Opdivo

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

 CareFirst Opdivo SGM 1894-A SOC 5374-A – 08/2024.

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

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., Keytruda, Imfinzi)?
❒ Yes, *Continue to 2*
❒ No, *Continue to 4*

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 the patient currently receiving treatment with the requested medication?
❒ Yes, *Continue to 136*
❒ No, *Continue to 5*

5. What is the diagnosis?
❒ Cutaneous melanoma, *Continue to 6*
❒ Non-small cell lung cancer (NSCLC), *Continue to 14*
❒ Renal cell carcinoma, *Continue to 21*
❒ Classical Hodgkin lymphoma (cHL), *Continue to 26*
❒ Cervical cancer, *Continue to 32*
❒ Head and neck cancers, *Continue to 36*
❒ Urothelial carcinoma - Bladder cancer, *Continue to 39*
❒ Urothelial carcinoma - Primary carcinoma of the urethra, *Continue to 44*
❒ Urothelial carcinoma - Upper genitourinary tract tumor or urothelial carcinoma of the prostate, *Continue to 49*
❒ Colorectal cancer (including appendiceal adenocarcinoma and anal adenocarcinoma), *Continue to 55*
❒ Small bowel adenocarcinoma, *Continue to 87*
❒ Ampullary adenocarcinoma, *Continue to 90*
❒ Hepatocellular carcinoma, *Continue to 57*
❒ Uveal melanoma, *Continue to 58*
❒ Anal carcinoma, *Continue to 60*
❒ Merkel cell carcinoma, *Continue to 63*
❒ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer, *Continue to 67*
❒ Gestational trophoblastic neoplasia, *Continue to 71*
❒ Pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, *Continue to 75*
❒ Esophageal and esophagogastric junction cancer, *Continue to 78*
❒ Extranodal NK/T-cell lymphoma, *Continue to 86*
❒ Endometrial carcinoma, *Continue to 93*

❒ Vulvar cancer, *Continue to 96*
❒ Gastric cancer, *Continue to 100*
❒ Small cell lung cancer, *Continue to 111*
❒ Pediatric diffuse high-grade gliomas, *Continue to 114*
❒ Pediatric primary mediastinal large B-Cell lymphoma, *Continue to 116*
❒ Kaposi sarcoma, *Continue to 118*
❒ Bone cancer, *Continue to 122*
❒ Biliary Tract Cancer (Cholangiocarcinoma and Gallbladder Cancer), *Continue to 127*
❒ Soft tissue sarcoma, *Continue to 131*
❒ Anaplastic thyroid carcinoma, *Continue to 134*
❒ Other, please specify. _____, *No further questions*

6. What is the clinical setting in which the requested drug will be used?
❒ Adjuvant treatment, *Continue to 7*
❒ Neoadjuvant treatment, *Continue to 9*
❒ Unresectable disease, *Continue to 13*
❒ Metastatic disease, *Continue to 13*
❒ Other, please specify. _____ *No further questions*

7. What is the clinical setting in which the requested drug will be used?
❒ Stage III or IV disease, *Continue to 8*
❒ Stage IIB and IIC, *Continue to 11*
❒ Other, please specify. _____ *No further questions*

8. Will the requested drug be used following complete resection or no evidence of disease?
❒ Yes, *Continue to 10*
❒ No, *Continue to 10*

9. What is the clinical setting in which the requested drug will be used?
❒ Resectable disease, *Continue to 10*
❒ Other, please specify. _____, *Continue to 10*

10. Will the requested drug be used in any of the following regimens?
❒ Single agent, *No further questions*
❒ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent), *No further questions*
❒ Other, please specify. _____, *No further questions*

11. Will the requested drug be used following complete resection?
❒ Yes, *Continue to 12*
❒ No, *Continue to 12*

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

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

❒ Single agent, *No Further Questions*
❒ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Single agent, *Continue to 15*

❒ In a regimen containing ipilimumab (Yervoy), *Continue to 16*

❒ In combination with platinum-doublet chemotherapy (e.g., docetaxel and cisplatin), *Continue to 19*

❒ Other, please specify. _____ , *No Further Questions*

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

❒ First-line treatment, *Continue to 16*

❒ Subsequent treatment, *Continue to 16*

16. Is the patient positive for any of the following: EGFR exon 19 deletions, L858R mutations or ALK rearrangements? ***ACTION REQUIRED***: Please attach chart note(s) or test results of EGFR exon 19 deletions or L858R mutations and ALK rearrangements, where applicable.

❒ Yes ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 18*

❒ No ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 18*

❒ Unknown, *Continue to 17*

17. Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?
❒ Yes, *Continue to 18*
❒ No, *Continue to 18*

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

❒ Recurrent disease, *No Further Questions*

❒ Advanced disease, *No Further Questions*

❒ Metastatic disease, *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

19. Will the requested drug be used as neoadjuvant treatment?
❒ Yes, *Continue to 20*
❒ No, *Continue to 20*

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

❒ Resectable disease, *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Relapsed disease, *Continue to 22*

❒ Advanced disease, *Continue to 22*

❒ Stage IV disease, *Continue to 22*

❒ Other, please specify. _____, *Continue to 22*

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

❒ Single agent, *Continue to 23*

❒ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent), *Continue to 25*

❒ In combination with cabozantinib, *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

23. What is the histology?

❒ Clear cell, *Continue to 24*

❒ Non-clear cell, *No Further Questions*

24. 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*

25. What is the histology?

❒ Clear cell, *No Further Questions*

❒ Non-clear cell, *No Further Questions*

26. Will the requested drug be used as a single agent, in combination with brentuximab vedotin or in combination with ICE (ifosfamide, carboplatin, etoposide)?

❒ Yes, as a single agent, *Continue to 27*

❒ Yes, in combination with brentuximab vedotin, *Continue to 31*

❒ Yes, in combination with ICE (ifosfamide, carboplatin, etoposide), *Continue to 31*

❒ Other, please specify. _____, *No Further Questions*

27. Is the disease refractory to at least three lines of prior therapy?

❒ Yes, *No Further Questions*

❒ No, *Continue to 28*

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

❒ Relapsed disease, *Continue to 29*

❒ Refractory disease, *Continue to 29*

❒ Other, please specify. _____, *Continue to 29*

29. Which of the following applies to the patient?

❒ The patient was heavily pretreated, *Continue to 30*

❒ There was a decrease in cardiac function, *Continue to 30*

❒ Other, please specify. _____, *Continue to 30*

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

❒ Subsequent therapy, *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

31. 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*

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

❒ Yes, *Continue to 33*

❒ No, *Continue to 33*

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

❒ Recurrent disease, *Continue to 34*

❒ Metastatic disease, *Continue to 34*

❒ Other, please specify. _____, *Continue to 34*

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

❒ First-line treatment, *Continue to 35*

❒ Subsequent treatment, *Continue to 35*

35. Is the patient's disease positive for programmed death ligand 1 (PD-L1) combined positive score [CPS] 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*

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

❒ Unresectable disease, *Continue to 37*

❒ Recurrent disease, *Continue to 37*

❒ Persistent disease, *Continue to 37*

❒ Metastatic disease, *Continue to 37*

❒ Other, please specify. _____, *Continue to 37*

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

❒ Non-nasopharyngeal cancer, *No Further Questions*

❒ Nasopharyngeal cancer, *Continue to 38*

38. Will the requested drug be used in combination with cisplatin and gemcitabine?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

39. What is the requested regimen?

❒ In combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy, *Continue to 40*

❒ As a single agent, *Continue to 41*

❒ Other, please specify. _____, *No Further Questions*

40. 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*

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

❒ Locally advanced disease, *Continue to 42*

❒ Metastatic disease, *Continue to 42*)

❒ Recurrent disease, *Continue to 42*

❒ Persistent disease, *Continue to 42*

❒ High risk of recurrence after undergoing resection, *Continue to 43*

❒ Other, please specify. _____, *No Further Questions*

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

❒ First-line treatment, *Continue to 43*

❒ Subsequent treatment, *No Further Questions*

43. Will the requested drug be used as adjuvant treatment?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

44. What is the requested regimen?

❒ In combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy, *Continue to 45*

❒ As a single agent, *Continue to 46*

❒ Other, please specify. _____, *No Further Questions*

45. 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*

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

❒ Recurrent disease, *Continue to 47*

❒ Locally advanced disease, *Continue to 47*

❒ Metastatic disease, *Continue to 47*

❒ High risk of recurrence after undergoing resection, *Continue to 48*

❒ Other, please specify. _____, *Continue to 47*

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

❒ First-line treatment (If checked, *no further questions*)

❒ Subsequent treatment (If checked, *no further questions*)

48. Will the requested drug be used as adjuvant treatment?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

49. What is the requested regimen?
❒ In combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy, *Continue to 50*

❒ As a single agent, *Continue to 52*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Metastatic upper genitourinary (GU) tract tumors, *Continue to 51*

❒ Metastatic urothelial carcinoma of the prostate, *Continue to 51*

❒ Other, please specify. _____, *Continue to 51*

51. 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*

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

❒ Locally advanced disease, *Continue to 53*

❒ Metastatic disease, *Continue to 53*

❒ High risk of recurrence after undergoing resection, *Continue to 54*

❒ Other, please specify. _____, *Continue to 53*

53. 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*

54. Will the requested drug be used as adjuvant treatment?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

55. 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 56*

❒ No, *Continue to 56*

❒ Unknown, *Continue to 56*

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

❒ Single agent, *No Further Questions*

❒ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

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

❒ As a single agent, *No Further Questions*

❒ In combination with ipilimumab (Yervoy), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Metastatic disease, *Continue to 59*

❒ Unresectable disease, *Continue to 59*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Single agent, *No Further Questions*

❒ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Yes, *Continue to 61*

❒ No, *Continue to 61*

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. 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*

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

❒ Node positive disease, *Continue to 64*)

❒ Node negative locally advanced disease, *Continue to 64*

❒ Metastatic disease, *No Further Questions*

❒ Unresectable disease, *Continue to 66*

❒ Recurrent disease, *Continue to 66*

❒ Stage IV disease, *Continue to 66*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Yes, *Continue to 65*

❒ No, *Continue to 65*

65. Will the requested drug be used as neoadjuvant treatment?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

66. Will the requested drug be used in combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

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

❒ Single agent, *Continue to 68*
❒ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent), *Continue to 70*

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

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

❒ Melanoma, *No Further Questions*

❒ Non-small cell lung cancer, *Continue to 69*

❒ Other, please specify. _____, *Continue to 69*

69. 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*

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

❒ Melanoma, *No Further Questions*

❒ Non-small cell lung cancer, *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

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

72. Is the disease resistant to multi-agent chemotherapy?
❒ Yes, *Continue to 73*
❒ No, *Continue to 73*

73. What type of disease does the patient have?
❒ Intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor), *Continue to 74*

❒ High-risk disease, *No Further Questions*

❒ Other, please specify. _____, *Continue to 74*

74. 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*

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

❒ First-line therapy, *Continue to 77*

❒ Subsequent treatment, *Continue to 76*

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

❒ Single agent, *No Further Questions*

❒ In combination with ipilimumab (Yervoy), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

77. Will the requested drug be used in combination with ipilimumab (Yervoy)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

78. Will the requested drug be used as adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease?

❒ Yes, *No Further Questions*

❒ No, *Continue to 79*

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

❒ Patient is not a surgical candidate, *Continue to 80*

❒ Unresectable locally advanced disease, *Continue to 80*

❒ Recurrent disease, *Continue to 80*

❒ Metastatic disease, *Continue to 80*

❒ Neoadjuvant treatment, *Continue to 82*

❒ Perioperative treatment, *Continue to 82*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Yes, *No Further Questions*

❒ No, *Continue to 81*

81. How will the requested drug be used?

❒ In combination with ipilimumab (Yervoy), *No Further Questions*

❒ In combination with chemotherapy, *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

82. Will the requested drug be used to treat esophageal or esophagogastric junction adenocarcinoma?

❒ Yes, *Continue to 83*

❒ No, *Continue to 83*

83. 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 ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 84*

❒ No, *Continue to 84*

❒ Unknown, *Continue to 84*

84. Is the patient medically fit for surgery?
❒ Yes, *Continue to 85*
❒ No, *Continue to 85*

85. How will the requested drug be used?

❒ As a single agent, *No Further Questions*

❒ In combination with ipilimumab (Yervoy), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

86. 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*

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

❒ Single agent, *Continue to 88*
❒ In combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent), *Continue to 88*

❒ Other, please specify. _____, *Continue to 88*

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

❒ Advanced disease. *Continue to 89*

❒ Metastatic disease, *Continue to 89*

❒ Other, please specify. _____ , *Continue to 889*

89. 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*

90. Will the requested drug be used in combination with ipilimumab (Yervoy) (4 doses of ipilimumab, followed by Opdivo as a single agent)?
❒ Yes, *Continue to 91*
❒ No, *Continue to 91*

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

❒ Progressive disease, *Continue to 92*

❒ Unresectable disease, *Continue to 92*

❒ Metastatic disease, *Continue to 92*

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

92. 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 ***ACTION REQUIRED***: Submit supporting documentation, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

93. 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 ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 94*

❒ No, *Continue to 94*

❒ Unknown, *Continue to 94*

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

❒ Recurrent disease, *Continue to 95*

❒ Metastatic disease, *Continue to 95*

❒ Other, please specify. _____ *Continue to 95*

95. 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*

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

❒ [] Advanced disease, *Continue to 97*

❒ [] Recurrent disease, *Continue to 97*

❒ [] Metastatic disease, *Continue to 97*

❒ [] Other, please specify. _____, *Continue to 97*

97. Is the disease HPV-related?

❒ Yes, *Continue to 98*

❒ No, *Continue to 98*

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

❒ First line therapy, *Continue to 99*

❒ Subsequent therapy, *Continue to 99*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

100. Has the patient completed endoscopic resection?

❒ Yes, *Continue to 101*

❒ No, *Continue to 105*

101. Is the patient's disease in early stage?
❒ Yes, *Continue to 102*
❒ No, *Continue to 102*

102. Which of the following applies to the patient? ***ACTION REQUIRED***: Attach chart note(s) or test results confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or HER-2 overexpression status.
❒ Microsatellite instability-high (MSI-H) tumor ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 103*
❒ Mismatch repair deficient (dMMR) tumor ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 103*
❒ HER-2 overexpression negative disease ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 104*
❒ None of the above or unknown, *No Further Questions*

103. What is the requested regimen?
❒ In combination with ipilimumab (Yervoy), *No Further Questions*
❒ In combination with chemotherapy, *No Further Questions*
❒ Other, please specify. _____, *No Further Questions*

104. What is the requested regimen?
❒ In combination with chemotherapy, *No Further Questions*
❒ Other, please specify. _____, *No Further Questions*

105. What is the clinical setting in which the requested drug will be used?
❒ Patient is not a surgical candidate, *Continue to 106*
❒ Unresectable disease, *Continue to 106*
❒ Recurrent disease, *Continue to 106*
❒ Metastatic disease, *Continue to 106*
❒ Neoadjuvant treatment, *Continue to 107*
❒ Perioperative treatment, *Continue to 107*
❒ Other, please specify. _____, *No Further Questions*

106. Will the requested drug be used in combination with ipilimumab (Yervoy) or chemotherapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

107. Will the requested drug be used to treat gastric adenocarcinoma?
❒ Yes, *Continue to 108*
❒ No, *Continue to 108*

108. 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 ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 109*

❒ No, *Continue to 109*

❒ Unknown, *Continue to 109*

109. Is the patient medically fit for surgery?
❒ Yes, *Continue to 110*
❒ No, *Continue to 110*

110. How will the requested drug be used?

❒ As a single agent, *No Further Questions*

❒ In combination with ipilimumab (Yervoy), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Relapsed disease, *Continue to 112*

❒ Progressive disease, *Continue to 112*

❒ Other, please specify. _____, *Continue to 112*

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

❒ First line therapy, *Continue to 113*

❒ Subsequent therapy, *Continue to 113*

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

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

❒ As adjuvant treatment, *Continue to 115*

❒ Recurrent disease, *Continue to 115*

❒ Progressive disease, *Continue to 115*

❒ Other, please specify. _____, *Continue to 115*

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

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

❒ As a single agent, *Continue to 117*

❒ In combination with brentuximab vedotin (Adcetris), *Continue to 117*

❒ Other, please specify. _____, *Continue to 117*

117. 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*

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

❒ Classic Kaposi sarcoma, *Continue to 119*

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

119. Will the requested drug be used in combination with ipilimumab (Yervoy)?
❒ Yes, *Continue to 120*
❒ No, *Continue to 120*

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

❒ First-line therapy, *Continue to 121*

❒ Subsequent therapy, *Continue to 121*

121. 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*

122. Will the requested drug be used in combination with ipilimumab (Yervoy)?
❒ Yes, *Continue to 123*
❒ No, *Continue to 123*

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

❒ Unresectable disease, *Continue to 124*

❒ Metastatic disease, *Continue to 124*

❒ Other, please specify. _____, *Continue to 124*

124. Is the tumor mutation burden-high (TMB-H) [equal or greater to10 mutations/megabase (mut/Mb)] tumors?
ACTION REQUIRED: If Yes, attach chart note(s) or test results confirming tumor mutation burden-high (TMB-H) status.

❒ Yes ***ACTION REQUIRED***: Submit supporting documentation, *Continue to 125*

❒ No, *Continue to 125*

❒ Unknown, *Continue to 125*

125. Has the disease progressed following prior treatment?
❒ Yes, *Continue to 126*
❒ No, *Continue to 126*

126. Are there satisfactory alternative treatment options available for the patient's disease?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

127. Will the requested drug be used in combination with ipilimumab (Yervoy)?
❒ Yes, *Continue to 128*
❒ No, *Continue to 128*

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

❒ First-line therapy, *Continue to 129*

❒ Subsequent therapy, *Continue to 129*

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

❒ Unresectable gross residual (R2) disease, *Continue to 130*

❒ Resected gross residual (R2) disease, *Continue to 130*

❒ Metastatic disease, *Continue to 130*

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

130. Is the tumor mutation burden-high (TMB-H)? ***ACTION REQUIRED***: If Yes, attach chart note(s) or test results confirming mutation burden-high (TMB-H) status.

❒ Yes ***ACTION REQUIRED***: Submit supporting documentation, *No Further Questions*

❒ No, *No Further Questions*

❒ Unknown, *No Further Questions*

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

❒ Extremity/body wall sarcomas, *Continue to 132*

❒ Head/neck sarcomas, *Continue to 132*

❒ Retroperitoneal/intra-abdominal sarcomas, *Continue to 132*

❒ Rhabdomyosarcoma, *Continue to 132*

❒ Angiosarcoma, *Continue to 133*

❒ Other, please specify. _____, *No Further Questions*

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

❒ Single agent, *No Further Questions*

❒ In combination with ipilimumab (Yervoy), *No Further Questions*

❒ Other, please specify. _____, *No Further Questions*

133. Will the requested drug be used in combination with ipilimumab (Yervoy)?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

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

❒ Stage IVC disease, *Continue to 135*

❒ Other, please specify. _____, *Continue to 135*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

136. What is the diagnosis?

❒ Cutaneous melanoma, *Continue to 137*

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

❒ Renal cell carcinoma, *Continue to 146*

❒ Classical Hodgkin lymphoma (cHL), *Continue to 162*

❒ Head and neck cancers, *Continue to 162*

❒ Urothelial carcinoma - Bladder cancer, *Continue to 157*

❒ Urothelial carcinoma - Primary carcinoma of the urethra, *Continue to 157*
❒ Urothelial carcinoma - Upper genitourinary tract tumor or urothelial carcinoma of the prostate, *Continue to 157*
❒ Colorectal cancer (including appendiceal adenocarcinoma and anal adenocarcinoma), *Continue to 162*
❒ Small bowel adenocarcinoma, *Continue to 162*
❒ Ampullary adenocarcinoma, *Continue to 162*
❒ Hepatocellular carcinoma, *Continue to 162*
❒ Uveal melanoma, *Continue to 162*
❒ Anal carcinoma, *Continue to 162*
❒ Merkel cell carcinoma, *Continue to 162*
❒ Central nervous system (CNS) brain metastases in patients with melanoma or non-small cell lung cancer, *Continue to 162*
❒ Gestational trophoblastic neoplasia, *Continue to 162*
❒ Pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma, *Continue to 140*
❒ Esophageal and esophagogastric junction cancer, *Continue to 152*
❒ Extranodal NK/T-cell lymphoma, *Continue to 162*
❒ Endometrial carcinoma, *Continue to 162*
❒ Vulvar squamous cell carcinoma, *Continue to 162*
❒ Gastric cancer, *Continue to 149*
❒ Small cell lung cancer, *Continue to 162*
❒ Cervical cancer, *Continue to 162*
❒ Pediatric Diffuse High-Grade Gliomas, *Continue to 162*
❒ Pediatric primary mediastinal large B-Cell lymphoma, *Continue to 162*
❒ Kaposi sarcoma, *Continue to 162*
❒ Bone cancer, *Continue to 162*
❒ Biliary Tract Cancer, (Cholangiocarcinoma and Gallbladder Cancer), *Continue to 162*
❒ Soft tissue sarcoma, *Continue to 162*
❒ Anaplastic thyroid carcinoma, *Continue to 162*)
❒ Other, please specify. _____, *No Further Questions*

137. Is the requested drug prescribed for the adjuvant treatment of melanoma?
❒ Yes, *Continue to 138*
❒ No, *Continue to 162*

138. Is there evidence of disease recurrence or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 139*
❒ No, *Continue to 139*

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

140. Will the requested drug be used in combination with ipilimumab or in combination with platinum-doublet chemotherapy?

❒ Yes, *Continue to 141*
❒ No, *Continue to 162*

141. Is this request for neoadjuvant treatment of NSCLC?
❒ Yes, *Continue to 142*
❒ No, *Continue to 144*

142. Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 143*
❒ No, *Continue to 143*

143. How many months has the patient received therapy with the requested drug?
_____ months, *No further questions*

144. Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 145*
❒ No, *Continue to 145*

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

146. Will the requested drug be used in combination with cabozantinib?
❒ Yes, *Continue to 147*
❒ No, *Continue to 162*

147. Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 148*
❒ No, *Continue to 148*

148. How many continuous months of treatment has the patient received with the requested drug in combination with cabozantinib?
_____ months, *No further questions*

149. Has the patient completed endoscopic resection or will the requested drug be used in combination with chemotherapy?
❒ Yes, the patient has completed endoscopic resection, *Continue to 150*
❒ Yes, the requested drug will be used in combination with chemotherapy, *Continue to 150*
❒ No, *Continue to 162*

150. Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 151*
❒ No, *Continue to 151*

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

152. Which of the following applies to the patient's disease?
❒ Esophageal squamous cell carcinoma in combination with ipilimumab, *Continue to 153*

❒ Esophageal squamous cell carcinoma in combination with chemotherapy, *Continue to 153*
❒ Unresectable advanced esophageal squamous cell carcinoma single agent treatment, *Continue to 162*
❒ Recurrent esophageal squamous cell carcinoma single agent treatment, *Continue to 162*
❒ Metastatic esophageal squamous cell carcinoma single agent treatment, *Continue to 162*
❒ Resected esophageal cancer used as a single agent adjuvant treatment, *Continue to 155*
❒ Resected esophagogastric junction cancer used as a single adjuvant agent treatment, *Continue to 155*
❒ Esophagogastric junction cancer in combination with chemotherapy, *Continue to 153*
❒ Esophageal adenocarcinoma in combination with chemotherapy, *Continue to 153*
❒ Other, please specify. _____, *Continue to 162*

153. Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 154*
❒ No, *Continue to 154*

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

155. Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 156*
❒ No, *Continue to 156*

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

157. Is this request for adjuvant treatment of urothelial carcinoma or the requested drug is used in combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy?
❒ Yes, adjuvant treatment of urothelial carcinoma, *Continue to 158*
❒ Yes, the requested drug is used in combination with gemcitabine and cisplatin for up to 6 cycles followed by nivolumab maintenance therapy, *Continue to 160*
❒ No, *Continue to 162*

158. Is there evidence of disease recurrence or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 159*
❒ No, *Continue to 159*

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

160. Is there evidence of disease progression or unacceptable toxicity while on the current regimen?
❒ Yes, *Continue to 161*
❒ No, *Continue to 161*

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

162. Is there evidence of disease progression or unacceptable toxicity while 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