #8*

❒ Tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) solid tumor, *Continue to #8*

❒ None of the above, *Continue to #12*

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

❒ Yes, *Continue to #9*

❒ No, *Continue to #9*

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

❒ Unresectable disease, *Continue to #10*

❒ Metastatic disease, *Continue to #10*

❒ Other, *Continue to #10*

10. Has the patient experienced disease progression following prior treatment?

❒ Yes, *Continue to #11*

❒ No, *Continue to #11*

11. Are there other satisfactory alternative treatment options available for the patient?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

12. What is the diagnosis?

❒ Cutaneous melanoma, *Continue to #13*

❒ Non-small cell lung cancer, *Continue to #20*

❒ Cutaneous squamous cell carcinoma, *Continue to #65*

❒ Head and neck squamous cell carcinoma with mixed subtypes (HNSCC) and nasopharyngeal cancer, *Continue to #70*

❒ Classical Hodgkin lymphoma, *Continue to #80*

❒ Urothelial carcinoma, *Continue to #90*

❒ Anaplastic thyroid carcinoma, *Continue to #490*

❒ Follicular, hürthle cell, or papillary thyroid carcinoma, *Continue to #500*

❒ Medullary thyroid carcinoma, *Continue to #510*

❒ Colorectal cancer (including appendiceal carcinoma), *Continue to #160*

❒ Small Bowel Adenocarcinoma, *Continue to #520*

❒ Merkel Cell Carcinoma, *Continue to #190*

❒ Gastric cancer, *Continue to #200*

❒ Esophageal cancer and Esophagogastric Junction Cancer, *Continue to #220*

❒ Cervical cancer, *Continue to #240*

❒ Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma, *Continue to #250*

❒ Uveal melanoma, *Continue to #260*

❒ Testicular cancer, *Continue to #270*

❒ Endometrial carcinoma, *Continue to #280*

❒ Anal carcinoma, *Continue to #291*

❒ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer, *Continue to #300*

❒ Primary mediastinal large B-cell lymphoma, *Continue to #310*

❒ Pancreatic adenocarcinoma, *Continue to #320*

❒ Hepatobiliary cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer), *Continue to #330*

❒ Hepatocellular carcinoma, *Continue to #350*

❒ Vulvar cancer, *Continue to #360*

❒ Renal cell carcinoma, *Continue to #380*

❒ Thymic carcinoma, *Continue to #390*

❒ Primary Cutaneous Lymphomas, *Continue to #395*

❒ Extranodal NK/T-cell lymphoma, *Continue to #410*

❒ Gestational trophoblastic neoplasia, *Continue to #420*

❒ Neuroendocrine and Adrenal Tumors (adrenocortical carcinoma), *Continue to #440*

❒ Soft Tissue Sarcomas, *Continue to #450*

❒ Breast Cancer (TNBC), *Continue to #600*

❒ Occult primary cancer, *Continue to #470*

❒ Prostate cancer, *Continue to #40*

❒ Small cell lung cancer, *Continue to #140*

❒ Pediatric Diffuse High-Grade Gliomas, *Continue to #610*

❒ Ampullary adenocarcinoma, *Continue to #120*

❒ Kaposi sarcoma, *Continue to #615*

❒ Other, *No Further Questions*

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

❒ Adjuvant treatment, *Continue to #14*

❒ Unresectable disease, *Continue to #15*

❒ Recurrent disease, *Continue to #15*

❒ Metastatic disease, *Continue to #15*

❒ Subsequent therapy, *Continue to #16*

❒ Other, *No Further Questions*

14. Has the patient had a complete lymph node surgical resection or complete resection of stage IIB, IIC, III or metastatic disease?

❒ Yes, *Continue to #15*

❒ No, *Continue to #15*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

16. Will the requested drug be used for disease progression of metastatic or unresectable tumors?

❒ Yes, *Continue to #17*

❒ No, *Continue to #17*

17. Will the requested drug be used in any of the following regimens?

❒ Single agent, *No Further Questions*

❒ In combination with ipilimumab, *No Further Questions*

❒ Other, *No Further Questions*

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

❒ Recurrent disease, *Continue to #21*

❒ Advanced disease, *Continue to #21*

❒ Metastatic disease, *Continue to #21*

❒ Stage IB (T2a ≥4 cm), *Continue to #31*

❒ Stage II, *Continue to #31*

❒ Stage IIIA, *Continue to #31*

❒ Other, *No Further Questions*

21. Is the tumor negative for EGFR exon 19 deletions, L858R mutations and ALK rearrangements? ***ACTION REQUIRED****: If Yes, please attach chart note(s) or test results of EGFR exon 19 deletions, L858R mutations, and ALK rearrangements, where applicable*

❒ Yes, *Continue to #23*

❒ No, *Continue to #28*

❒ Unknown, *Continue to #22*

22. Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?

❒ Yes, *Continue to #23*

❒ No, *Continue to #28*

23. Will the requested drug be used in any of the following regimens?

❒ As first-line therapy, *Continue to #24*

❒ As maintenance therapy, *Continue to #25*

❒ In combination with pemetrexed and either carboplatin or cisplatin, *Continue to #26*

❒ In combination with carboplatin and either paclitaxel or albumin-bound paclitaxel, *Continue to #27*

❒ Other, *No Further Questions*

24. Does the patient have programmed death ligand 1 (PDL1) positive disease? ***ACTION REQUIRED****: Please attach chart note(s) or test results of programmed death ligand 1 (PD-L1) tumor expression*

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

26. What is the patient's disease histology?

❒ Nonsquamous cell histology, *No Further Questions*

❒ Squamous cell histology, *No Further Questions*

27. What is the patient's disease histology?

❒ Nonsquamous cell histology, *No Further Questions*

❒ Squamous cell histology, *No Further Questions*

28. Is the tumor programmed death ligand 1 (PD-L1) positive? ***Action required***: If 'Yes', attach chart note(s) or test results for PD-L1 expression

❒ Yes, *Continue to #29*

❒ No, *Continue to #29*

❒ Unknown, *Continue to #29*

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

❒ Yes, *Continue to #30*

❒ No, *Continue to #30*

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

❒ First-line treatment, *No Further Questions*

❒ Subsequent treatment, *No Further Questions*

31. Will the requested drug be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin)?

❒ Yes, *Continue to #32*

❒ No, *Continue to #32*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

40. Will the requested drug be used for treatment of castration-resistant distant metastatic prostate cancer?

❒ Yes, *Continue to #41*

❒ No, *Continue to #41*

41. 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 chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient tumor or tumor mutational burden-high (TMB-H) ≥10 mutations/megabase status

❒ Yes, *Continue to #42*

❒ No, *Continue to #42*

❒ Unknown, *Continue to #42*

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

❒ First-line treatment, *Continue to #43*

❒ Subsequent treatment, *Continue to #43*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Yes, *Continue to #66*

❒ No, *Continue to #66*

66. Is the disease curable by surgery or radiation?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Very advanced disease, *Continue to #71*

❒ Other, *Continue to #71*

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

❒ Yes, *Continue to #72*

❒ No, *Continue to #74*

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

❒ First-line treatment, *Continue to #73*

❒ Subsequent treatment, *No Further Questions*

73. Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1, are microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [≥ 10 mut/Mb]? ***Action required***: If 'Yes', attach chart note(s) or test results for PD-L1 expression, microsatellite instability-high, mismatch repair deficient or tumor mutational burden high status

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

74. Will the requested drug be used as part of any of the following regimens?

❒ In combination with chemotherapy, *No Further Questions*

❒ Other, *No Further Questions*

Classical Hodgkin lymphoma

80. Will the requested drug be used in any of the following regimens?

❒ Single agent, *Continue to #81*

❒ In combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin), *Continue to #81*

❒ Other, *Continue to #81*

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

❒ Refractory disease, *No Further Questions*

❒ Relapsed disease, *No Further Questions*

❒ Progressive disease, *No Further Questions*

❒ Other, *No Further Questions*

Urothelial carcinoma

90. What is the requested regimen?

❒ As a single agent, *Continue to #91*
❒ In combination with enfortumab vedotin (Padcev), *Continue to #103*
❒ Other, *No Further Questions*

91. Which of the following applives to the patient's disease?

❒ Urothelial carcinoma of the bladder, *Continue to #92*
❒ Primary carcinoma of the urethra, *Continue to #99*
❒ Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate, *Continue to #101*
❒ Other, *No Further Questions*

92. What is the place in therapy in which the requested drug will be used?
❒ First-line treatment, *Continue to #93*
❒ Subsequent treatment, *Continue to #95*

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

❒ Locally advanced disease, *Continue to #94*

❒ Metastatic disease, *Continue to #94*

❒ Other, *Continue to #94*

94. Is the patient eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

95. Is the requested drug prescribed for the treatment of high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)?

❒ Yes, *Continue to #96*

❒ No, *No Further Questions*

96. Is the disease responsive to Bacillus Calmette-Guerin (BCG)?

❒ Yes, *Continue to #97*

❒ No, *Continue to #97*

97. Is the patient eligible for cystectomy?

❒ Yes, *Continue to #98*

❒ No, *No Further Questions*

98. Has the patient elected not to undergo cystectomy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

99. What is the clinical setting in which the requested drug will be used?
❒ Recurrent disease, *Continue to #100*
❒ Locally advanced disease, *Continue to #100*
❒ Metastatic disease, *Continue to #100*
❒ Other, *Continue to #100*

100. Is the patient eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

101. What is the clinical setting in which the requested drug will be used*?*
❒ Metastatic disease, *Continue to #102*
❒ Other, *Continue to #102*

102. Is the patient eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

103. What is the clinical setting in which the requested drug will be used?
❒ Locally advanced disease, *Continue to #104*
❒ Metastatic disease, *Continue to #104*
❒ Other, *Continue to #104*

104. Is the patient eligible for cisplatin containing chemotherapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Ampullary adenocarcinoma

120. 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', attach chart note(s) or test Results confirming microsatellite instability-high, mismatch repair deficient tumor or high tumor mutational burden (≥10 mutations/megabase [mut/Mb]) status

❒ Yes, *Continue to #121*

❒ No, *Continue to #121*

❒ Unknown, *Continue to #121*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Small cell lung cancer

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

❒ Yes, *Continue to #141*

❒ No, *Continue to #141*

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

❒ Relapsed disease, *Continue to #142*

❒ Progressive disease, *Continue to #142*

❒ Other, *Continue to #142*

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

❒ First-line treatment, *No Further Questions*

❒ Subsequent treatment, *No Further Questions*

Colorectal cancer (including appendiceal carcinoma)

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

❒ Yes, *Continue to #161*

❒ No, *Continue to #161*

161. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? ***Action required***: If 'Yes', attach chart note(s) or test results confirming microsatellite instability-high or mismatch repair deficient tumor status

❒ Yes, *Continue to #162*

❒ No, *Continue to #162*

❒ Unknown, *Continue to #162*

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

❒ Inoperable disease, *No Further Questions*

❒ Advanced disease, *No Further Questions*

❒ Metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

Merkel Cell Carcinoma

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

❒ Recurrent disease, *No Further Questions*

❒ Metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

Gastric cancer

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

❒ Unresectable locally advanced disease, *Continue to #202*

❒ Recurrent disease, *Continue to #202*

❒ Metastatic disease, *Continue to #202*

❒ Other, *Continue to #201*

201. Is the patient a surgical candidate?

❒ Yes, *Continue to #202*

❒ No, *Continue to #202*

202. Will the requested drug be used as part of any of the following regimens?

❒ Single agent, *Continue to #203*

❒ In combination with trastuzumab, platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy, *Continue to #205*

❒ Other, *No Further Questions*

203. 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', attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient tumor or high tumor mutational burden (≥10 mutations/megabase [mut/Mb]) status

❒ Yes, *Continue to #204*

❒ No, *Continue to #204*

❒ Unknown, *Continue to #204*

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

❒ First-line treatment, *No Further Questions*

❒ Subsequent treatment, *No Further Questions*

205. What is the patient's histology?

❒ Adenocarcinoma, *Continue to #206*

❒ Other, *Continue to #206*

206. Is the patient's disease HER2-positive? ***Action required***: If 'Yes' attach chart note(s) or test results confirming HER2 status

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

Esophageal cancer, including esophagogastric junction (EGJ) cancer

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

❒ Unresectable locally advanced disease, *Continue to #222*

❒ Recurrent disease, *Continue to #222*

❒ Metastatic disease, *Continue to #222*

❒ Other, *Continue to #221*

221. Is the patient a surgical candidate?

❒ Yes, *Continue to #222*

❒ No, *Continue to #222*

222. 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, *Continue to #223*

❒ Combination with trastuzumab, platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy, *Continue to #225*

❒ No, *Continue to #226*

223. Is the tumor HER2 overexpression negative adenocarcinoma? ***Action required***: If 'Yes', attach chart note(s) or test results confirming HER2 overexpression negative

❒ Yes, *No Further Questions*

❒ No, *Continue to #224*

❒ Unknown, *Continue to #224*

224. Does the patient's disease express squamous or non-squamous histology?

❒ Squamous cell carcinoma, *No Further Questions*

❒ Non- squamous cell carcinoma, *No Further Questions*

225. Is the tumor HER2 overexpression positive? ***Action required***: If 'Yes', attach chart note(s) or test results confirming HER2 overexpression positive

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

226. 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', attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient or mutational burden (TMB) high (≥10 mutations/megabase) tumor status

❒ Yes, *Continue to #227*

❒ No, *Continue to #229*

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

❒ First-line treatment, *Continue to #228*

❒ Subsequent treatment, *Continue to #228*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

229. 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 chart note(s) or test results for PD-L1 expression

❒ Yes, *Continue to #230*

❒ No, *Continue to #230*

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

❒ First-line treatment, *Continue to #231*

❒ Subsequent treatment, *Continue to #231*

231. Does the patient's disease express squamous or nonsquamous histology?

❒ Squamous cell carcinoma, *No Further Questions*

❒ Nonsquamous cell carcinoma, *No Further Questions*

Cervical cancer

240. Will the requested drug be used as part of any of the following regimens?

❒ As a single agent, *Continue to #242*

❒ In combination with chemotherapy, *Continue to #241*

❒ Other, *No Further Questions*

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

❒ Persistent disease, *Continue to #244*

❒ Recurrent disease, *Continue to #244*

❒ Metastatic disease, *Continue to #244*

❒ Other, *Continue to #244*

242. Has the patient experienced disease progression on or after chemotherapy?

❒ Yes, *Continue to #243*

❒ No, *Continue to #245*

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

❒ Recurrent disease, *Continue to #244*

❒ Metastatic disease, *Continue to #244*

❒ Other, *Continue to #244*

244. Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1? ***Action required***: If 'Yes', attach chart note(s) or test results for PD-L1 expression

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

245. Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1 or microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? ***Action required***: If 'Yes', attach chart note(s) or test results confirming PD-L1 expression, microsatellite instability-high or mismatch repair deficient status

❒ Yes, *Continue to #246*

❒ No, *Continue to #246*

❒ Unknown, *Continue to #246*

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

❒ Persistent disease, *Continue to #247*

❒ Recurrent disease, *Continue to #247*

❒ Metastatic disease, *Continue to #247*

❒ Other, *Continue to #247*

247. Will the requested drug be used as subsequent therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma

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

❒ Yes, *Continue to #251*

❒ No, *Continue to #251*

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

❒ Recurrent disease, *Continue to #252*

❒ Persistent disease, *Continue to #252*

❒ Other, *Continue to #252*

252. 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', attach chart note(s)

or test results confirming tumor mutational burden-high tumor status, microsatellite instability-high or mismatch repair deficient tumor status

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

Uveal melanoma

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

❒ Yes, *Continue to #261*

❒ No, *Continue to #261*

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

❒ Distant metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

Testicular cancer

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

❒ Yes, *Continue to #271*

❒ No, *Continue to #271*

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

❒ First-line treatment, *Continue to #272*

❒ Second-line treatment, *Continue to #272*

❒ Third-line or subsequent treatment, *Continue to #272*

272. 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', attach chart note(s) or test results confirming tumor mutational burden-high tumor status, microsatellite instability-high or mismatch repair deficient tumor status

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

Endometrial carcinoma

280. Will the requested medication be used in combination with carboplatin and paclitaxel?

❒ Yes, *Continue to #281*

❒ No, *Continue to #282*

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

❒ Recurrent disease, *No Further Questions*

❒ Stage III-IV disease, *No Further Questions*

❒ Other, *No Further Questions*

282. Will the requested drug be used in combination with lenvatinib (Lenvima)?

❒ Yes, *Continue to #283*

❒ No, *Continue to #284*

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

❒ Advanced disease, *Continue to #284*
❒ Metastatic disease, *Continue to #284*
❒ Recurrent disease, *Continue to #284*
❒ Other, *Continue to #284*

284. Which of the following applies to the patient's disease? ***Action Required: Attach chart note(s) or test results confirming mismatch repair proficient, microsatellite instability-high, mismatch repair deficient, or mutational burden-high tumor status***

❒ Mismatch repair proficient (pMMR) tumors, *No Further Questions*
❒ Microsatellite instability-high (MSI-H) tumor, *Continue to #286*
❒ Mismatch repair deficient (dMMR) tumor, *Continue to #285*
❒ Tumor mutational burden-high (TMB-H) (>= 10 mutations/megabase [mut/MB]) tumor, *Continue to #286*

285. Has the patient experienced disease progression following prior platinum-based chemotherapy?

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ Recurrent unresectable disease, *Continue to #287*
❒ Metastatic disease, *Continue to #287*
❒ Other, *Continue to #287*

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

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Anal carcinoma

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

❒ Yes, *Continue to #292*
❒ No, *Continue to #292*

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

❒ Metastatic disease, *Continue to #293*
❒ Other, *Continue to #293*

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

❒ First-line treatment, *No Further Questions*
❒ Subsequent treatment, *No Further Questions*

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

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

❒ Yes, *Continue to #301*
❒ No, *Continue to #301*

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

❒ Melanoma, *No Further Questions*

❒ Non-small cell lung cancer, *Continue to #302*

❒ Other, *Continue to #302*

302. Is the patient's disease positive for programmed death ligand 1 (PD-L1)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Primary mediastinal large B-cell lymphoma

310. Will the requested drug be used as part of any of the following regimens?

❒ As a single agent, *Continue to #311*

❒ In combination with brentuximab vedotin (Adcetris), *Continue to #311*

❒ Other, *Continue to #311*

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

❒ Relapsed disease, *No Further Questions*

❒ Refractory disease, *No Further Questions*

❒ Other, *No Further Questions*

Pancreatic adenocarcinoma

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

❒ Yes, *Continue to #321*

❒ No, *Continue to #321*

321. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb]? ***Action required***: If 'Yes', attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient tumor, or tumor mutational burden high status

❒ Yes, *Continue to #322*

❒ No, *Continue to #322*

❒ Unknown, *Continue to #322*

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

❒ Local recurrence in the pancreatic operative bed after resection, *No Further Questions*

❒ Recurrent metastatic disease, *No Further Questions*

❒ Other, *Continue to #323*

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

❒ First-line therapy, *Continue to #324*

❒ Subsequent therapy, *Continue to #325*

❒ Maintenance therapy, *Continue to #324*

❒ Other, *No Further Questions*

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

❒ Metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

325. Has the disease progressed following prior treatment?

❒ Yes, *Continue to #326*

❒ No, *Continue to #326*

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

❒ Locally advanced disease, *No Further Questions*

❒ Metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

Hepatobiliary cancers, including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer

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

❒ Yes, *Continue to #331*

❒ No, *Continue to #331*

331. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? ***Action required***: If 'Yes', attach chart note(s) or test results confirming microsatellite instability-high or mismatch repair deficient tumor status

❒ Yes, *Continue to #332*

❒ No, *Continue to #332*

❒ Unknown, *Continue to #332*

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

❒ Unresectable disease, *No Further Questions*

❒ Metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

Hepatocellular carcinoma

350. Has the patient previously been treated with sorafenib (Nexavar)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Vulvar cancer

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

❒ Yes, *Continue to #361*

❒ No, *Continue to #361*

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

❒ First-line treatment, *Continue to #362*

❒ Subsequent treatment, *Continue to #362*

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

❒ Advanced disease, *Continue to #363*

❒ Recurrent disease, *Continue to #363*

❒ Metastatic disease, *Continue to #363*

❒ Other, *Continue to #363*

363. Does the disease express squamous or nonsquamous histology?

❒ Squamous, *Continue to #364*

❒ Nonsquamous, *Continue to #364*

364. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [≥ 10 mut/Mb]? ***Action required***: If 'Yes', attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient tumor or tumor mutational burden high 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 mut/Mb], *No Further Questions*

❒ No, *Continue to #365*

365. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1? ***Action required***: If 'Yes', attach chart note(s) or test results for PD-L1 expression

❒ Yes, *Continue to #366*

❒ No, *Continue to #366*

❒ Unknown, *Continue to #366*

366. Has the patient experienced disease progression on or after chemotherapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Renal cell carcinoma

380. Will the requested drug be used as part of any of the following regimens?

❒ As a single agent, *Continue to #381*

❒ In combination with axitinib (Inlyta), *Continue to #383*

❒ In combination with Lenvatinib (Lenvima), *Continue to #383*

❒ Other, *No Further Questions*

381. How will the requested drug be used?

❒ For treatment of relapsed disease, *Continue to #382*

❒ For treatment of stage IV disease, *Continue to #382*

❒ As adjuvant therapy, *Continue to #387*

❒ Other, *No Further Questions*

382. Does the tumor express non-clear cell histology?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ First-line treatment, *Continue to #384*

❒ Subsequent treatment, *Continue to #385*

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

❒ Advanced disease, *No Further Questions*

❒ Relapsed disease, *No Further Questions*

❒ Stage IV disease, *No Further Questions*

❒ Other, *No Further Questions*

385. Does the tumor express clear cell histology?

❒ Yes, *Continue to #386*

❒ No, *Continue to #386*

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

❒ Relapsed disease, *No Further Questions*

❒ Stage IV disease, *No Further Questions*

❒ Other, *No Further Questions*

387. 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, *No Further Questions*

❒ High risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions, *No Further Questions*

❒ Other, *No Further Questions*

Thymic carcinoma

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

❒ Yes, *Continue to #391*

❒ No, *Continue to #391*

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

❒ Unresectable disease, *No Further Questions*

❒ Locally advanced disease, *No Further Questions*

❒ Metastatic disease, *No Further Questions*

❒ Other, *Continue to #392*

392. Will the requested drug be used as postoperative therapy for residual tumor in member who cannot tolerate first-line combination regimens?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Primary Cutaneous Lymphomas

395. Which of the following applies to the patient's disease?

❒ Mycosis Fungoides/Sezary syndrome, *No Further Questions*

❒ Anaplastic Large Cell Lymphoma (ALCL), *Continue to #396*

❒ Other, *Continue to #396*

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

❒ Relapsed disease, *Continue to #397*

❒ Refractory disease, *Continue to #397*

❒ Other, *Continue to #397*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Extranodal NK/T-cell lymphoma

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

❒ Relapsed disease, *No Further Questions*

❒ Refractory disease, *No Further Questions*

❒ Other, *No Further Questions*

Gestational trophoblastic neoplasia

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

❒ Yes, *Continue to #421*

❒ No, *Continue to #421*

421. Is the disease resistant to multi-agent chemotherapy?

❒ Yes, *Continue to #422*

❒ No, *Continue to #422*

422. What type of disease does the patient have?

❒ Intermediate trophoblastic tumor, *Continue to #423*

❒ High-risk disease, *No Further Questions*

❒ Other, *No Further Questions*

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

❒ Recurrent disease, *Continue to #424*

❒ Progressive disease, *Continue to #424*

❒ Other, *Continue to #424*

424. Has the patient previously received treatment with a platinum/etoposide-containing regimen?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Neuroendocrine and Adrenal Tumors (adrenocortical carcinoma)

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

❒ Adrenocortical carcinoma, *Continue to #441*

❒ Other, *Continue to #441*

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

❒ Unresectable disease, *No Further Questions*

❒ Metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

Soft Tissue Sarcoma (alveolar soft part sarcoma (ASPS) and cutaneous angiosarcoma)

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

❒ Alveolar soft part sarcoma (ASPS), *Continue to #451*

❒ Cutaneous angiosarcoma, *Continue to #452*

❒ Extremity/body wall sarcoma, *Continue to #453*

❒ Head/neck sarcoma, *Continue to #453*

❒ Retroperitoneal/intra-abdominal sarcoma, *Continue to #453*

❒ Rhabdomyosarcoma, *Continue to #453*

❒ Other, *No Further Questions*

451. Will the requested drug be used in any of the following regimens?

❒ Single agent, *No Further Questions*

❒ In combination with axitinib (Inlyta), *No Further Questions*

❒ Other, *No Further Questions*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Yes, *Continue to #454*

❒ No, *Continue to #454*

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

❒ First-line therapy, *No Further Questions*

❒ Subsequent therapy, *No Further Questions*

Occult primary cancer

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

❒ Yes, *Continue to #471*

❒ No, *Continue to #471*

471. 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 deficient tumor status

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

Anaplastic thyroid carcinoma

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

❒ Yes, *Continue to #491*

❒ No, *Continue to #491*

491. 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 chart note(s) or test results confirming tumor mutational burden-high tumor status

❒ Yes, *Continue to #492*

❒ No, *Continue to #492*

❒ Unknown, *Continue to #492*

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

❒ Metastatic disease, *No Further Questions*

❒ Other, *No Further Questions*

Follicular, Hürthle cell, or Papillary thyroid carcinoma

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

❒ Unresectable disease, *Continue to #501*

❒ Metastatic disease, *Continue to #502*

❒ Other, *No Further Questions*

501. 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 chart note(s) or test results confirming tumor mutational burden-high tumor status

❒ Yes, *Continue to #502*

❒ No, *Continue to #502*

❒ Unknown, *Continue to #502*

502. Is the disease amenable to radioactive iodine therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

Medullary thyroid carcinoma

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

❒ Unresectable disease, *Continue to #511*

❒ Recurrent disease, *Continue to #511*

❒ Metastatic disease, *Continue to #511*

❒ Other, *Continue to #511*

511. 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 chart note(s) or test results confirming tumor mutational burden-high tumor status

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

Small bowel adenocarcinoma

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

❒ Yes, *Continue to #521*

❒ No, *Continue to #521*

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

❒ Advanced disease, *Continue to #522*

❒ Metastatic disease, *Continue to #522*

❒ Other, *Continue to #522*

522. Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)? ***Action required***: If 'Yes', attach chart note(s) or test results confirming microsatellite instability-high or mismatch repair deficient tumor status

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

Breast Cancer (TNBC)

600. Is the patient's diagnosis confirmed by the breast cancer cells testing negative for ALL of the following receptors? ***Action Required***: If yes, please attach chart note(s) or 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, *Continue to #601*

❒ No, *Continue to #601*

❒ Unknown, *Continue to #601*

601. What is the clinical setting in which the requested medication will be used?

❒ The patient had no response to preoperative systemic therapy, *Continue to #602*

❒ Locally recurrent unresectable disease, *Continue to #602*

❒ Metastatic disease, *Continue to #602*

❒ High-risk early-stage disease, *Continue to #604*

❒ Other, *No Further Questions*

602. Does the patient's disease express programmed death ligand 1 (PD-L1)? ***Action required***: If 'Yes', attach chart note(s) or test results for PD-L1 expression

❒ Yes, *Continue to #603*

❒ No, *Continue to #603*

❒ Unknown, *Continue to #603*

603. Will the requested drug be used in combination with chemotherapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Neoadjuvant treatment, *Continue to #605*

❒ *Continued adjuvant treatment after surgery, Continue to #606*

❒ Other, *No Further Questions*

605. Will the requested drug be used in combination with chemotherapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Pediatric Diffuse High-Grade Gliomas

610. What is the clinical setting in which the requested drug will be used?
❒ As adjuvant treatment, *Continue to #611*
❒ Recurrent disease, *Continue to #611*
❒ Progressive disease, *Continue to #611*
❒ Other, *Continue to #611*

611. Is the tumor hypermutant?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

Kaposi Sarcoma

615. Which of the following type of Kaposi sarcoma applies to the patient?
❒ Endemic Kaposi sarcoma, *Continue to #616*
❒ Classic Kaposi sarcoma, *Continue to #616*
❒ Other, *Continue to #616*

616. Will the requested drug be used as a single agent?
❒ Yes, *Continue to #617*
❒ No, *Continue to #617*

617. What is the place in therapy in which the requested drug will be used?
❒ First-line treatment, *Continue to #618*
❒ Subsequent treatment, *Continue to #618*

618. What is the clinical setting in which the requested drug will be used?
❒ Relapsed/refractory disease, *No Further Questions*
❒ Other, *No Further Questions*

Continuation of therapy

900. What is the diagnosis?
❒ Cutaneous melanoma, *Continue to #902*
❒ Non-small cell lung cancer, *Continue to #901*
❒ Cutaneous squamous cell carcinoma, *Continue to #910*
❒ Head and neck squamous cell cancer, *Continue to #910*
❒ Classical Hodgkin lymphoma, *Continue to #910*
❒ Urothelial carcinoma of the bladder, *Continue to #906*
❒ Primary carcinoma of the urethra, *Continue to #910*
❒ Urolthelial carcinoma of the upper genitourinary tract tumor or urothelial carcinoma of the prostate, *Continue to #910*
❒ Colorectal cancer (including appendiceal carcinoma), *Continue to #910*
❒ Merkel Cell Carcinoma, *Continue to #910*

❒ Gastric cancer, *Continue to #910*

❒ Esophageal cancer, *Continue to #910*

❒ Cervical cancer, *Continue to #910*

❒ Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma, *Continue to #910*

❒ Uveal melanoma, *Continue to #915*

❒ Testicular cancer, *Continue to #910*

❒ Endometrial carcinoma, *Continue to #910*

❒ Anal carcinoma, *Continue to #915*

❒ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer, *Continue to #915*

❒ Primary mediastinal large B-cell lymphoma, *Continue to #910*

❒ Pancreatic adenocarcinoma, *Continue to #910*

❒ Hepatobiliary cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer), *Continue to #910*

❒ Hepatocellular carcinoma, *Continue to #910*

❒ Vulvar cancer, *Continue to #905*

❒ Renal cell carcinoma, *Continue to #901*

❒ Thymic carcinoma, *Continue to #915*

❒ Primary Cutaneous Lymphomas, *Continue to #915*

❒ Extranodal NK/T-cell lymphoma, *Continue to #915*

❒ Gestational trophoblastic neoplasia, *Continue to #915*

❒ Neuroendocrine tumors, *Continue to #910*

❒ Adrenal tumors, *Continue to #915*

❒ Salivary gland tumors, *Continue to #910*

❒ Anaplastic thyroid carcinoma, *Continue to #910*

❒ Follicular, hürthle cell, or papillary thyroid carcinoma, *Continue to #910*

❒ Medullary thyroid carcinoma, *Continue to #910*

❒ Small bowel adenocarcinoma, *Continue to #910*

❒ Soft tissue sarcomas, *Continue to #915*

❒ Occult primary cancer, *Continue to #910*

❒ Microsatellite instability-high or mismatch repair deficient solid tumor, *Continue to #910*

❒ Tumor mutational burden-high solid tumor, *Continue to #910*

❒ Triple-Negative Breast Cancer (TNBC), locally recurrent unresectable or metastatic, *Continue to #910*

❒ Triple-Negative Breast Cancer (TNBC), high-risk early-stage disease, *Continue to #902*

❒ Breast cancer, *Continue to #910*

❒ Esophagogastric junction cancer, *Continue to #910*

❒ Prostate cancer, *Continue to #910*

❒ Bone cancer (Chondrosarcoma, Ewing Sarcoma, Osteosarcoma, Chordoma), *Continue to #910*

❒ Penile cancer, *Continue to #910*

❒ Uterine sarcoma, *Continue to #910*

❒ Small cell lung cancer, *Continue to #915*

❒ Pediatric Diffuse High-Grade Gliomas, *Continue to #915*

❒ Ampullary adenocarcinoma, *Continue to #910*

❒ Kaposi sarcoma, *Continue to #915*

❒ Other, *No Further Questions*

Continuation of therapy – adjuvant treatment of melanoma, high-risk early-stage TNBC, RCC, or NSCLC

901. Is the request for the adjuvant treatment of renal cell carcinoma or non-small cell lung cancer?

❒ Yes, *Continue to #903*

❒ No, *Continue to #910*

902. Is the requested drug prescribed for treatment of adjuvant melanoma or adjuvant high-risk early-stage TNBC?

❒ Yes, *Continue to #903*

❒ No, *Continue to #915*

903. Is there evidence of disease recurrence or unacceptable toxicity on the current regimen?

❒ Yes, *Continue to #904*

❒ No, *Continue to #904*

904. How many months of treatment has the patient received with the requested drug? (Please use fill-in-the-blank format on fax form.)

❒ Greater than or equal to 12 months

❒ 11 months, *No Further Questions*

❒ 10 months, *No Further Questions*

❒ 9 months, *No Further Questions*

❒ 8 months, *No Further Questions*

❒ 7 months, *No Further Questions*

❒ 6 months or less, *No Further Questions*

Vulvar cancer

905. 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, *Continue to #910*

❒ PD-L1 expression with CPS score greater than or equal to 1, *Continue to #915*

Urothelial carcinoma of the bladder

906. Is the requested drug prescribed for the treatment of high-risk BCG-unresponsive non-muscle invasive bladder cancer?

❒ Yes, *Continue to #907*

❒ No, *Continue to #908*

907. Is the disease persistent or recurrent?

❒ Yes, *Continue to #908*

❒ No, *Continue to #908*

908. Is there evidence of disease progression or unacceptable toxicity on the current regimen?

❒ Yes, *Continue to #909*

❒ No, *Continue to #909*

909. How many continuous months of treatment has the patient received with the requested drug? (Please use fill-in-the-blank format on fax form.)

❒ Greater than or equal to 24 months

❒ 23 months, *No Further Questions*

❒ 22 months, *No Further Questions*

❒ 21 months, *No Further Questions*

❒ 20 months, *No Further Questions*

❒ 19 months, *No Further Questions*

❒ 18 months or less, *No Further Questions*

Continuation of therapy – Non-small cell lung cancer, Head and neck squamous cell carcinoma, Classical Hodgkin lymphoma, Primary mediastinal large B-cell lymphoma, Urothelial Carcinoma (primary carcinoma of the urethra, upper genitourinary tract tumor, urothelial carcinoma of the prostate), Colorectal cancer, Microsatellite instability-high or mismatch repair deficient tumors, Gastric cancer, Esophageal cancer, Esophagogastric junction cancer, Cervical cancer, Hepatocellular carcinoma, Merkel cell carcinoma, Renal cell carcinoma (not adjuvant), Endometrial carcinoma, Tumor mutational burden-high cancer, Cutaneous squamous cell carcinoma, Triple-Negative Breast Cancer [(TNBC) locally recurrent unresectable or metastatic], Small bowel adenocarcinoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma, neuroendocrine tumors, breast cancer, salivary gland tumors, bone cancer, penile cancer, uterine sarcoma, ampullary adenocarcinoma

910. Is there evidence of disease progression or unacceptable toxicity on the current regimen?

❒ Yes, *Continue to #911*

❒ No, *Continue to #911*

911. How many continuous months of treatment has the patient received with the requested drug? (Please use fill-in-the-blank format on fax form.)

❒ Greater than or equal to 24 months

❒ 23 months, *No Further Questions*

❒ 22 months, *No Further Questions*

❒ 21 months, *No Further Questions*

❒ 20 months, *No Further Questions*

❒ 19 months, *No Further Questions*

❒ 18 months or less, *No Further Questions*

Continuation of therapy – other indications

915. Is there evidence of disease progression or unacceptable toxicity on the current regimen?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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