Keytruda

CareFirst 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*

What is the ICD-10 code? _____

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

Site of Service Questions (SOS):

A. Where will this drug be administered?
- ❑ On Campus Outpatient Hospital, *continue to B*
- ❑ Off Campus Outpatient Hospital, *continue to B*
- ❑ 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?
❑ Yes, *skip to Clinical Criteria Questions* ❑ No, *Continue to C*

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, *Continue to D*

D. Is this request to continue previously established treatment with the requested regimen?
- ❑ No – This is a new therapy request (patient has not received 6 months or more of requested regimen). ***ACTION REQUIRED: Please attach supporting clinical documentation.*** *Skip to Clinical Criteria Questions*
- ❑ Yes – This is a continuation of existing treatment (patient has received requested regimen for 6 months). ***ACTION REQUIRED: Please attach supporting clinical documentation.*** *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), *Continue to E*

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, *Continue to F*

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, *Continue to G*

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, *Continue to H*

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, *Continue to I*

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, *skip to Clinical Criteria Questions* ❑ No, *Continue to J*

J. Are ***all*** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? ***ACTION REQUIRED: If Yes, please attach supporting documentation.***
❑ Yes, *Continue to Clinical Criteria Questions* ❑ No, *Continue to Clinical Criteria Questions*

Criteria Questions:

1. Has the patient experienced disease progression while on 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 227*

5. Is the requested drug prescribed for a pediatric patient with tumor mutational burden-high (TMB-H) central nervous system (CNS) cancer?

❒ 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 227*
❒ 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***: 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 8*
❒ Mismatch repair deficient (dMMR) solid tumor ***ACTION REQUIRED****: Submit supporting documentation, Continue to 8*
❒ Tumor mutational burden-high (TMB-H) (greater than or equal to 10 mutations/megabase [mut/Mb]) solid tumor ***ACTION REQUIRED****: Submit supporting documentation, 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 12*

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, please specify. _____, *Continue to 12*

10. Has the patient experienced disease progression following prior treatment?
❒ Yes, *Continue to 11*
❒ No, *Continue to 12*

11. Are there other satisfactory alternative treatment options available for the patient?
❒ Yes, *Continue to 12*
❒ No, *No Further Questions*

12. What is the diagnosis?

❒ Ampullary adenocarcinoma, *Continue to 64*

❒ Anal carcinoma, *Continue to 135*

❒ Anaplastic thyroid carcinoma, *Continue to 191*
❒ Biliary tract cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer), *Continue to 146*

❒ Breast Cancer (TNBC), *Continue to 203*
❒ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer, *Continue to 138*

❒ Cervical cancer, *Continue to 109*

❒ Classical Hodgkin lymphoma, *Continue to 49*

❒ Colorectal cancer (including appendiceal carcinoma), *Continue to 69*

❒ Cutaneous melanoma, *Continue to 13*

❒ Cutaneous squamous cell skin carcinoma, *Continue to 41*

❒ Endometrial carcinoma, *Continue to 126*
❒ 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 118*

❒ Esophageal cancer and Esophagogastric Junction Cancer, *Continue to 91*

❒ Extranodal NK/T-cell lymphoma, *Continue to 178*

❒ Follicular, oncocytic (hurthle cell), or papillary thyroid carcinoma, *Continue to 195*

❒ Gastric cancer, *Continue to 74*

❒ Gestational trophoblastic neoplasia, *Continue to 179*
❒ Head and neck squamous cell carcinoma with mixed subtypes (HNSCC) or nasopharyngeal cancer, *Continue to 44*

❒ Hepatocellular carcinoma, *Continue to 153*

❒ Kaposi sarcoma, *Continue to 212*

❒ Medullary thyroid carcinoma, *Continue to 198*

❒ Merkel Cell Carcinoma, *Continue to 72*

❒ Mesothelioma, *Continue to 223*

❒ Neuroendocrine and Adrenal Tumors, *Continue to 183*
❒ Non-small cell lung cancer, *Continue to 22*
❒ Occult primary cancer, *Continue to 189*
❒ Pancreatic adenocarcinoma, *Continue to 143*
❒ Pediatric Diffuse High-Grade Gliomas, *Continue to 210*
❒ Primary Cutaneous Lymphomas, *Continue to 175*
❒ Primary mediastinal large B-cell lymphoma, *Continue to 141*
❒ Prostate cancer, *Continue to 37*
❒ Renal cell carcinoma, *Continue to 164*
❒ Small Bowel Adenocarcinoma, *Continue to 200*
❒ Small cell lung cancer, *Continue to 66*
❒ Soft Tissue Sarcomas, *Continue to 184*
❒ Testicular cancer, *Continue to 123*
❒ Thymomas and thymic carcinoma, *Continue to 172*
❒ Urothelial carcinoma, *Continue to 51*
❒ Uveal melanoma, *Continue to 121*
❒ Vaginal cancer, *Continue to 216*
❒ Vulvar cancer, *Continue to 158*
❒ Other, please specify. _____, *No further questions*

13. Does the patient have a BRAF V600 activating mutation disease?
❒ Yes, *Continue to 14*
❒ No, *Continue to 17*

14. What is the clinical setting in which the requested drug will be used?
❒ Metastatic disease, *Continue to 15*
❒ Unresectable disease, *Continue to 15*
❒ Other, please specify. _____, *Continue to 15*

15. What is the place in therapy in which the requested drug will be used?
❒ Subsequent or re-induction therapy, *Continue to 16*
❒ Other, please specify. _____, *Continue to 16*

16. Will the requested drug be used in combination with trametinib and dabrafenib?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

17. What is the clinical setting in which the requested drug will be used?
❒ Adjuvant treatment, *Continue to 18*
❒ Unresectable disease, *Continue to 19*
❒ Recurrent disease, *Continue to 19*
❒ Metastatic disease, *Continue to 19*

❒ Subsequent therapy, *Continue to 20*

❒ Other, please specify. _____, *No further questions*

18. Has the patient had a complete lymph node surgical resection or complete resection of stage IIB, IIC, III or metastatic disease?
❒ Yes, *Continue to 19*
❒ No, *Continue to 19*

19. Will the requested drug be used as a single agent?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

20. Will the requested drug be used for disease progression of metastatic or unresectable tumors?
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

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

❒ Single agent, *No further questions*

❒ In combination with ipilimumab (Yervoy) or lenvatinib (Lenvima), *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Recurrent disease, *Continue to 23*

❒ Advanced disease, *Continue to 23*

❒ Metastatic disease, *Continue to 23*

❒ Stage IB (T2a to greater than or equal to 4 cm), *Continue to 33*

❒ Stage II, *Continue to 33*

❒ Stage III, *Continue to 33*

❒ Resectable (tumors greater or equal to 4 cm or node positive) disease, *Continue to 35*

❒ Other, please specify. _____, *No further questions*

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

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*

❒ No ***ACTION REQUIRED****: Submit supporting documentation, Continue to 30*

❒ Unknown, *Continue to 24*

24. Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?
❒ Yes, *Continue to 25*
❒ No, *Continue to 30*

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

❒ As first-line therapy, *Continue to 26*

❒ As maintenance therapy, *Continue to 27*

❒ In combination with pemetrexed and either carboplatin or cisplatin, *Continue to 28*

❒ In combination with carboplatin and either paclitaxel or albumin-bound paclitaxel, *Continue to 29*

❒ Other, please specify. _____, *No further questions*

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

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

27. What is the requested regimen?

❒ Single agent, *No further questions*

❒ In combination with pemetrexed, *No further questions*

❒ Other, please specify. _____, *No further questions*

28. What is the patient's disease histology?

❒ Nonsquamous cell histology, *No further questions*

❒ Squamous cell histology, *No further questions*

29. What is the patient's disease histology?

❒ Nonsquamous cell histology, *No further questions*

❒ Squamous cell histology, *No further questions*

30. 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 31*

❒ No, *Continue to 31*

❒ Unknown, *Continue to 31*

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

❒ Yes, *Continue to 32*

❒ No, *Continue to 32*

32. 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*

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

❒ Yes, *Continue to 34*

❒ No, *Continue to 34*

34. Will the requested drug be used as a single agent?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

35. Will the requested drug be used as neoadjuvant treatment in combination with platinum containing chemotherapy (e.g., cisplatin, carboplatin)?
❒ Yes, *Continue to 36*
❒ No, *Continue to 36*

36. Will the requested drug be continued as a single agent adjuvant therapy after surgery?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

37. Will the requested drug be used for treatment of castration-resistant distant metastatic prostate cancer?
❒ Yes, *Continue to 38*
❒ No, *Continue to 38*

38. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H) (greater than or equal to 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) greater than or equal to 10 mutations/megabase status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 39*

❒ No, *Continue to 39*

❒ Unknown, *Continue to 39*

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

❒ First-line treatment, *Continue to 40*

❒ Subsequent treatment, *Continue to 40*

40. Will the requested drug be used as a single agent?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

41. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 42*
❒ No, *Continue to 42*

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

❒ Locally advanced disease, *Continue to 43*

❒ Recurrent disease, *Continue to 43*

❒ Metastatic disease, *Continue to 43*

❒ Other, please specify. _____, *Continue to 43*

43. Is the disease curable by surgery or radiation?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ Very advanced disease, *Continue to 45*

❒ Other, please specify. _____, *Continue to 45*

45. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 46*
❒ No, *Continue to 48*

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

❒ First-line treatment, *Continue to 47*

❒ Subsequent treatment, *No further questions*

47. Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of greater than 1, are microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [greater than or equal to 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 ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

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

❒ In combination with chemotherapy, *No further questions*

❒ In combination with cetuximab, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Single agent, *Continue to 50*

❒ In combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin), *Continue to 50*

❒ In combination with ICE (ifosfamide, carboplatin, etoposide), *Continue to 50*

❒ Other, please specify. _____, *Continue to 50*

50. 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, please specify. _____, *No further questions*

51. What is the requested regimen?

❒ As a single agent, *Continue to 52*

❒ In combination with enfortumab vedotin-ejfv (Padcev), *Continue to 63*

❒ Other, please specify. _____, *No further questions*

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

❒ Urothelial carcinoma of the bladder, *Continue to 53*

❒ Primary carcinoma of the urethra, *Continue to 59*

❒ Urothelial carcinoma of the upper genitourinary tract or urothelial carcinoma of the prostate, *Continue to 61*

❒ Other, please specify. _____, *No further questions*

53. 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 54*
❒ No, *Continue to 56*

54. Is the disease responsive to Bacillus Calmette-Guerin (BCG)?
❒ Yes, *Continue to 55*
❒ No, *Continue to 55*

55. Will the patient undergo cystectomy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ First-line treatment, *Continue to 57*

❒ Subsequent treatment, *No further questions*

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

❒ Locally advanced disease, *Continue to 58*

❒ Metastatic disease, *Continue to 58*

❒ Other, please specify. _____, *Continue to 58*

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

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

❒ Recurrent disease, *Continue to 60*

❒ Locally advanced disease, *Continue to 60*

❒ Metastatic disease, *Continue to 60*

❒ Other, please specify. _____, *Continue to 60*

60. Which of the following applies to the patient?

❒ The patient is post-platinum (e.g., cisplatin, carboplatin) or other chemotherapy, *No further questions*
❒ The patient is not eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin), *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Metastatic disease, *Continue to 62*

❒ Other, please specify. _____, *Continue to 62*

62. Which of the following applies to the patient?

❒ The patient is post-platinum (e.g., cisplatin, carboplatin) or other chemotherapy, *No further questions*
❒ The patient is not eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin), *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Stage II disease, *No further questions*

❒ Recurrent disease, *No further questions*

❒ Locally advanced disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

64. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden (TMB) high (greater than or equal to 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 (greater than or equal to 10 mutations/megabase [mut/Mb]) status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 65*

❒ No, *Continue to 65*

❒ Unknown, *Continue to 65*

65. Will the requested drug be used as a single agent?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

66. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 67*
❒ No, *Continue to 67*

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

❒ Relapsed disease, *Continue to 68*

❒ Progressive disease, *Continue to 68*

❒ Other, please specify. _____, *Continue to 68*

68. 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*

69. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 70*
❒ No, *Continue to 70*

70. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient, or polymerase epsilon/delta tumor status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 71*

❒ No, *Continue to 71*

❒ Unknown, *Continue to 71*

71. 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, please specify. _____, *No further questions*

72. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 73*
❒ No, *Continue to 73*

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

❒ Locally advanced disease, *No further questions*

❒ Recurrent disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Unresectable locally advanced disease, *Continue to 76*

❒ Recurrent disease, *Continue to 76*

❒ Metastatic disease, *Continue to 76*

❒ Other, please specify. _____, *Continue to 75*

75. Is the patient a surgical candidate?
❒ Yes, *Continue to 85*
❒ No, *Continue to 76*

76. Will the requested drug be used to treat HER2 overexpression positive adenocarcinoma or HER2-negative adenocarcinoma? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results of HER2 status.
❒ Yes, HER2 overexpression positive adenocarcinoma ***ACTION REQUIRED****: Submit supporting documentation, Continue to 77*
❒ Yes, HER2-negative adenocarcinoma ***ACTION REQUIRED****: Submit supporting documentation, Continue to 78*

❒ No, *Continue to 80*

77. What is the requested regimen?

❒ In combination with trastuzumab (Herceptin) and chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

78. What is the requested regimen?

❒ In combination with chemotherapy, *Continue to 79*

❒ Other, please specify. _____, *Continue to 79*

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

❒ First-line treatment, *No further questions*

❒ Subsequent therapy, *No further questions*

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

❒ First-line treatment, *Continue to 81*

❒ Subsequent treatment, *Continue to 83*

81. Is the tumor microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results of microsatellite instability-high or deficient mismatch repair tumors status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 82*

❒ No, *Continue to 82*

❒ Unknown, *Continue to 82*

82. What is the requested regimen?

❒ As a single agent, *No further questions*

❒ In combination with chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

83. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden (TMB) high (greater than or equal to 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 (greater than or equal to 10 mutations/megabase [mut/Mb]) status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 84*

❒ No, *Continue to 84*

❒ Unknown, *Continue to 84*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

85. Will the requested drug be used to treat early stage or surgically unresectable locoregional disease?

❒ Yes, early stage disease, *Continue to 86*

❒ Yes, surgically unresectable locoregional disease, *Continue to 86*

❒ No, *Continue to 89*

86. Which of the following applies to the patient's disease? ***ACTION REQUIRED***: Attach chart note(s) or test results confirming HER2 overexpression status.

❒ HER2 overexpression positive disease ***ACTION REQUIRED****: Submit supporting documentation, Continue to 88*

❒ HER2 overexpression negative with PD-L1 tumor expression by CPS greater than or equal to 10 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 87*

❒ Other, please specify. _____, *No further questions*

❒ Unknown, *No further questions*

87. What is the requested regimen?

❒ In combination with chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

88. What is the requested regimen?

❒ In combination with trastuzumab and chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

89. Is the tumor microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results of microsatellite instability-high or deficient mismatch repair tumors status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 90*

❒ No, *Continue to 90*

❒ Unknown, *Continue to 90*

90. What is the requested regimen?

❒ As a single agent, *No further questions*

❒ In combination with chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Unresectable locally advanced disease, *Continue to 93*

❒ Recurrent disease, *Continue to 93*

❒ Metastatic disease, *Continue to 93*

❒ Other, please specify. _____, *Continue to 92*

92. Is the patient a surgical candidate?
❒ Yes, *Continue to 106*
❒ No, *Continue to 93*

93. Will the requested drug be used to treat adenocarcinoma?
❒ Yes, *Continue to 94*
❒ No, *Continue to 97*

94. What is the tumor HER2 overexpression status? ***ACTION REQUIRED***: Attach chart note(s) or test results confirming HER2 status and PD-L1, where applicable.
❒ HER2 overexpression negative adenocarcinoma with PD-L1 tumor expression by CPS greater than or equal to 10 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 95*
❒ HER2 overexpression positive adenocarcinoma ***ACTION REQUIRED****: Submit supporting documentation, Continue to 96*

❒ Unknown, *No further questions*

95. What is the requested regimen?
❒ In combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

96. What is the requested regimen?
❒ In combination with trastuzumab and platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

97. Will the requested drug be used to treat squamous cell carcinoma?
❒ Yes, *Continue to 98*
❒ No, *Continue to 101*

98. What is the requested regimen?

❒ As a single agent, *Continue to 99*
❒ In combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy, *Continue to 100*

❒ Other, please specify. _____, *No further questions*

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

❒ First-line treatment, *Continue to 100*

❒ Subsequent treatment, *Continue to 100*

100. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of greater than or equal to 10? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results for PD-L1 expression.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

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

❒ First-line treatment, *Continue to 102*

❒ Subsequent treatment, *Continue to 104*

102. Is the tumor microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results of microsatellite instability-high or deficient mismatch repair tumors status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 103*

❒ No, *Continue to 103*

❒ Unknown, *Continue to 103*

103. What is the requested regimen?

❒ As a single agent, *No further questions*
❒ In combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

104. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden (TMB) high (greater than or equal to 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 (greater than or equal to 10 mutations/megabase (mut/Mb) tumor status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 105*

❒ No, *Continue to 105*

❒ Unknown, *Continue to 105*

105. Will the requested drug be used as a single agent?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

106. Which of the following applies to the patient? ***ACTION REQUIRED***: Attach chart note(s) or test results of microsatellite instability-high, deficient mismatch repair tumors or HER2 status.
❒ Microsatellite instability-high (MSI-H) tumor ***ACTION REQUIRED****: Submit supporting documentation, Continue to 108*
❒ Deficient mismatch repair (dMMR) tumor ***ACTION REQUIRED****: Submit supporting documentation, Continue to 108*
❒ HER2 overexpression positive adenocarcinoma ***ACTION REQUIRED****: Submit supporting documentation, Continue to 107*

❒ Unknown, *No further questions*

107. What is the requested regimen?
❒ In combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy and trastuzumab, *No further questions*

❒ Other, please specify. _____, *No further questions*

108. What is the requested regimen?

❒ As a single agent, *No further questions*
❒ In combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

109. Will the requested drug be used for treatment of The International Federation of Gynecology and Obstetrics (FIGO) stage III-IVA disease?
❒ Yes, *Continue to 110*
❒ No, *Continue to 111*

110. Will the requested drug be used in combination with chemoradiotherapy (CRT)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ As a single agent, *Continue to 113*

❒ In combination with chemotherapy with or without bevacizumab (Avastin), *Continue to 112*

❒ Other, please specify. _____, *No further questions*

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

❒ Persistent disease, *Continue to 115*

❒ Recurrent disease, *Continue to 115*

❒ Metastatic disease, *Continue to 115*

❒ Other, please specify. _____, *Continue to 113*

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

❒ Recurrent disease, *Continue to 114*

❒ Metastatic disease, *Continue to 114*

❒ Other, please specify. _____, *Continue to 114*

114. Has the patient experienced disease progression on or after chemotherapy?
❒ Yes, *Continue to 115*
❒ No, *Continue to 116*

115. Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of greater than or equal to 1? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results for PD-L1 expression.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

116. Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of greater than or equal to 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 117*

❒ No, *Continue to 117*

❒ Unknown, *Continue to 117*

117. 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*

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

❒ Recurrent disease, *Continue to 119*

❒ Persistent disease, *Continue to 119*

❒ Other, please specify. _____, *Continue to 119*

119. What is the requested regimen?

❒ As a single agent, *Continue to 120*

❒ In combination with oral cyclophosphamide and bevacizumab, *No further questions*

❒ Other, please specify. _____, *Continue to 120*

120. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (tumors greater than or equal to 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 ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

121. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 122*
❒ No, *Continue to 122*

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

❒ Unresectable disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

123. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 124*
❒ No, *Continue to 124*

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

❒ First-line treatment, *Continue to 125*

❒ Second-line treatment, *Continue to 125*

❒ Third-line or subsequent treatment, *Continue to 125*

125. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (tumors greater than or equal to 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 ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

126. Will the requested medication be used in combination with carboplatin and paclitaxel and continued as single agent maintenance therapy (for up to 20 cycles total)?
❒ Yes, *Continue to 127*
❒ No, *Continue to 128*

127. 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, please specify. _____, *No further questions*

128. Will the requested drug be used in combination with lenvatinib (Lenvima)?
❒ Yes, *Continue to 129*
❒ No, *Continue to 132*

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

❒ Advanced disease, *Continue to 130*

❒ Metastatic disease, *Continue to 130*

❒ Recurrent disease, *Continue to 130*

❒ Other, please specify. _____, *Continue to 130*

130. 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 ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Mismatch repair deficient (dMMR) tumor ***ACTION REQUIRED****: Submit supporting documentation, Continue to 131*
❒ Other, please specify _____ ***ACTION REQUIRED****: Submit supporting documentation, Continue to 131*

131. Has the patient experienced disease progression following prior platinum-based chemotherapy (e.g., cisplatin, carboplatin)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

132. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 133*
❒ No, *Continue to 133*

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

❒ Recurrent unresectable disease, *Continue to 134*

❒ Metastatic disease, *Continue to 134*

❒ Other, please specify. _____, *Continue to 134*

134. Which of the following applies to the patient's disease? ***ACTION REQUIRED***: Attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient, or mutational burden-high tumor status.
❒ Microsatellite instability-high (MSI-H) tumor ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Mismatch repair deficient (dMMR) tumor ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Tumor mutational burden-high (TMB-H) (greater than or equal to 10 mutations/megabase [mut/Mb]), *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Yes, *Continue to 136*
❒ No, *Continue to 136*

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

❒ Metastatic disease, *Continue to 137*

❒ Other, please specify. _____, *Continue to 137*

137. 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*

138. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 139*
❒ No, *Continue to 139*

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

❒ Melanoma, *No further questions*

❒ Non-small cell lung cancer, *Continue to 140*

❒ Other, please specify. _____, *Continue to 140*

140. Is the patient's disease positive for programmed death ligand 1 (PD-L1)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results for PD-L1 expression.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

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

❒ As a single agent, *Continue to 142*

❒ In combination with brentuximab vedotin (Adcetris), *Continue to 142*

❒ Other, please specify. _____, *Continue to 142*

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

❒ Relapsed disease, *No further questions*

❒ Refractory disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

143. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 144*
❒ No, *Continue to 144*

144. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [greater than or equal to 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 145*

❒ No, *Continue to 145*

❒ Unknown, *Continue to 145*

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

❒ Recurrent disease, *No further questions*

❒ Locally advanced disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

146. Will the requested drug be used for neoadjuvant treatment of resectable locoregionally advanced gallbladder cancer?

❒ Yes, *Continue to 147*

❒ No, *Continue to 149*

147. What is the requested regimen?

❒ In combination with cisplatin and gemcitabine, *No further questions*

❒ As a single agent, *Continue to 148*

❒ Other, please specify. _____, *Continue to 148*

148. Is the tumor microsatellite instability-high (MSI-H) and/or mismatch repair deficient (dMMR)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results confirming MSI-H and/or dMMR tumor status.

❒ Yes, *No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

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

❒ As a single agent, *Continue to 150*

❒ In combination with gemcitabine and cisplatin, *Continue to 152*

❒ Other, please specify. _____, *No further questions*

150. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [greater than or equal to 10 mut/Mb]? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient, or mutational burden high tumor status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 151*

❒ No, *Continue to 151*

❒ Unknown, *Continue to 151*

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

❒ Unresectable disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Resected gross residual (R2) disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Locally advanced unresectable disease, *No further questions*

❒ Resected gross residual (R2) disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

153. Is the disease secondary to hepatitis B?
❒ Yes, *Continue to 154*
❒ No, *Continue to 156*

154. Has the patient received prior systemic therapy other than a PD1/PD-L1- containing regimen?
❒ Yes, *Continue to 155*
❒ No, *Continue to 155*

155. Will the requested drug be used as a single agent?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ Unresectable disease, *Continue to 157*

❒ Metastatic disease, *Continue to 157*

❒ Other, please specify. _____, *Continue to 157*

157. Will the requested drug be used as a single agent?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

158. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 159*
❒ No, *Continue to 159*

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

❒ First-line treatment, *Continue to 160*

❒ Subsequent treatment, *Continue to 160*

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

❒ Advanced disease, *Continue to 161*

❒ Recurrent disease, *Continue to 161*

❒ Metastatic disease, *Continue to 161*

❒ Other, please specify. _____, *Continue to 161*

161. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H) [greater than or equal to 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) ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, mismatch repair deficient (dMMR) ***ACTION REQUIRED****: Submit supporting documentation, No further questions*
❒ Yes, tumor mutational burden high (TMB-H [greater than or equal to 10 mut/Mb] ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *Continue to 162*

162. Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of greater than or equal to 1? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results for PD-L1 expression.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 163*

❒ No, *Continue to 163*

❒ Unknown, *Continue to 163*

163. Has the patient experienced disease progression on or after chemotherapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ As a single agent, *Continue to 165*

❒ In combination with axitinib (Inlyta), *Continue to 167*

❒ In combination with lenvatinib (Lenvima), *Continue to 167*

❒ Other, please specify. _____, *No further questions*

165. How will the requested drug be used?

❒ For treatment of relapsed disease, *Continue to 166*

❒ For treatment of stage IV disease, *Continue to 166*

❒ As adjuvant therapy, *Continue to 171*

❒ Other, please specify. _____, *No further questions*

166. Does the tumor express non-clear cell histology?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ First-line treatment, *Continue to 168*

❒ Subsequent treatment, *Continue to 169*

168. 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, please specify. _____, *No further questions*

169. Does the tumor express clear cell histology?
❒ Yes, *Continue to 170*
❒ No, *Continue to 170*

170. 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, please specify. _____, *No further questions*

171. 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, please specify. _____, *No further questions*

172. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 173*
❒ No, *Continue to 173*

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

❒ Recurrent disease, *No further questions*

❒ Unresectable disease, *No further questions*

❒ Locally advanced disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *Continue to 174*

174. Will the requested drug be used as pre or postoperative therapy in a patient who cannot tolerate first-line combination regimens?
❒ Yes, *No further questions*
❒ No, *No further questions*

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

❒ Mycosis Fungoides/Sezary syndrome, *No further questions*

❒ Anaplastic Large Cell Lymphoma (ALCL), *Continue to 176*

❒ Other, please specify. _____, *No further questions*

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

❒ Relapsed disease, *Continue to 177*

❒ Refractory disease, *Continue to 177*

❒ Other, please specify. _____, *Continue to 177*

177. Will the requested drug be used as a single agent?
❒ Yes, *No further questions*
❒ No, *No further questions*

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

❒ Relapsed disease, *No further questions*

❒ Refractory disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

179. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 180*
❒ No, *Continue to 180*
180. Is the disease resistant to multi-agent chemotherapy?
❒ Yes, *Continue to 181*
❒ No, *Continue to 181*

181. What type of disease does the patient have?

❒ Intermediate trophoblastic tumor, *Continue to 182*

❒ High-risk disease, *No further questions*

❒ Other, please specify. _____, *Continue to 182*

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

❒ Recurrent disease, *No further questions*

❒ Progressive disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

183. 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, please specify. _____, *No further questions*

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

❒ Alveolar soft part sarcoma (ASPS), *Continue to 185*

❒ Cutaneous angiosarcoma, *Continue to 186*

❒ Extremity/body wall sarcoma, *Continue to 187*

❒ Head/neck sarcoma, *Continue to 187*

❒ Retroperitoneal/intra-abdominal sarcoma, *Continue to 187*

❒ Rhabdomyosarcoma, *Continue to 187*

❒ Other, please specify. _____, *No further questions*

185. 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, please specify. _____, *No further questions*

186. Will the requested drug be used as a single agent?
❒ Yes, *No further questions*
❒ No, *No further questions*
187. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 188*
❒ No, *Continue to 188*

188. 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*

189. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 190*
❒ No, *Continue to 190*
190. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (greater than or equal to 10 mutations/megabase [mut/Mb])? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results confirming tumor mutational burden-high microsatellite instability-high or mismatch repair deficient tumor status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

191. What is the requested regimen?

❒ As a single agent, *Continue to 192*

❒ In combination with lenvatinib (Lenvima), *Continue to 194*

❒ Other, please specify. _____, *No further questions*

192. 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 193*

❒ No, *Continue to 193*

❒ Unknown, *Continue to 193*

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

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Stage IVC disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Unresectable disease, *Continue to 196*

❒ Metastatic disease, *Continue to 196*

❒ Other, please specify. _____, *Continue to 196*

196. Does the disease have microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or 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 microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high tumor status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 197*

❒ No, *Continue to 197*

❒ Unknown, *Continue to 197*

197. Is the disease amenable to radioactive iodine therapy?
❒ Yes, *No further questions*
❒ No, *No further questions*

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

❒ Unresectable disease, *Continue to 199*

❒ Recurrent disease, *Continue to 199*

❒ Metastatic disease, *Continue to 199*

❒ Other, please specify. _____, *No further questions*

199. Does the disease have microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or 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 microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high tumor status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

200. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 201*
❒ No, *Continue to 201*

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

❒ Advanced disease, *Continue to 202*

❒ Metastatic disease, *Continue to 202*

❒ Other, please specify. _____, *Continue to 202*

202. Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results confirming microsatellite instability-high, mismatch repair deficient, or polymerase epsilon/delta tumor status.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, No further questions*

❒ No, *No further questions*

❒ Unknown, *No further questions*

203. Is the patient's diagnosis confirmed by the breast cancer cells testing negative for ALL of the following receptors: A) Human epidermal growth factor receptor 2 (HER-2), B) Estrogen, and C) Progesterone? ***ACTION REQUIRED***: If Yes, 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.

❒ Yes ***ACTION REQUIRED****: Submit supporting documentation, Continue to 204*

❒ No, *Continue to 204*

❒ Unknown, *Continue to 204*

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

❒ The patient had no response to preoperative systemic therapy, *Continue to 205*

❒ Recurrent unresectable disease, *Continue to 205*

❒ Metastatic disease, *Continue to 205*

❒ High-risk early-stage disease, *Continue to 207*

❒ Other, please specify _____, *No further questions*

205. 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 206*

❒ No, *Continue to 206*

❒ Unknown, *Continue to 206*

206. What is the requested regimen?

❒ Single agent, *No further questions*

❒ In combination with chemotherapy, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ Neoadjuvant treatment, *Continue to 208*

❒ *Continued adjuvant treatment after surgery, Continue to 209*

❒ Other, please specify. _____, *No further questions*

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

209. Will the requested drug be used as a single agent?
❒ Yes, *No further questions*
❒ No, *No further questions*

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

❒ As adjuvant treatment, *Continue to 211*

❒ Recurrent disease, *Continue to 211*

❒ Progressive disease, *Continue to 211*

❒ Other, please specify. _____, *Continue to 211*

211. Is the tumor hypermutant?
❒ Yes, *No further questions*
❒ No, *No further questions*

212. Which of the following type of Kaposi sarcoma applies to the patient?

❒ Endemic Kaposi sarcoma, *Continue to 213*

❒ Classic Kaposi sarcoma, *Continue to 213*

❒ Other, please specify. _____, *Continue to 213*

213. Will the requested drug be used as a single agent?
❒ Yes, *Continue to 214*
❒ No, *Continue to 214*

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

❒ First-line treatment, *Continue to 215*

❒ Subsequent treatment, *Continue to 215*

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

❒ Relapsed/refractory disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

216. Will the requested drug be used in combination with cisplatin or carboplatin, paclitaxel, and with or without bevacizumab?
❒ Yes, *Continue to 217*
❒ No, *Continue to 218*

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

❒ Recurrent disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

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

❒ First line therapy, *Continue to 219*

❒ Subsequent therapy, *Continue to 219*

219. Which of the following applies to the patient's disease? ***ACTION REQUIRED***: Attach chart note(s) or test results confirming PD-L1, microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden-high (TMB-H is greater than or equal to 10 mut/Mb) tumors status.

❒ The disease is PD-L1 positive ***ACTION REQUIRED****: Submit supporting documentation, Continue to 220*
❒ The disease with microsatellite instability-high (MSI-H) tumor ***ACTION REQUIRED****: Submit supporting documentation, Continue to 220*
❒ The disease with mismatch repair deficient (dMMR) tumor ***ACTION REQUIRED****: Submit supporting documentation, Continue to 220*
❒ The disease with tumor mutational burden-high (TMB-H is greater than or equal to 10 mut/Mb) tumor ***ACTION REQUIRED****: Submit supporting documentation, Continue to 222*

❒ Other, please specify. _____, *No further questions*

❒ Unknown, *No further questions*

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

❒ Recurrent disease, *Continue to 221*

❒ Metastatic disease, *Continue to 221*

❒ Other, please specify. _____, *Continue to 221*

221. Will the requested drug be used as a single agent?
❒ Yes, *No further questions*
❒ No, *No further questions*

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

❒ Unresectable disease, *No further questions*

❒ Metastatic disease, *No further questions*

❒ Other, please specify. _____, *No further questions*

223. Will the requested drug be used for malignant pleural mesothelioma?
❒ Yes, *Continue to 224*
❒ No, *Continue to 224*

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

❒ First-line treatment, *Continue to 225*

❒ Subsequent treatment, *Continue to 225*

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

❒ Unresectable advanced disease, *Continue to 226*

❒ Metastatic disease, *Continue to 226*

❒ Other, please specify. _____, *Continue to 226*

226. Will the requested drug be used in combination with pemetrexed and platinum chemotherapy (e.g., cisplatin, carboplatin)?
❒ Yes, *No further questions*
❒ No, *No further questions*

227. What is the diagnosis?

❒ Adrenal tumors, *Continue to 241*

❒ Ampullary adenocarcinoma, *Continue to 239*

❒ Anal carcinoma, *Continue to 241*

❒ Anaplastic thyroid carcinoma, *Continue to 239*
❒ Biliary tract cancers (including intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, gallbladder cancer), *Continue to 239*

❒ Bone cancer (Chondrosarcoma, Ewing Sarcoma, Osteosarcoma, Chordoma), *Continue to 239*

❒ Breast cancer, *Continue to 239*

❒ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer, *Continue to 241*

❒ Cervical cancer, *Continue to 239*

❒ Classical Hodgkin lymphoma, *Continue to 239*

❒ Colorectal cancer (including appendiceal carcinoma), *Continue to 239*

❒ Cutaneous melanoma, *Continue to 229*

❒ Cutaneous squamous cell skin carcinoma, *Continue to 239*

❒ Endometrial carcinoma, *Continue to 239*

❒ 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 239*

❒ Esophageal cancer, *Continue to 239*

❒ Esophagogastric junction cancer, *Continue to 239*

❒ Extranodal NK/T-cell lymphoma, *Continue to 241*

❒ Follicular, oncocytic (hurthle cell), or papillary thyroid carcinoma, *Continue to 239*

❒ Gastric cancer, *Continue to 239*

❒ Gestational trophoblastic neoplasia, *Continue to 241*

❒ Head and neck squamous cell carcinoma with mixed subtypes (HNSCC) or nasopharyngeal cancer, *Continue to 239*

❒ Hepatocellular carcinoma, *Continue to 239*

❒ Kaposi sarcoma, *Continue to 241*

❒ Malignant pleural mesothelioma, *Continue to 239*

❒ Medullary thyroid carcinoma, *Continue to 239*

❒ Merkel Cell Carcinoma, *Continue to 239*

❒ Microsatellite instability-high or mismatch repair deficient solid tumor, *Continue to 239*

❒ Neuroendocrine tumors, *Continue to 239*

❒ Non-small cell lung cancer, *Continue to 228*

❒ Occult primary cancer, *Continue to 239*

❒ Pancreatic adenocarcinoma, *Continue to 239*

❒ Pediatric Diffuse High-Grade Gliomas, *Continue to 241*

❒ Penile cancer, *Continue to 239*

❒ Primary carcinoma of the urethra, *Continue to 239*

❒ Primary Cutaneous Lymphomas, *Continue to 241*

❒ Primary mediastinal large B-cell lymphoma, *Continue to 239*

❒ Prostate cancer, *Continue to 239*

❒ Renal cell carcinoma, *Continue to 228*

❒ Salivary gland tumors, *Continue to 239*

❒ Small Bowel Adenocarcinoma, *Continue to 239*

❒ Small cell lung cancer, *Continue to 241*

❒ Soft Tissue Sarcomas, *Continue to 241*

❒ Testicular cancer, *Continue to 239*

❒ Thymomas and thymic carcinoma, *Continue to 241*

❒ Triple-Negative Breast Cancer (TNBC), high-risk early-stage disease, *Continue to 229*

❒ Triple-Negative Breast Cancer (TNBC), locally recurrent unresectable or metastatic, *Continue to 239*

❒ Tumor mutational burden-high solid tumor, *Continue to 239*

❒ Urothelial carcinoma of bladder, *Continue to 233*

❒ Urothelial carcinoma of the upper genitourinary tract tumor or urothelial carcinoma of the prostate, *Continue to 238*

❒ Uterine sarcoma, *Continue to 239*

❒ Uveal melanoma, *Continue to 241*

❒ Vaginal cancer, *Continue to 241*

❒ Vulvar cancer, *Continue to 232*

❒ Other, please specify. _____, *No further questions*

228. Is the request for the adjuvant treatment of renal cell carcinoma, adjuvant treatment of non-small cell lung cancer, or neoadjuvant therapy and then continuing as adjuvant therapy of non-small cell lung cancer?

❒ Yes, adjuvant treatment of renal cell carcinoma, *Continue to 230*

❒ Yes, adjuvant treatment of non-small cell lung cancer, *Continue to 230*

❒ Yes, neoadjuvant treatment and then continuing as adjuvant treatment of non-small cell lung cancer, *Continue to 230*

❒ No, *Continue to 239*

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

❒ Yes, *Continue to 230*

❒ No, *Continue to 241*

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

❒ Yes, *Continue to 231*

❒ No, *Continue to 231*

231. How many months of treatment has the patient received with the requested drug?

_____months, *No further questions*

232. 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 239*

❒ PD-L1 expression with CPS score greater than or equal to 1, *Continue to 241*

233. Is the requested drug be used in combination with enfortumab vedotin-ejfv (Padcev)?

❒ Yes, *Continue to 241*

❒ No, *Continue to 234*

234. Is the requested drug prescribed for the treatment of high-risk BCG-unresponsive non-muscle invasive bladder cancer?
❒ Yes, *Continue to 235*
❒ No, *Continue to 236*
235. Is the disease persistent or recurrent?
❒ Yes, *Continue to 236*
❒ No, *Continue to 236*
236. Is there evidence of disease progression or unacceptable toxicity on the current regimen?
❒ Yes, *Continue to 237*
❒ No, *Continue to 237*
237. How many continuous months of treatment has the patient received with the requested drug?

_____months, *No further questions*

238. Is the requested drug be used to treat urothelial carcinoma in combination with enfortumab vedotin-ejfv (Padcev)?
❒ Yes, *Continue to 241*
❒ No, *Continue to 239*
239. Is there evidence of disease progression or unacceptable toxicity on the current regimen?
❒ Yes, *Continue to 240*
❒ No, *Continue to 240*
240. How many continuous months of treatment has the patient received with the requested drug?

_____months, *No further questions*

241. 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