aetna®

Keytruda® (pembrolizumab) Injectable Medication Precertification Request

(All fields must be completed and legible for Precertification Review.)

Aetna Precertification Notification
503 Sunport Lane, Orlando, FL 32809
Phone: 1-866-503-0857
FAX: 1-888-267-3277

For Medicare Advantage Part B:
FAX: 1-844-268-7263

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:		
Address:	City:	State:	ZIP:
Home Phone:	Work Phone:	Cell Phone:	
DOB:	Allergies:	Email:	

Current Weight: _____ lbs or _____ kgs Height: _____ inches or _____ cms

B. INSURANCE INFORMATION

Aetna Member ID #: _____ Does patient have other coverage? ☐ Yes ☐ No
Group #: _____ If yes, provide ID#: _____ Carrier Name: _____
Insured: _____ 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 ☐ Mail Order
☐ 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):
☐ Yes ☐ No Has the patient experienced disease progression following a prior anti-PD1 therapy (e.g., nivolumab (Opdivo), pembrolizumab (Keytruda), atezolizumab (Tecentriq), avelumab (Bavencio), and durvalumab (Imfinzi))?

☐ **Anal adenocarcinoma** ☐ **Appendiceal carcinoma** ☐ **Colorectal cancer** ☐ **Small bowel adenocarcinoma**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
- ☐ Yes ☐ No Does the cancer demonstrate a defective mismatch repair (dMMR)?
  - → Please indicate the tumor's microsatellite instability (MSI) status:
    Select one: ☐ Microsatellite-stable (MSS) ☐ Low microsatellite instability (MSI-L) ☐ High microsatellite instability (MSI-H)
- ☐ Yes ☐ No Does the patient have unresectable metachronous metastases?
  - → ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used for primary treatment of cancer?
    - → ☐ Yes ☐ No Has the patient had previous adjuvant treatment? ***If yes***, please identify adjuvant treatment tried:
      ☐ FOLFOX ☐ CapeOx ☐ Other: please identify: _____
      Please provide the **last** adjuvant treatment date: ____/____/____
- ☐ Yes ☐ No Does the patient have unresectable advanced or metastatic disease? ☐ unresectable advanced disease ☐ metastatic disease
  - → ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used for initial therapy?
    - → ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used for subsequent therapy?
      - → Which of the following therapies has the patient previously received? (Check all that apply)
        ☐ oxaliplatin ☐ irinotecan ☐ fluoropyrimidine based therapy ☐ nivolumab (Opdivo)
        ☐ pembrolizumab (Keytruda) ☐ Other, please identify: _____
        Please provide the date range of use: ____/____/____ to ____/____/____
  - → ☐ Yes ☐ No Is this patient appropriate for intensive therapy?

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

☐ **Gastric cancer**

- ☐ Yes ☐ No Does the patient have recurrent locally advanced or metastatic gastric cancer? ☐ Recurrent locally advanced ☐ Metastatic
- ☐ Yes ☐ No Does the patient have gastroesophageal junction (GEJ) adenocarcinoma?
- ☐ Yes ☐ No Are tumors positive for PD-L1 expression?
- ☐ Yes ☐ No Is the Combined Positive Score (CPS) ≥1?
- ☐ Yes ☐ No Has the patient experienced disease progression **on or after** two or more prior lines of therapy?
- ☐ Yes ☐ No Has the patient been previously treated with fluoropyrimidine- and platinum- containing chemotherapy?
  - → Which of the following platinum-containing chemotherapy regimens has the patient tried?
    ☐ Carboplatin ☐ Cisplatin ☐ Eloxatin ☐ Oxaliplatin ☐ Paraplatin ☐ Platinol ☐ Other - Please identify: _____
    Please provide the date range of use: ___/___/___ to ___/___/___
  - → Which of the following fluoropyrimidine-containing chemotherapy regimens has the patient tried?
    ☐ Capecitabine ☐ Floxuridine ☐ Fluororacil (5FU) ☐ Other - Please identify: _____
    Please provide the date range of use: ___/___/___ to ___/___/___
- ☐ Yes ☐ No Is the cancer classified as human epidermal growth factor receptor 2 positive?
- ☐ Yes ☐ No Has the patient previously received treatment with an approved human epidermal growth factor receptor 2 targeted therapy?
  - → Please indicate therapy tried: ☐ Herceptin (trastuzumab) ☐ None of the above

☐ **Head and neck cancer**

- ☐ Yes ☐ No Does the patient have head and neck squamous cell carcinoma?
  - → Please indicate the type: ☐ Non-nasopharyngeal ☐ Nasopharyngeal ☐ Other - Please identify: _____
- ☐ Yes ☐ No Does the patient have persistent or very advanced and recurrent disease? ☐ Persistent ☐ Very advanced and recurrent
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
- ☐ Yes ☐ No Has the patient tried a platinum-containing chemotherapy regimen?
  - → Please indicate the platinum-containing chemotherapy regimens the patient tried:
    ☐ Carboplatin ☐ Cisplatin ☐ Eloxatin ☐ Oxaliplatin ☐ Paraplatin ☐ Platinol ☐ Other - Please identify: _____
    Please provide the date range of use: ___/___/___ to ___/___/___
    ☐ Yes ☐ No Has there been disease progression **on** platinum-containing chemotherapy treatment?
    ☐ Yes ☐ No Has there been disease progression **after** platinum-containing chemotherapy treatment?

Please indicate the patient's ECOG performance status: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

Please indicate the patient's disease state: ***check all that apply:*** ☐ Newly diagnosed with very advanced local disease (T4b) ☐ Unfit for surgery
☐ Regional lymph nodes involvement (N) ☐ Unresectable nodal disease with no metastases ☐ Second primary with prior radiation therapy (RT)
☐ Metastatic (M1) disease at initial presentation ☐ Recurrent/persistent disease with distant metastases ☐ No distant metastasis (M0)
☐ Unresectable locoregional recurrence and no prior radiation therapy (RT) ☐ Unresectable locoregional recurrence
☐ Other- Please identify: _____

☐ **Hodgkin lymphoma**

- ☐ Yes ☐ No Is there documentation that the patient has been diagnosed with Classical Hodgkin lymphoma?
- ☐ Yes ☐ No Does the patient have refractory or relapsed disease? ☐ Refractory ☐ Relapsed
  - → Please indicate the previous treatment and date range taken: _____ Date range: ___/___/___ - ___/___/___
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as single agent therapy?
- ☐ Yes ☐ No Has the patient relapsed after 3 or more prior lines of therapy?
  - → Please indicate the previous treatments and date range of use:
    First line of therapy: _____ Date range: ___/___/___ - ___/___/___
    Second line of therapy: _____ Date range: ___/___/___ - ___/___/___
    Third line of therapy: _____ Date range: ___/___/___ - ___/___/___
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as additional therapy?
  - → ☐ Yes ☐ No Has the patient been treated previously with brentuximab vedotin?
    If yes, please provide date range: ___/___/___ - ___/___/___
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as palliative therapy?

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

☐ **Melanoma**

☐ Yes ☐ No Does the patient have unresectable melanoma?
☐ Yes ☐ No Does the patient have metastatic melanoma?
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as first line therapy?
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as second-line or subsequent therapy? ☐ Second-line therapy ☐ Subsequent therapy
→ Please indicate the previous treatment and date range used: _____ Date range: ____/____/____ - ____/____/____
☐ Yes ☐ No Did the patient experience disease progression with the previous treatment?
☐ Yes ☐ No Was the previous treatment an anti-PD1 monotherapy?
☐ Yes ☐ No Did the patient reach the maximum clinical benefit from BRAF targeted therapy?
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as re-induction therapy?
→ ☐ Yes ☐ No Has the patient experienced disease control with no residual toxicity?
☐ Yes ☐ No Has the patient experienced disease progression or relapse after treatment discontinuation? ☐ Disease progression ☐ Relapse
→ Please indicate the start date of treatment: ____/____/____
Please indicate the patient's ECOG performance status: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

☐ **Merkel cell carcinoma**

Please select the indication: ☐ Distant metastatic disease ☐ Disseminated recurrence ☐ Other- Please specify: _____
Please indicate how Keytruda (pembrolizumab) will be used: ☐ With surgery ☐ With radiation ☐ Without surgery or radiation

☐ **Non-small cell lung cancer (NSCLC)**

☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as subsequent therapy or first line treatment? ☐ subsequent therapy ☐ first line treatment
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
→ ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used in combination with pemetrexed and carboplatin?
☐ Yes ☐ No Does the patient have a documented diagnosis of nonsquamous NSCLC?
☐ Yes ☐ No Does the patient have metastatic disease?
☐ Yes ☐ No Is there documentation that the disease expresses positive PD-L1 protein (>50%)?
→ ☐ Yes ☐ No Is there clinical evidence that the patient has recurrent or metastatic disease? ☐ Recurrent ☐ Metastatic
Please indicate the patient's disease:
☐ Sensitizing EGFR mutation-positive tumors
→ ☐ Yes ☐ No Has the patient had prior erlotinib, afatinib, gefitinib, or osimertinib therapy?
If yes, Please select: ☐ erlotinib (Tarceva) ☐ afatinib (Gilotrif) ☐ gefitinib (Iressa) ☐ osimertinib (Tagrisso)
☐ ALK rearrangement-positive tumors
→ ☐ Yes ☐ No Has the patient had prior brigatinib, crizotinib, ceritinib, or alectinib therapy?
If yes, Please select: ☐ brigatinib (Alunbrig) ☐ crizotinib (Xalkori) ☐ ceritinib (Zykadia) ☐ alectinib (Alecensa)
☐ ROS1 rearrangement-positive tumors
→ ☐ Yes ☐ No Has the patient had prior crizotinib therapy?
☐ Tumors that are EGFR, ALK, and ROS1 negative or unknown
☐ Yes ☐ No Is there documentation that the disease expresses a PD-L1 protein? ***If yes***, please provide the percentage: ____%
→ Please indicate the patient's ECOG performance status: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
☐ Yes ☐ No Does the patient have metastatic disease?
☐ Yes ☐ No Has the patient already received systemic immune checkpoint inhibitors?
If yes, please indicate: ☐ Bavencio (avelumab) ☐ Imfinzi (durvalumab) ☐ Tecentriq (atezolizumab)
☐ Keytruda (pembrolizumab) ☐ Opdivo (nivolumab) ☐ Other: _____
→ ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as subsequent therapy following disease progression on a first- line cytotoxic regimen or for further progression on other systemic therapy? ***If yes***, Please select:
☐ Following progression on a first-line cytotoxic regimen
☐ For further progression on other systemic therapy

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☐ **Mycosis fungoides or Sezary syndrome**

☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as second–line systemic therapy?

Please select which disease stage applies to the patient:

☐ Stage IB-IIA ☐ Yes ☐ No Is the patient diagnosed with mycosis fungoides?
☐ Yes ☐ No Is there histologic evidence of folliculotropic or large cell transformation?
Please select: ☐ Folliculotropic cell transformation ☐ Large cell transformation

☐ Stage IIB ☐ Yes ☐ No Is the patient diagnosed with mycosis fungoides?
☐ Yes ☐ No Does the patient have generalized tumor lesions?
☐ Yes ☐ No Are the lesions being treated with or without skin- directed therapy?
Please select: ☐ With skin-directed therapy ☐ Without skin-directed therapy

☐ Stage III ☐ Yes ☐ No Is the patient diagnosed with mycosis fungoides or Sezary syndrome? ☐ Mycosis fungoides ☐ Sezary syndrome
☐ Yes ☐ No Has the disease progressed or is refractory to multiple previous therapies?
Please select: ☐ Disease progressed ☐ Refractory to multiple therapies
Please provide the name and date of the previous therapy: _____ Date: ___/___/___

☐ Stage IV ☐ Yes ☐ No Is the patient diagnosed with non-Sezary or visceral disease? ☐ Non-Sezary ☐ Visceral disease

☐ **Solid tumors**

Please identify the solid tumor type: ☐ Ampullary ☐ Biliary ☐ Breast ☐ Cervical ☐ Endometrial ☐ Esophageal ☐ Gastric ☐ Hepatocellular ☐ Ovarian ☐ Prostate ☐ Renal cell ☐ Sarcoma ☐ Other- Please specify: _____

Please select which applies to the tumor: ☐ Microsatellite instability-high (MSI-H) solid tumor ☐ Mismatch repair deficient solid tumors ☐ Other: _____

☐ Yes ☐ No Is the tumor unresectable or metastatic? ☐ Unresectable ☐ Metastatic

☐ Yes ☐ No Has the patient's disease progressed following prior treatment?
Please indicate the prior treatment: _____ Date range: ___/___/___ - ___/___/___

☐ Yes ☐ No Does the patient have any other satisfactory alternative treatment options?

☐ **Urothelial carcinomas**

☐ **Bladder cancer:**

☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
Please indicate clinical stage of the disease: ☐ TX-T1, NX-3, M0 ☐ T2-T4a, N 1-3, M0 ☐ T4b, NX-3, M0 ☐ Other please identify: _____
Please select which applies to the patient's disease state:

☐ Metastatic disease
→ ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as subsequent systemic therapy?

☐ Post cystectomy
→ ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used for recurrence?

☐ Other, please explain: _____

☐ **Primary carcinoma of the urethra**

☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
Please indicate the patient's disease state: ☐ Recurrent disease ☐ Metastatic disease ☐ Other- Please specify: _____
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as subsequent therapy?

☐ **Upper genitourinary tract tumors**

☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
☐ Yes ☐ No Does the patient have a metastatic disease?
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as subsequent therapy?

☐ **Urothelial carcinoma of the prostate**

☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
☐ Yes ☐ No Does the patient have a metastatic disease?
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as subsequent therapy?

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

For Continuation Requests:

Please indicate the start date of therapy: _____

☐ Yes ☐ No Has the patient experienced disease progression while on Keytruda (pembrolizumab)?

→ Please specify the type of disease progression:

- ☐ Locoregional metastasis
- ☐ Distant nodal metastasis
- ☐ Soft tissue metastasis
- ☐ Lung metastasis
- ☐ Visceral metastasis other than lung (i.e.: liver, brain, bone)
- ☐ Other – please specify: _____

☐ Yes ☐ No Has the patient developed an intolerance or toxicity to Keytruda (pembrolizumab)?

→ Please specify the type of disease progression:

- ☐ Immune-mediated pneumonitis
- ☐ Immune-mediated colitis
- ☐ Immune-mediated hepatitis
- ☐ Infusion-related reactions
- ☐ Immune-mediated endocrinopathies
- ☐ Renal failure and Immune-mediated nephritis
- ☐ Other Immune-mediated adverse reactions – Please specify: _____
- ☐ Other – Please specify: _____

H. ACKNOWLEDGEMENT

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.