Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Please indicate: ☐ Start of treatment: Start date ____/____/____
☐ Continuation of therapy, Date of last treatment ____/____/____

Precertification Requested By: _____ Phone: _____ Fax: _____

A. PATIENT INFORMATION

First Name:	Last Name:		DOB:	
Address:		City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	Email:	
Patient Current Weight: ____ lbs or ____ kgs Patient Height: ____ inches or ____ cms			Allergies:	

B. INSURANCE INFORMATION

Aetna Member ID #: _____
Group #: _____
Insured:

Does patient have other coverage? ☐ Yes ☐ No
If yes, provide ID#: _____ Carrier Name: _____
Insured:

Medicare: ☐ Yes ☐ No If yes, provide ID #:

Medicaid: ☐ Yes ☐ No If yes, provide ID #:

C. PRESCRIBER INFORMATION

First Name:	Last Name:			*(Check One):* ☐ M.D. ☐ D.O. ☐ N.P. ☐ P.A.	
Address:		City:		State:	ZIP:
Phone:	Fax:	St Lic #:	NPI #:	DEA #:	UPIN:
Provider Email:		Office Contact Name:		Phone:	

Specialty *(Check one):* ☐ **Oncologist** ☐ **Other**: _____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☐ Outpatient Infusion Center Phone: _____
Center Name: _____
☐ Home Infusion Center Phone: _____
Agency Name: _____
☐ Administration code(s) (CPT): _____
Address: _____

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☐ Other: _____
Name: _____
Address: _____
Phone: _____ Fax: _____
TIN: _____ PIN: _____

E. PRODUCT INFORMATION

Request is for: Keytruda (pembrolizumab)
Dose: _____ **Frequency:** _____

F. DIAGNOSIS INFORMATION - Please indicate primary ICD code and specify any other where applicable.

Primary ICD Code: _____ **Secondary ICD Code:** _____ **Other ICD Code:** _____

G. CLINICAL INFORMATION - Required clinical information must be completed in its entirety for all precertification requests.

For All Requests (clinical documentation required for all requests):

Please list ***all*** additional medications that will be used as part of this treatment regimen (This includes supportive care agents such as anti-emetics, growth factors, etc. A copy of the complete order may be submitted in lieu of listing out each treatment):

Medication: _____ Dose: _____ Frequency: _____
Medication: _____ Dose: _____ Frequency: _____
Medication: _____ Dose: _____ Frequency: _____
Medication: _____ Dose: _____ Frequency: _____
Medication: _____ Dose: _____ Frequency: _____

☐ Yes ☐ No Has the patient experienced disease progression while receiving another programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor (e.g., Opdivo (nivolumab), Tecentriq (atezolizumab), Keytruda (pembrolizumab), Bavencio (avelumab), or Imfinzi (durvalumab))?

→ ☐ Yes ☐ No Is the requested drug prescribed as second-line or subsequent treatment for metastatic or unresectable melanoma?

→ ☐ Yes ☐ No Will the requested drug be used in combination with ipilimumab (Yervoy) following disease progression on single agent anti-PD-1 immunotherapy?

Continued on next page

Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

If the patient has not experienced disease progression while receiving another programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) Inhibitor:

☐ Yes ☐ No Is the requested drug prescribed for a pediatric patient with microsatellite instability-high (MSI-H) or tumor mutational burden-high (TMB-H) central nervous system cancer? ☐ microsatellite instability-high CNS cancer ☐ tumor mutational burden-high CNS cancer

☐ Yes ☐ No Does the patient have a solid tumor that meets any of the following criteria [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]?

→ **If "No", please select the diagnosis from below**

☐ Microsatellite instability-high (MSI-H) solid tumor ☐ Mismatch repair deficient (dMMR) solid tumor

☐ Tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) solid tumor

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

→ **If "No", please select the diagnosis from below**

Please indicate the clinical setting in which the requested drug will be used:

☐ Unresectable disease ☐ Metastatic disease ☐ Other, please identify and select the diagnosis from below: _____

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

→ **If "No", please select the diagnosis from below**

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

→ **If "Yes", please select the diagnosis from below**

☐ **Anal carcinoma**

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

Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Other

Please select the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment

☐ **Anaplastic thyroid carcinoma**

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

☐ Yes ☐ No ☐ Unknown Does the disease have tumor mutational burden-high tumors (greater than or equal to 10 mutations per megabase [mut/Mb])?

Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Other

☐ **Ampullary adenocarcinoma**

☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb))?

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

☐ **Breast Cancer (TNBC)**

☐ Yes ☐ No ☐ Unknown 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?

Please indicate the clinical setting in which the requested medication will be used:

☐ The patient had no response to preoperative systemic therapy ☐ Locally recurrent unresectable disease ☐ Metastatic disease

→ ☐ Yes ☐ No ☐ Unknown Does the patient's disease express programmed death ligand 1 (PD-L1)?

☐ Yes ☐ No Will the requested drug be used in combination with chemotherapy?

☐ High-risk early-stage disease

→ Please indicate the place in therapy in which the requested drug will be used:

☐ Neoadjuvant treatment

→ ☐ Yes ☐ No Will the requested drug be used in combination with chemotherapy?

☐ Continued adjuvant treatment after surgery

→ ☐ Yes ☐ No Will the requested drug be used as a single agent?

☐ Other place in therapy

☐ Other clinical setting

☐ **Central nervous system brain metastases in patients with melanoma or non-small cell lung cancer**

☐ Yes ☐ No Does the patient have a diagnosis of melanoma or non-small cell lung cancer?

→ Please explain: ☐ Melanoma ☐ Non-small cell lung cancer ☐ Other

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

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

Continued on the next page

Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Cervical cancer**
Please indicate which of the following applies to the patient's disease:
☐ Persistent disease ☐ Recurrent disease ☐ Metastatic disease ☐ Other
Please indicate the requested regimen:
☐ Single agent
→ ☐ Yes ☐ No Has the patient experienced disease progression on or after chemotherapy?
→ ☐ Yes ☐ No Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1 or microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
☐ Yes ☐ No Will the requested drug be used as subsequent therapy?
→ ☐ Yes ☐ No Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1?
☐ In combination with chemotherapy
→ ☐ Yes ☐ No Does the tumor express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1?
☐ Other

☐ **Classical Hodgkin lymphoma**
Please indicate the regimen: ☐ Single agent ☐ In combination with GVD (gemcitabine, vinorelbine, liposomal doxorubicin) ☐ Other
Please indicate the clinical setting in which the requested drug will be used: ☐ Relapsed disease ☐ Refractory disease ☐ Progressive disease ☐ Other

☐ **Colorectal cancer (including appendiceal carcinoma)**
Please select which of the following applies to the patient: ☐ Colorectal cancer ☐ Appendiceal carcinoma
☐ Yes ☐ No Will the requested drug be used as a single agent?
☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
Please indicate the clinical setting in which the requested drug will be used:
☐ Inoperable disease ☐ Metastatic disease ☐ Advanced disease ☐ Other

☐ **Cutaneous melanoma**
Please indicate the requested drug regimen: ☐ Single agent ☐ In combination with ipilimumab ☐ Other
Please indicate the clinical setting in which the requested drug will be used:
☐ Adjuvant treatment
→ ☐ Yes ☐ No Has the patient had a complete lymph node surgical resection or complete resection of stage IIB, IIC, III or metastatic disease?
☐ Unresectable disease
☐ Metastatic disease
☐ Recurrent disease
☐ Subsequent therapy
→ ☐ Yes ☐ No Will the requested drug be used for disease progression of metastatic or unresectable tumors?

☐ **Cutaneous squamous cell carcinoma**
☐ Yes ☐ No Will the requested drug be used as a single agent?
☐ Yes ☐ No Is the disease curable by surgery or radiation?

☐ **Endometrial carcinoma**
Please select which of the following applies to the patient's disease:
☐ Mismatch repair proficient (pMMR) tumors
→ Please indicate the clinical setting in which the requested drug will be used:
☐ Advanced disease ☐ Metastatic disease ☐ Recurrent disease ☐ Other
☐ Yes ☐ No Will the requested drug be used in combination with lenvatinib (Lenvima)?
☐ Yes ☐ No Has the patient experienced disease progression following prior systemic therapy?
☐ Yes ☐ No Is the disease curable by surgery or radiation?
☐ Microsatellite instability-high (MSI-H) tumor ☐ Mismatch repair deficient (dMMR) tumor ☐ Tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) tumor
→ Please indicate the clinical setting in which the requested drug will be used:
☐ Recurrent unresectable disease ☐ Metastatic disease ☐ Other
☐ Yes ☐ No Will the requested drug be used as a single agent?

☐ **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**
☐ Yes ☐ No Will the requested drug be used as a single agent?
Please indicate the clinical setting in which the requested drug will be used: ☐ Recurrent disease ☐ Persistent disease ☐ Other
☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (tumors ≥10 mutations/megabase [mut/Mb])?

Continued on next page

Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Esophageal cancer and Esophagogastric Junction Cancer**
Please select the clinical setting in which the requested drug will be used:
☐ Unresectable locally advanced disease ☐ Metastatic disease ☐ Recurrent disease ☐ The patient is not a surgical candidate ☐ Other
What is the requested regimen?
☐ Combination with platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy
→ ☐ Yes ☐ No ☐ Unknown Is the tumor HER2 overexpression negative adenocarcinoma?
If no or unknown: What is the patient's disease histology? ☐ Squamous cell carcinoma ☐ Non-squamous cell carcinoma
☐ Combination with trastuzumab, platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy
→ ☐ Yes ☐ No ☐ Unknown Is the tumor HER2 overexpression positive?
☐ None of the above regimen
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb))?
→ ☐ Yes ☐ No Will the requested drug be used as a single agent?
☐ Yes ☐ No ☐ Unknown Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of ≥ 10?
→ What is the patient's disease histology? ☐ Squamous cell carcinoma ☐ Non- squamous cell carcinoma

☐ **Extranodal NK/T-Cell Lymphoma**
Please select the clinical setting in which the requested drug will be used: ☐ Relapsed disease ☐ Refractory disease ☐ Other

☐ **Follicular, hürthle cell, or papillary thyroid carcinoma**
Please select the clinical setting in which the requested drug will be used: ☐ Unresectable disease ☐ Metastatic disease ☐ Other
☐ Yes ☐ No ☐ Unknown Does the disease have tumor mutational burden-high tumors (greater than or equal to 10 mutations per megabase [mut/Mb])?
☐ Yes ☐ No Is the disease amenable to radioactive iodine therapy?

☐ **Gastric cancer**
Please select the clinical setting in which the requested drug will be used:
☐ Unresectable locally advanced disease ☐ Metastatic disease ☐ Recurrent disease ☐ The patient is not a surgical candidate ☐ Other
Please identify the regimen the requested drug will be used:
☐ Single agent
→ ☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb))?
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
☐ In combination with trastuzumab, platinum (e.g., cisplatin, oxaliplatin) and fluoropyrimidine-based (e.g., fluorouracil, capecitabine) chemotherapy
Please identify the patient's histology: ☐ Adenocarcinoma ☐ Other
→ ☐ Yes ☐ No ☐ Unknown Is the patient's disease HER2-positive?
☐ Other clinical setting

☐ **Gestational trophoblastic neoplasia**
☐ Yes ☐ No Will the requested drug be used as a single agent?
Please select which of the following applies to the patient's disease:
☐ Recurrent intermediate trophoblastic tumor
→ ☐ Yes ☐ No Has the patient had treatment with platinum/etoposide-containing regimen?
☐ Progressive intermediate trophoblastic tumor
→ ☐ Yes ☐ No Has the patient had treatment with platinum/etoposide-containing regimen?
☐ High-risk disease
☐ Other

☐ **Head and neck cancer squamous cell carcinoma with mixed subtypes (HNSCC) and nasopharyngeal cancer**
Please select the clinical setting in which the requested drug will be used: ☐ Very advanced disease ☐ Other
☐ Yes ☐ No Will the requested drug be used as a single agent?
→ Please indicate the requested drug regimen: ☐ In combination with chemotherapy ☐ Other
→ What is the place in therapy in which the requested drug will be used?
☐ First-line therapy
→ ☐ Yes ☐ No ☐ Unknown Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of ≥ 1, are microsatellite instability-high (MSI-H)), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [≥ 10 mut/Mb]?
☐ Subsequent therapy

☐ **Hepatobiliary cancers (including gallbladder, intrahepatic/extrahepatic cholangiocarcinoma)**
☐ Yes ☐ No Will the requested drug be used as a single agent?
☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
Please indicate the clinical setting in which the requested drug will be used: ☐ Unresectable disease ☐ Metastatic disease ☐ Other

Continued on next page

Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Hepatocellular carcinoma (HCC)**
- ☐ Yes ☐ No Has the patient received previous treatment with sorafenib (Nexavar)?

☐ **Kaposi sarcoma**
- Please indicate the type: ☐ Endemic Kaposi sarcoma ☐ Classic Kaposi sarcoma ☐ Other
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
- Please indicate the clinical setting in which the requested drug will be used: ☐ Relapsed/refractory disease ☐ Other

☐ **Medullary thyroid carcinoma**
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Unresectable disease ☐ Recurrent disease ☐ Metastatic disease ☐ Other
- ☐ Yes ☐ No ☐ Unknown Does the disease have tumor mutational burden-high tumors (greater than or equal to 10 mutations per megabase [mut/Mb])?

☐ **Merkel cell carcinoma**
- Please indicate the clinical setting in which the requested drug will be used: ☐ Recurrent disease ☐ Metastatic disease ☐ Other

☐ **Neuroendocrine and Adrenal Tumors (adrenocortical carcinoma)**
- Please indicate the clinical setting in which the requested drug will be used: ☐ Unresectable disease ☐ Metastatic disease ☐ Other

☐ **Non-small cell lung cancer (NSCLC)**
- For stage IB (T2a ≥4 cm), II, or IIIA disease
- ☐ Yes ☐ No Will the requested drug be used as adjuvant treatment following resection and platinum-based chemotherapy (e.g., cisplatin, carboplatin)?
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- For tumor *negative* for EGFR exon 19 deletions, L858R mutations and ALK rearrangements or genomic tumor aberrations *not* feasible due to insufficient tissue:
- Please indicate the clinical setting in which the requested drug will be used: ☐ Recurrent disease ☐ Advanced disease ☐ Metastatic disease ☐ Other
- ☐ Yes ☐ No ☐ Unknown Is the tumor negative for EGFR exon 19 deletions, L858R mutations and ALK rearrangements?
  - → ☐ Yes ☐ No Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?
- Please indicate the regimen:
- ☐ As first-line therapy
  - → ☐ Yes ☐ No Does the patient have programmed death ligand 1 (PDL1) positive disease?
- ☐ As maintenance therapy
  - → ☐ Yes ☐ No Will the requested drug be used as a single agent?
- ☐ In combination with pemetrexed and either carboplatin or cisplatin or ☐ In combination with carboplatin and either paclitaxel or albumin-bound paclitaxel
  - → What is the patient's disease histology? ☐ Nonsquamous cell histology ☐ Squamous cell histology
- ☐ Other
- For tumor *positive* for EGFR exon 19 deletions, L858R mutations and ALK rearrangements or genomic tumor aberrations *feasible* due to insufficient tissue:
- Please indicate the clinical setting in which the requested drug will be used: ☐ Recurrent disease ☐ Advanced disease ☐ Metastatic disease ☐ Other
- ☐ Yes ☐ No ☐ Unknown Is the tumor negative for EGFR exon 19 deletions, L858R mutations and ALK rearrangements?
  - → ☐ Yes ☐ No Is testing for these genomic tumor aberrations not feasible due to insufficient tissue?
- ☐ Yes ☐ No ☐ Unknown Is the tumor programmed death ligand 1 (PD-L1) positive?
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- Please indicate is the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment

☐ **Occult primary cancer**
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- ☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb])?

☐ **Pancreatic adenocarcinoma**
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- ☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tumor mutational burden high (TMB-H) [≥ 10 mut/Mb]?
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Local recurrence in the pancreatic operative bed after resection
- ☐ Recurrent metastatic disease
- ☐ Other
  - → Please indicate the place in therapy in which the requested drug will be used:
    - ☐ First-line therapy OR ☐ Maintenance therapy
      - → Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Other
    - ☐ Subsequent therapy
      - → ☐ Yes ☐ No Has the disease progressed following prior treatment?
      - Please indicate the clinical setting in which the requested drug will be used: ☐ Locally advanced disease ☐ Metastatic disease ☐ Other
    - ☐ Other therapy

Continued on next page

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Pediatric Diffuse High-Grade Gliomas**
Please indicate the clinical setting in which the requested drug will be used:
☐ As adjuvant treatment ☐ Recurrent disease ☐ Progressive disease ☐ Other
☐ Yes ☐ No Is the tumor hypermutant?

☐ **Primary carcinoma of the urethra**
☐ Yes ☐ No Will the requested drug be given as a single agent?
Please indicate the clinical setting in which the requested drug will be used:
☐ Recurrent disease ☐ Locally advanced disease ☐ Metastatic disease ☐ Other
Please indicate is the place in therapy in which the requested drug will be used:
☐ First-line treatment
→ ☐ Yes ☐ No Is the patient eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin)?
☐ Subsequent treatment

☐ **Primary Cutaneous Lymphomas**
Please indicate which of the following applies to the patient:
☐ Mycosis Fungoides/Sezary syndrome
☐ Anaplastic Large Cell Lymphoma (ALCL)
→ What is the clinical setting in which the requested drug will be used? ☐ Relapsed disease ☐ Refractory disease ☐ Other
☐ Yes ☐ No Will the requested drug be given as a single agent?

☐ **Primary mediastinal large B-cell lymphoma (PMBCL)**
☐ Yes ☐ No Will the requested drug be given as a single agent?
Please indicate the clinical setting in which the requested drug will be used: ☐ Relapsed disease ☐ Refractory disease ☐ Other

☐ **Prostate cancer**
☐ Yes ☐ No Will the requested drug be used for treatment of castration-resistant distant metastatic prostate cancer?
☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb])?
Please indicate is the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
☐ Yes ☐ No Will the requested drug be given as a single agent?

☐ **Renal cell carcinoma**
Please indicate how the requested drug will be used:
☐ As a single agent ☐ In combination with axitinib (Inlyta) ☐ In combination with lenvatinib (Lenvima) ☐ Other
Please indicate how the requested drug will be used: ☐ For treatment of advanced disease ☐ For treatment of relapsed disease ☐ For treatment of stage IV disease ☐ Other
☐ Yes ☐ No Will the requested medication be used as adjuvant therapy?
→ Please indicate the disease cell histology: ☐ Clear cell histology ☐ Non-clear cell histology
Please indicate is the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
→ What is the clinical setting in which the requested drug will be used?
☐ Intermediate-high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions
☐ High risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions
☐ Other

☐ **Small Bowel Adenocarcinoma**
☐ Yes ☐ No Will the requested drug be used as a single agent?
Please indicate the clinical setting in which the requested drug will be used: ☐ Advanced disease ☐ Metastatic disease ☐ Other
☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?

☐ **Small cell lung cancer**
☐ Yes ☐ No Will the requested drug be used as a single agent?
Please indicate the clinical setting in which the requested drug will be used: ☐ Relapsed disease ☐ Progressive disease ☐ Other
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Second-line treatment

☐ **Soft Tissue Sarcomas (alveolar soft part sarcoma (ASPS) and cutaneous angiosarcoma)**
Please indicate which of the following applies to the patient's disease:
☐ Alveolar soft part sarcoma (ASPS)
→ Please indicate the treatment regimen: ☐ Single agent ☐ In combination with axitinib (Inlyta) ☐ Other
☐ Cutaneous angiosarcoma
→ ☐ Yes ☐ No Will the requested drug be used as a single agent?
☐ Other

Continued on next page

Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION *(continued)* – Required clinical information must be completed in its entirety for all precertification requests.

☐ **Testicular cancer**
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- Please indicate the place in therapy in which the requested drug will be used:
- ☐ First-line treatment ☐ Second-line treatment ☐ Third-line or subsequent treatment
- ☐ Yes ☐ No ☐ Unknown Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden-high (TMB-H) (tumors ≥10 mutations/megabase [mut/Mb])?

☐ **Thymic carcinoma**
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Unresectable disease ☐ Locally advanced disease ☐ Metastatic disease ☐ Other
- *If Other clinical setting*: ☐ Yes ☐ No Will the requested drug be used as postoperative therapy for residual tumor in member who cannot tolerate first-line combination regimens?

☐ **Upper genitourinary (GU) tract tumors or** ☐ **Urothelial carcinoma of the prostate**
- ☐ Yes ☐ No Will the requested drug be given as a single agent?
- Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Other
- Please indicate the place in therapy in which the requested drug will be used:
- ☐ First-line treatment
  - → ☐ Yes ☐ No Is the patient eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin)?
- ☐ Subsequent treatment

☐ **Urothelial carcinoma- Bladder cancer**
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- Please indicate the place in therapy in which the requested drug will be used:
- ☐ First-line treatment
  - → Please indicate the clinical setting in which the requested drug will be used: ☐ Locally advanced disease ☐ Metastatic disease ☐ Other
  - ☐ Yes ☐ No Is the patient eligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin)?
- ☐ Subsequent therapy
  - → ☐ Yes ☐ No Is the requested drug prescribed for the treatment of high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS)?
    - → ☐ Yes ☐ No Is the disease responsive to Bacillus Calmette-Guerin (BCG)?
    - ☐ Yes ☐ No Is the patient eligible for cystectomy?
      - → ☐ Yes ☐ No Has the patient elected not to undergo cystectomy?

☐ **Uveal melanoma**
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- Please indicate the clinical setting in which the requested drug will be used: ☐ Distant metastatic disease ☐ Other

☐ **Vulvar cancer**
- ☐ Yes ☐ No Will the requested drug be used as a single agent?
- Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment
- Please indicate the clinical setting in which the requested drug will be used: ☐ Advanced disease ☐ Recurrent disease ☐ Metastatic disease ☐ Other
- What is the patient's disease histology? ☐ Squamous histology ☐ Nonsquamous histology
- ☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or tumor mutational burden high (TMB-H [≥ 10 mut/Mb]?
  - → ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of ≥ 1?
  - ☐ Yes ☐ No Has the patient had disease progression on or after chemotherapy?
  - → Please select which of the following applies to the patient's disease:
  - ☐ Tumor microsatellite instability-high (MSI-H) ☐ Tumor mismatch repair deficient (dMMR)
  - ☐ Tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb])

For Continuation Requests (clinical documentation required for all requests):

Please indicate the start date of the requested drug therapy: ____/____/____

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

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

☐ Yes ☐ No Is this infusion request in an outpatient hospital setting?
- → ☐ Yes ☐ No Is the patient continuing on a maintenance regimen that includes provider administered combination chemotherapy?
  - → Please indicate the regimen:
  - ☐ Keytruda in combination with pemetrexed for NSCLC
  - Other, please explain: _____

Continued on next page

Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for precertification review.)

Aetna Precertification Notification
Phone: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Please Use Medicare Request Form

Patient First Name	Patient Last Name	Patient Phone	Patient DOB

G. CLINICAL INFORMATION ***(continued)*** – Required clinical information must be completed in its entirety for all precertification requests.

☐ Yes ☐ No Is the patient experiencing 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, conduction abnormalities)?
→ Please explain: _____

☐ Yes ☐ No Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (e.g., acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion?
→ Please explain: _____

☐ Yes ☐ No Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting?
Please explain: _____

☐ Yes ☐ No 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?
→ Please explain: _____

☐ Yes ☐ No 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?
→ Please provide a description of the condition:
☐ Cardiopulmonary: _____
☐ Respiratory: _____
☐ Renal: _____
☐ Other: _____

☐ Yes ☐ No Is the patient within the initial 6 months of starting therapy?
→ Please indicate how many continuous months of treatment the patient has received with the requested drug: _____

For adjuvant treatment of melanoma, adjuvant high-risk early-stage TNBC only, Renal cell carcinoma, or non-small lung cancer:
How many continuous months of adjuvant treatment has the patient received with the requested drug? _____
☐ Yes ☐ No Is there evidence of disease recurrence or unacceptable toxicity on the current regimen?

For Non-small cell lung cancer, Head and neck squamous cell carcinoma, Classical Hodgkin lymphoma, Primary mediastinal large B-cell lymphoma, Urothelial carcinoma (primary carcinoma of the urethra, upper genitourinary tract tumor, urothelial carcinoma of the prostate), Colorectal cancer (including appendiceal carcinoma), Microsatellite instability-high or mismatch repair deficient tumors, Gastric cancer, Esophagogastric junction cancer, Esophageal cancer, Cervical cancer, Hepatocellular carcinoma, Merkel cell carcinoma, Renal cell carcinoma (not adjuvant), Endometrial carcinoma, Tumor mutational burden-high cancer, Cutaneous squamous cell carcinoma, Triple-Negative Breast Cancer (TNBC) locally recurrent unresectable or metastatic, Small bowel adenocarcinoma, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, low-grade serous carcinoma, neuroendocrine tumors, breast cancer, salivary gland tumors, bone cancer, penile cancer, uterine sarcoma:
How many continuous months of treatment has the patient received with the requested drug? _____

For Bladder cancer only:
☐ Yes ☐ No Is the requested drug prescribed for the treatment of high-risk BCG-unresponsive non-muscle invasive bladder cancer?
→ ☐ Yes ☐ No Is the disease persistent or recurrent?

For Vulvar cancer only:
☐ Yes ☐ No 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?

H. ACKNOWLWEDGEMENT

Request Completed By ***(Signature Required):*** _____ **Date:** ____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties.

The plan may request additional information or clarification, if needed, to evaluate requests.