Attention Nurse Reviewer for Keytruda Prior Auth:

Our Provider Dr. Robert Wehbie is ordering Keytruda to be used in combination with Carbo and Taxol for Neoadjuvant Breast Cancer. This is based on two concurrent Phase II Trials. He notes these trials as KEYNOTE-522 and NSABP B-59 he also has them listed as: NCCTG Study 983252 and Clinical Breast Cancer, 2005; 6:425-32.

There was not a section on the PA Form about breast cancer so I am attaching a copy of his exam note and the Chemo treatment plan to provide the clinical documentation needed for your review. We understand you may need to deny the Keytruda since it is off label and based on Phase II Trials. We will need a denial in writing ASAP so we can seek free drug from the manufacturer.

This request is for [redacted]

Thanks,

Becky Davis | Pre-Arrival Specialist
Rex Hematology Oncology Associates
UNC REX Cancer Care
4420 Lake Boone Trail, Suite 200, Raleigh, NC 27607
p (919)784-7445 | f (919) 590-6524
rebekah.davis@unchealth.unc.edu

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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:
Phone: 1-866-503-0857
FAX: 1-844-268-7263

Please indicate: ☑ Start of treatment: Start date [redacted]
☐ Continuation of therapy, Date of last treatment ____/____/____

Precertification Requested By: Becky Davis Phone: (919) 784-7445 Fax: (919) 590-6524

A. PATIENT INFORMATION

First Name: [redacted]	Last Name: [redacted]		DOB: [redacted]	
Address: [redacted]		City: Wake Forest	State: NC	ZIP: 27587
Home Phone: [redacted]	Work Phone:	Cell Phone:	Email:	
Patient Current Weight: ____[redacted] lbs or ____ kgs Patient Height: ____[redacted] inches or ____ cms			Allergies: No Known Allergies	

B. INSURANCE INFORMATION

Aetna Member ID #: [redacted]
Group #: [redacted]
Insured: [redacted]

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

Medicare: ☑ Yes ☐ No If yes, provide ID #: 6KR0CM4KP13 **Medicaid:** ☐ Yes ☑ No If yes, provide ID #:

C. PRESCRIBER INFORMATION

First Name: Robert		Last Name: Wehbie		(Check One): ☑ M.D. ☐ D.O. ☐ N.P. ☐ P.A.	
Address: 11200 Governor Manly Way Ste 104			City: Raleigh	State: NC	ZIP: 27614
Phone: (919) 570-7550	Fax: (919) 570-7551	St Lic #: 38458	NPI #: 1842139852	DEA #: BW2097106	UPIN:
Provider Email:		Office Contact Name: Becky Davis		Phone: (919) 784-7445	

Specialty *(Check one)*: ☑ **Oncologist** ☐ **Other**: ____

D. DISPENSING PROVIDER/ADMINISTRATION INFORMATION

Place of Administration:
☐ Self-administered ☐ Physician's Office
☑ Outpatient Infusion Center Phone: (919) 784-7445
Center Name: Rex Hospital
☐ Home Infusion Center Phone: ____
Agency Name: ____
☐ Administration code(s) (CPT): ____
Address: 4420 Lake Boone Trl Raleigh, NC 27607

Dispensing Provider/Pharmacy: *Patient Selected choice*
☐ Physician's Office ☐ Retail Pharmacy
☐ Specialty Pharmacy ☑ Other: Outpatient Hospital
Name: Rex Hospital
Address: 4420 Lake Boone Trl Raleigh, NC 27607
Phone: (919) 784-7445 Fax: (919) 590-6524
TIN: 561509260 PIN: ____

E. PRODUCT INFORMATION

Request is for: Keytruda (pembrolizumab)
Dose: 200mg **Frequency:** Day 1 Every 28 days

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

Primary ICD Code: ☐ C50.112 **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:	Carvoplatin	Dose:	419.5mg	Frequency:	Day 1 Every 28 Days
Medication:	Taxol	Dose:	121.62mg	Frequency:	Day 1, 8, 15 Every 28 Days
Medication:	Emend	Dose:	150mg	Frequency:	Day 1 Every 28 Days
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))?

☐ **Anal carcinoma**
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
Please indicate the clinical setting in which the requested drug will be used: ☐ Metastatic disease ☐ Other, please explain: ____
Please select the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Second-line or subsequent treatment

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

☐ **Bladder cancer**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?

Please indicate the place in therapy in which the requested drug will be used:
- ☐ First-line systemic therapy
  - ☐ Yes ☐ No Is the patient eligible for any platinum-containing chemotherapy?
  - ☐ Yes ☐ No Is the patient eligible for cisplatin chemotherapy?
  - ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 10?
    Action required: If 'Yes', attach PD-L1 expression laboratory report.

  What is the clinical setting in which the requested drug will be used?
  - ☐ Stage II disease
    - ☐ Yes ☐ No Has the patient received primary treatment with concurrent chemoradiotherapy?
    - ☐ Yes ☐ No Is the tumor present following reassessment 2-3 months after primary treatment?
  - ☐ Stage IIIA disease
    - ☐ Yes ☐ No Has the patient received primary treatment with concurrent chemoradiotherapy?
    - ☐ Yes ☐ No Is the tumor present following reassessment 2-3 months after primary treatment?
  - ☐ Locally advanced disease
  - ☐ Metastatic disease
  - ☐ Post-cystectomy
    - ☐ Yes ☐ No Does the patient have metastatic disease or local recurrence post-cystectomy?
      - Please select: ☐ Local recurrence ☐ Metastatic disease ☐ Other, please explain: _____
- ☐ Subsequent systemic 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 Has the patient been previously treated with platinum-containing chemotherapy?

    Please indicate the clinical setting in which the requested drug will be used:
    - ☐ Locally advanced disease
    - ☐ Metastatic disease
    - ☐ Post-cystectomy
      - ☐ Yes ☐ No Does the patient have metastatic disease or local recurrence post-cystectomy?
        - Please select: ☐ Local recurrence ☐ Metastatic disease ☐ Other, please explain: _____
  - ☐ 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?

☐ **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, please explain: _____
- ☐ Yes ☐ No Does the patient have brain metastases?
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
- ☐ Yes ☐ No Is the patient's disease positive for programmed death ligand 1 (PD-L1)?

☐ **Cervical cancer**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?

What is the place in therapy in which the requested drug will be used? ☐ First-line treatment ☐ Subsequent treatment
- ☐ Yes ☐ No Does the patient have recurrent or metastatic disease?
  - Please explain: ☐ Recurrent disease ☐ Metastatic disease
- ☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
  Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.
  - ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1?
    Action required: If 'Yes', attach PD-L1 expression laboratory report.
- ☐ Yes ☐ No Has the patient experienced disease progression on or after chemotherapy treatment?
  - Please provide the name of the chemotherapy the patient tried: _____

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

☐ **Classical Hodgkin lymphoma**
- ☐ Yes ☐ No Is there documentation that the patient has been diagnosed with Classical Hodgkin lymphoma?
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Relapsed disease
  - → ☐ Yes ☐ No Has the patient received 2 or more prior lines of therapy?
  - ☐ Yes ☐ No Is the patient eligible for transplant?
  - ☐ Yes ☐ No Has the patient received a hematopoietic stem cell transplant?
- ☐ Refractory disease
- ☐ Other, please identify: _____

☐ **Colorectal cancer (including small bowel adenocarcinoma, appendiceal carcinoma, and anal adenocarcinoma)**
- Please select which of the following applies to the patient: ☐ Colorectal cancer ☐ Small bowel adenocarcinoma ☐ Appendiceal carcinoma ☐ Anal adenocarcinoma
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
- ☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
  Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.
- Please indicate the place in therapy in which the requested drug will be used:
- ☐ Primary/Initial therapy
  - → Please indicate the clinical setting in which the requested drug will be used:
  - ☐ Unresectable metachronous metastases
    - → ☐ Yes ☐ No Has the patient had previous adjuvant treatment within the past 12 months?
      - → Please select: ☐ FOLFOX (fluorouracil, leucovorin, and oxaliplatin) ☐ CapeOx (capecitabine and oxaliplatin) ☐ Other, please identify: _____
  - ☐ Unresectable advanced disease
    - → ☐ Yes ☐ No Is this patient a candidate for intensive therapy?
  - ☐ Metastatic disease
    - → ☐ Yes ☐ No Is this patient a candidate for intensive therapy?
  - ☐ Other, please identify: _____
- ☐ Subsequent therapy
  - → Please indicate the clinical setting in which the requested drug will be used: ☐ Unresectable advanced disease ☐ Metastatic disease ☐ Other, please identify: _____
  - ☐ Yes ☐ No Has the patient been previously treated with oxaliplatin, irinotecan, and/or fluoropyrimidine based therapy?

☐ **Cutaneous melanoma**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
- ☐ Yes ☐ No Will Keytruda be used as adjuvant therapy?
  - → ☐ Yes ☐ No Does the patient have metastatic or unresectable disease?
    - → Please identify: ☐ Metastatic disease ☐ Unresectable disease
  - → ☐ Yes ☐ No Has the patient had a complete lymph node surgical resection or complete resection of metastatic disease?

☐ **Endometrial cancer**
- ☐ Yes ☐ No 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:
  - ☐ Advanced disease ☐ Other (please specify): _____
  - ☐ Yes ☐ No Has the disease progressed following prior systemic therapy?
  - ☐ Yes ☐ No Is the patient a candidate for curative surgery or radiation?
  - ☐ Yes ☐ No Will the requested drug be used in combination with Lenvima (lenvatinib)?
  - → **Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**
  - Please indicate the clinical setting in which the requested drug will be used:
  - ☐ Recurrent disease ☐ Metastatic disease ☐ High-risk disease ☐ Other (please specify): _____
  - ☐ Yes ☐ No Has the disease progressed following prior cytotoxic chemotherapy?

☐ **Epithelial ovarian cancer** ☐ **Fallopian tube cancer** ☐ **Primary peritoneal cancer**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
- ☐ Yes ☐ No Does the patient have recurrent or persistent disease?
  - → Please identify: ☐ Recurrent disease ☐ Persistent disease ☐ Other (please specify): _____
- ☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
  Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.

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[redacted]	[redacted]	([redacted]	[redacted]7

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

☐ **Esophageal cancer**
Please select the clinical setting in which the requested drug will be used:
☐ Locally advanced disease ☐ Metastatic disease ☐ Recurrent disease ☐ The patient is not a surgical candidate
☐ Other (please specify): _____
☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
→ ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 10?
→ ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of ≥ 1?
→ ☐ Yes ☐ No Does the patient's disease express squamous or nonsquamous histology?
→ **Action required: If 'Yes' attach PD-L1 expression laboratory report.**
→ **Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Second-line or subsequent treatment ☐ Third-line or subsequent treatment
Please select how Keytruda (pembrolizumab) will be used: ☐ Single agent ☐ Other (please specify): _____

☐ **Extranodal NK/T-Cell Lymphoma**
☐ Yes ☐ No Does the patient have nasal type disease?
Please select the clinical setting in which the requested drug will be used: ☐ Relapsed disease ☐ Refractory disease ☐ Other (please specify) _____

☐ **Gastric cancer or esophagogastric junction (EGJ) cancer**
Please select how Keytruda (pembrolizumab) will be used: ☐ Single agent ☐ Other (please specify): _____
Please select the clinical setting in which the requested drug will be used:
☐ Locally advanced disease ☐ Metastatic disease ☐ Recurrent disease ☐ The patient is not a surgical candidate
☐ Other (please specify): _____
☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
→ ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1?
Action required: If 'Yes' attach PD-L1 expression laboratory report.
→ **Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**
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

☐ **Gestational trophoblastic neoplasia**
☐ Yes ☐ No Will Keytruda (pembrolizumab) 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
→ ☐ Yes ☐ No Is the patient's disease resistant to treatment with methotrexate?
☐ Other - Please identify: _____

☐ **Head and neck cancer**
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used for the treatment of head and neck squamous cell cancer (HNSCC)
Please select the clinical setting in which the requested drug will be used: ☐ Unresectable disease ☐ Metastatic disease ☐ Second primary disease ☐ Other, please identify: _____
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
→ Please indicate the requested drug regimen: ☐ In combination with fluorouracil and carboplatin ☐ In combination with fluorouracil and cisplatin ☐ Other, please identify: _____
→ What is the place in therapy in which the requested drug will be used?
☐ First-line therapy
→ ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1?
Action required: If 'Yes', attach PD-L1 expression laboratory report.
☐ Subsequent therapy

☐ **Hepatobiliary cancers (including gallbladder, intrahepatic/extrahepatic cholangiocarcinoma)**
Please select which of the following diagnosis applies to the patient: ☐ Gallbladder cancer ☐ Intrahepatic/extrahepatic cholangiocarcinoma
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.
Please indicate the place in therapy in which the requested drug will be used:
☐ Adjuvant treatment
→ What is the clinical setting in which the requested drug will be used? ☐ Resected gross residual disease ☐ Other, please identify: _____
☐ Primary treatment
→ Please indicate the clinical setting in which the requested drug will be used:
☐ Unresectable disease ☐ Metastatic disease ☐ Other, please identify: _____

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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 Nexavar (sorafenib)?

☐ **Kidney cancer (including renal cell carcinoma)**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be used in combination with axitinib (Inlyta)?
- 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:
    - ☐ Advanced disease ☐ Relapsed disease ☐ Stage IV disease ☐ Other, please identify: _____
- ☐ Subsequent treatment
  - → Please indicate the clinical setting in which the requested drug will be used:
    - ☐ Relapsed disease ☐ Stage IV disease ☐ Other, please identify: _____
    - ☐ Yes ☐ No Does the tumor express clear cell histology?

☐ **Malignant Pleural Mesothelioma**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) 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

☐ **Merkel cell carcinoma**
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Recurrent locally advanced disease ☐ Metastatic disease ☐ Other, please identify: _____

☐ **Mycosis fungoides** ☐ **Sezary Syndrome**
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Stage III Mycosis Fungoides ☐ Stage IV Sezary Syndrome ☐ Other, please identify: _____

☐ **Non-small cell lung cancer (NSCLC) - initiation**
- ☐ Yes ☐ No Does the patient have recurrent, advanced, or metastatic disease?
  - → Please explain: ☐ Recurrent disease ☐ Advanced disease ☐ Metastatic disease
- ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Tumor Proportion Score (TPS) of > 1%?
  - → What is the clinical setting in which the requested drug will be used?
    - ☐ Recurrent disease ☐ Advanced disease ☐ Metastatic disease ☐ Other, please identify: _____
    - ☐ Yes ☐ No Does the patient's disease express squamous or nonsquamous histology?
      - → ☐ Squamous cell histology
        - → ☐ Yes ☐ No Will the requested drug be used in combination with any of the following regimens?
          - → ☐ Cisplatin and paclitaxel ☐ Carboplatin and albumin-bound paclitaxel
          - ☐ Cisplatin and albumin-bound paclitaxel ☐ Carboplatin and paclitaxel
          - ☐ Other, please identify: _____
      - ☐ Nonsquamous cell histology
        - → ☐ Yes ☐ No Will the requested drug be used in combination with any of the following regimens?
          - → ☐ Pemetrexed and cisplatin ☐ Pemetrexed and carboplatin
          - ☐ Other, please identify: _____
        - ☐ Yes ☐ No Is the patient's disease EGFR positive?
          - → ☐ Yes ☐ No Has the patient received prior EGFR-targeted therapy?
        - ☐ Yes ☐ No Is the patient's disease ALK positive?
          - → ☐ Yes ☐ No Has the patient received prior ALK-targeted therapy?
  - → **Action required: If 'Yes', attach PD-L1 expression laboratory report**
    - ☐ Yes ☐ No Will the requested drug be used as a single agent?
    - ☐ Yes ☐ No Is the patient's disease EGFR positive?
      - → ☐ Yes ☐ No Has the patient received prior EGFR-targeted therapy?
    - ☐ Yes ☐ No Is the patient's disease ALK positive?
      - → ☐ Yes ☐ No Has the patient received prior ALK-targeted therapy?

☐ **Non-small cell lung cancer (NSCLC) – continuation maintenance**
- ☐ Yes ☐ No Does the patient's disease express squamous or nonsquamous histology?
  - → ☐ Squamous cell histology
    - → ☐ Yes ☐ No Was the requested drug previously used as any of the following regimens for recurrent, advanced, or metastatic disease?
      - → Please explain: ☐ Single agent ☐ Cisplatin and paclitaxel ☐ Cisplatin and albumin-bound paclitaxel
      - ☐ Carboplatin and paclitaxel ☐ Carboplatin and albumin-bound paclitaxel
      - ☐ Other, please identify: _____
    - ☐ Yes ☐ No Will the requested drug be used as a single agent?
    - ☐ Yes ☐ No Is there evidence of disease progression or unacceptable toxicity on the current regimen?
    - Please indicate how many months of treatment has the patient received with the requested drug: _____

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☐ Nonsquamous cell histology
→ ☐ Yes ☐ No Will the requested drug be used as a single agent?
→ ☐ Yes ☐ No Will the requested drug be used in combination with pemetrexed?
☐ Yes ☐ No Was the requested drug previously used as part of any of the following regimens as first-line treatment for recurrent, advanced, or metastatic disease?
→ Please explain: ☐ Pemetrexed and cisplatin ☐ Pemetrexed and carboplatin
☐ Other, please identify: _____
→ ☐ Yes ☐ No Was the requested drug previously used as a single agent for first-line treatment for recurrent, advanced, or metastatic disease?
☐ Yes ☐ No Is there evidence of disease progression or unacceptable toxicity on the current regimen?
Please indicate how many months of treatment has the patient received with the requested drug: _____

☐ **Other solid tumors with Microsatellite instability-high or mismatch repair deficiency**
☐ Yes ☐ No Is the requested drug prescribed for a pediatric patient with microsatellite instability-high (MSI-H) central nervous system cancer?
☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.
Please indicate the clinical setting in which the requested drug will be used:
☐ Unresectable disease ☐ Metastatic disease ☐ Other, please identify: _____
☐ Yes ☐ No Has the patient experienced disease progression following prior treatment?
☐ Yes ☐ No Are there other satisfactory alternative treatment options available for the patient?

☐ **Pancreatic adenocarcinoma**
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.
Please indicate the clinical setting in which the requested drug will be used:
☐ Locally advanced disease ☐ Metastatic disease ☐ Local recurrence in the pancreatic operative bed after resection
☐ Other-Please explain: _____
Please indicate the place in therapy in which the requested drug will be used: ☐ First-line treatment ☐ Subsequent treatment

☐ **Poorly differentiated neuroendocrine carcinoma/large or small cell carcinoma**
☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.
☐ Yes ☐ No Has the patient experienced disease progression following prior treatment?
☐ Yes ☐ No Are there other satisfactory alternative treatment options available for the patient?

☐ **Primary carcinoma of the urethra**
☐ Yes ☐ No Will Keytruda (pembrolizumab) 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 explain: _____
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?
→ ☐ Yes ☐ No Is the patient eligible for cisplatin chemotherapy?
☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of >10?
Action required: If 'Yes', attach PD-L1 expression laboratory report.
☐ Subsequent treatment
→ ☐ Yes ☐ No Has the patient previously received platinum-containing chemotherapy?

☐ **Primary mediastinal large B-cell lymphoma (PMBCL))**
Please indicate the clinical setting in which the requested drug will be used:
☐ Relapsed disease ☐ Refractory disease ☐ Other (please specify): _____

☐ **Small Cell Lung Cancer**
☐ Yes ☐ No Will Keytruda (pembrolizumab) be used as a single agent?
Please indicate the clinical setting in which the requested drug will be used:
☐ Relapsed disease
→ ☐ Yes ☐ No Has the disease relapsed within 6 months following complete or partial response or stable disease with initial treatment?
☐ Primary progressive disease
☐ Metastatic disease
→ ☐ Yes ☐ No Has the disease progressed on or after platinum-based chemotherapy AND at least one other prior line of chemotherapy?
☐ Other-Please explain: _____

Continued on next page

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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: 1-866-752-7021
FAX: 1-888-267-3277

For Medicare Advantage Part B:
Phone: 1-866-503-0857
FAX: 1-844-268-7263

Patient First Name	Patient Last Name	Patient Phone	Patient DOB
[redacted]	[redacted]	[redacted]	[redacted]

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

☐ **Testicular cancer**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) 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 Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
  Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.

☐ **Thymic carcinoma**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) 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:
- ☐ Unresectable disease ☐ Locally advanced disease ☐ Metastatic disease ☐ Other-Please explain: _____

☐ **Upper genitourinary (GU) tract tumors**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be given as a single agent?
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Locally advanced disease ☐ Metastatic disease ☐ Other-Please explain: _____
- 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?
    - → ☐ Yes ☐ No Is the patient eligible for cisplatin chemotherapy?
    - ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 10?
      Action required: If 'Yes', attach PD-L1 expression laboratory report.
- ☐ Subsequent treatment
  - → ☐ Yes ☐ No Has the patient previously received platinum-containing chemotherapy?

☐ **Urothelial carcinoma of the prostate**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) be given as a single agent?
- Please indicate the clinical setting in which the requested drug will be used:
- ☐ Locally advanced disease ☐ Metastatic disease ☐ Other-Please explain: _____
- 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?
    - → ☐ Yes ☐ No Is the patient eligible for cisplatin chemotherapy?
    - ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of >10?
      Action required: If 'Yes', attach PD-L1 expression laboratory report.
- ☐ Subsequent treatment
  - → ☐ Yes ☐ No Has the patient previously received platinum-containing chemotherapy?

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

☐ **Vulvar cancer**
- ☐ Yes ☐ No Will Keytruda (pembrolizumab) 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, please identify: _____
- ☐ Yes ☐ No Does the disease express squamous or nonsquamous histology?
  - → Please explain: ☐ Squamous histology ☐ Nonsquamous histology
- ☐ Yes ☐ No Is the tumor microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)?
  - → ☐ Yes ☐ No Does the patient's disease express programmed death ligand 1 (PD-L1) with a Combined Positive Score (CPS) of > 1?
    - → **Action required: If 'Yes', attach PD-L1 expression laboratory report.**
    - ☐ Yes ☐ No Has the patient had disease progression on or after chemotherapy
  - → **Action required: If 'Yes', attach laboratory report confirming microsatellite instability-high or mismatch repair deficient tumor status.**

Continued on next page

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

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

Please indicate the start date of Keytruda (pembrolizumab) therapy: ____/____/____

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

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

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

☐ 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: _____

☐ 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 melanoma:

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

For small cell lung cancer, head and neck squamous cell carcinoma, Classical Hodgkin lymphoma, Primary mediastinal large B-cell lymphoma, Urothelial carcinoma (primary carcinoma of the urethra, upper genitourinary tract tumor, urothelial carcinoma of the prostate), Colorectal cancer, Microsatellite instability-high tumors, Gastric cancer or esophagogastric junction cancer, Esophageal cancer, Cervical cancer, Hepatocellular carcinoma, Merkel cell carcinoma, Kidney cancer, Endometrial carcinoma:

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

For bladder cancer:

☐ 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 non-small cell lung cancer:

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

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

Please indicate the setting the requested drug is being used:

☐ As continuation maintenance after tumor response or stable disease is achieved

→ Please indicate the disease histology:

☐ Squamous

→ ☐ Yes ☐ No Was the requested drug previously used as part of any of the following regimens for recurrent, advanced, or metastatic disease?

→ Please identify: ☐ Single agent ☐ Cisplatin and paclitaxel ☐ Cisplatin and albumin-bound paclitaxel ☐ Carboplatin and paclitaxel ☐ Carboplatin and albumin bound paclitaxel ☐ Other: _____

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

Continued on next page

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Keytruda® (pembrolizumab) Injectable Medication Precertification Request

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

☐ Nonsquamous
→ Please indicate how Keytruda (pembrolizumab) will be used:
☐ Single agent
→ ☐ Yes ☐ No Was the requested drug previously used as a single agent for first-line treatment for recurrent, advanced or metastatic disease?
☐ In combination with pemetrexed
→ ☐ Yes ☐ No Was the requested drug previously used as part of any of the following regimens as first-line treatment for recurrent, advanced, or metastatic disease?
Please explain: ☐ In combination with pemetrexed and cisplatin ☐ In combination with pemetrexed and carboplatin
☐ Other: _____

☐ For treatment of recurrent, advanced, or metastatic disease

H. ACKNOWLEDGEMENT

Request Completed By *(Signature Required)*: Becky Davis **Date:** 07 / 28 / 2020

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.

[redacted] MRN: [redacted]

Office Visit 7/27/2020
REX HEMATOLOGY ONCOLOGY
GOV MANLY WAY WAKEFIELD

Provider: Robert Sam Wehbie, MD (Hematology and Oncology)
Primary diagnosis: Malignant neoplasm of central portion of left breast in female, estrogen receptor negative (CMS-HCC)
Reason for Visit: Routine Follow-up; Referred by Michael James, MD

Progress Notes

Robert Sam Wehbie, MD (Physician) • Hematology and Oncology

UNC HEALTH

Hematology/Oncology* Follow Up *Note

UNC Rex Hematology Oncology Associates
Rex Cancer Center of Wakefield
11200 Governor Manly Way, Suite 102
Raleigh, North Carolina 27614
(919) 570-7550
(919) 570-7551 (fax)

Patient Name: [redacted]
Patient Age: [redacted]
Encounter Date: [redacted]

Referring Physician: Rachel Nicole Jendro, Do3100 Duraleigh RoadSuite 205Raleigh, NC 27612-8105. 919-784-2708

PCP: Michael James, MD

Reason(s) for Consult: Left Breast ? TNBC - cT1c c N1 (Stage IIB)

History/Assessment/Plan:

1.	**Left Breast ? TNBC - cT1c c N1 (Stage IIB)**	[redacted] who presents to see us in follow up regarding management/treatment of Breast Cancer. As previously outlined and detailed in the Oncology History table below, in approximately May Joyce palpated a mass in her left axilla. Diagnostic mammography was performed that showed enlarged left axillary lymph nodes up to 3.2 cm, but no apparent breast mass. A biopsy of the left axillary lymph node on 6/16/2020 showed carcinoma that was weakly ER positive (21%), PR negative, and HER-2 negative.On 6/23/20 breast MRI was performed at Raleigh Radiology which showed a 1.1 cm mass in the

		11–12 o'clock position of left breast, 6 CFN. Enlarged axillary lymph nodes were noted. Her right breast and axilla were benign. A small 8 mm lesion was noted in the left hepatic lobe that appeared benign. A chest CT scan performed that same day showed enlarged lymph nodes in the left axilla, no lytic or blastic disease within the bones, and an 8 mm benign appearing hemangioma in the liver. On 6/24/2020 left breast ultrasound biopsy was performed. This showed infiltrating ductal carcinoma that was grade 3 and triple negative. Several weeks ago she had negative staging abdominal/pelvic CT and bone scan. A small left hepatic lesion was found and was felt to be consistent with a hemangioma. She has had a Port-A-Cath placed. I again reviewed and discussed extensively with the patient, and with her husband, her course to date. We outlined her node positive disease and probability that she has TNBC. We discussed the recommendation of neoadjuvant, and within this context discussed standard neoadjuvant chemotherapy,including traditional dose–dense AC followed by weekly paclitaxel, neoadjuvant chemo immunotherapy per the KEYNOTE-522 trial, and an open clinical trial, NSABP B-59. For various reasons, she does not wish to pursue treatment on B-59. We discussed the potential of delivering chemotherapy plus pembrolizumab per the KEYNOTE-522 trial, pending insurance approval. We reviewed potential side effects of chemotherapy including, but not limited to cytopenias, nausea, alopecia, and neuropathy. We discussed possible untoward effects of immunotherapy including autoimmune diseases. Through this discussion she provided consent to proceed. **From this long discussion, our plans are as follows:** A. We will plan to proceed with neoadjuvant therapy per the KEYNOTE-522 trial First neoadjuvant treatment - Four, 3 week cycles of: • Pembrolizumab (200 mg) • Paclitaxel (80 mg per square meter of body-surface area once weekly) • Carboplatin (at a dose based on an area under the concentration–time curve of 5 mg per milliliter per minute once every 3 weeks or 1.5 mg per milliliter per minute once weekly in the first 12 weeks) Second neoadjuvant treatment followed by four cycles of pembrolizumab plus AC (doxorubicin (60 mg per square meter)plus cyclophosphamide (600 mg per square meter once every 3 weeks in the subsequent 12 weeks)) In the adjuvant phase, patients received radiation therapy as indicated and pembrolizumab or placebo once every 3 weeks for up to nine cycles. B. We will respect her wishes for full CODE STATUS C. We will follow her closely for toxicities All of the above, and their questions were discussed in detail, in the exam room, and with verification of the patient's and their husband's understanding.
2.	**Health maintenance issues**	PV-13 on 4/17/12

		We again reviewed risk factors for COVID-19 and other communicable disease exposures. We discussed protective measures and recent overall recommendations, including personal distancing, handwashing, and a protective facemask. We discussed increased morbidity and mortality from this infection with increased age. We also discussed their individual increased risk of complications from COVID-19 based upon their comorbid disease(s). We reviewed signs and symptoms of infection, actions to take should such symptoms develop, and testing sites. We outlined that the whole situation is very dynamic and recommendations may shift and change. We also discussed that her potential acquisition of COVID-19 is increased from medical area exposures, and potential exposure to this infection must be weighed against any potential benefit from medical therapy. We note her tobacco use history and have advised proceeding forward yearly low-dose chest CT imaging for at least 10 years post smoking cessation.
3.	**Symptomology**	Today she reports pertinent ROS issues as noted previously. Distress screening was reviewed and discussed during consult, and No additional action taken.

Oncology History Overview Note

Left Breast ? TNBC - cT1c c N1 (Stage IIB)

Date	Treatment	Notes
		She has a paternal and maternal cousin with breast cancer. She denies a family history of ovarian cancer. She has 2 children and did breast-feed. She is postmenopausal and used hormone replacement therapy for 12 years.
1998		Benign right breast excisional biopsy
11/10/06		Colonoscopy - hyperplastic rectal polyp
1/31/11		Cardiac cath: - LVEF 70% - Scant CAD
6/8/18		Stress echo: EF 65%
6/28/19		TTE: EF 60-65%
6/11/20		Bilateral 3D diagnostic mammogram and left breast ultrasound at Raleigh Radiology - 2 enlarged lymph nodes in the left axilla measuring 2.5 cm and 3.2 cm - No breast masses, microcalcifications, or areas of architectural distortion - BI-RADS 4.
6/16/20		Left axillary bx: - Carcinoma - ER 1+ (21%) - PR neg - HER2 neg
6/23/20		Breast MRI at Raleigh Radiology: - Normal right breast

		- 1.1 cm mass in the 11 to 12 o'clock position of the left breast 6 cm from the nipple - 2 enlarged lymph nodes in the left axilla measuring 3.6 cm and 2.3 cm with additional smaller lymph nodes seen - no internal mammary adenopathy - 8 mm lesion in the left lobe of the liver that is benign Chest CT: - Enlarged lymph nodes in the left axilla measuring 3.6 cm and 2 cm - No focal lytic or blastic lesions in the thoracic cage - 8 mm benign hemangioma in the liver
6/24/20		Left breast U/S: 1.1 cm mass in the 12 o'clock position of the left breast 5 cm from the nipple correlating to the MRI finding Left breast Bx: - IDC - Grade 3 - Triple neg
7/10/20		CT A/P Ral Rads: 1. 1.0 cm left hepatic lobe hypoattenuated lesion, favor hemangioma 2. Otherwise normal exam Bone Scan: No metastatic disease
7/16/20		Port-A-Cath placed
		KEYNOTE-522 trial First neoadjuvant treatment - Four, 3 week cycles of: Pembrolizumab (200 mg) Paclitaxel (80 mg per square meter of body-surface area once weekly) Carboplatin (at a dose based on an area under the concentration–time curve of 5 mg per milliliter per minute once every 3 weeks or 1.5 mg per milliliter per minute once weekly in the first 12 weeks) Second neoadjuvant treatment followed by four cycles of pembrolizumab plus AC (doxorubicin (60 mg per square meter)plus cyclophosphamide (600 mg per square meter once every 3 weeks in the subsequent 12 weeks)) In the adjuvant phase, patients received radiation therapy as indicated and pembrolizumab or placebo once every 3 weeks for up to nine cycles.

Malignant neoplasm of central portion of left breast in female, estrogen receptor negative (CMS-HCC)
6/30/2020 - **Cancer Staged**

Staging form: Breast, AJCC 8th Edition
- Clinical stage from 6/30/2020: Stage IIB (cT1c, cN1, cM0, G3, ER-, PR-, HER2-) - Signed by Rachel Nicole Jendro, DO on 7/2/2020

7/2/2020 **Initial Diagnosis**
Malignant neoplasm of central portion of left breast in female, estrogen receptor negative (CMS-HCC)

7/29/2020 - 7/29/2020 **Chemotherapy**
OP BREAST PACLitaxel WEEKLY / CARBOplatin EVERY 3 WEEKS
PACLitaxel 80 mg/m2 IV on days 1, 8, 15, CARBOplatin AUC 6 IV on day 1, every 21-day cycle x 4 cycles

7/30/2020 - 7/30/2020 **Chemotherapy**
OP LUNG CARBOPLATIN/PACLITAXEL/PEMBROLIZUMAB
pembrolizumab 200 mg IV on day 1, PACLitaxel 200 mg/m2 IV on day 1, CARBOplatin IV AUC6 on day 1, every 21 days for 4 cycles, FOLLOWED BY, pembrolizumab 200 mg IV on day 1, every 21 days

Past Medical History:

Diagnosis	Date
• Allergic rhinitis	
• Anxiety	
• Arrhythmia	
• Arthritis	
• Cancer (CMS-HCC) *Breast*	
• Cigarette smoker	
• Coronary artery disease	
• Hearing aid worn *Pt has Bilateral Hearing Aids*	
• High cholesterol	
• Osteoporosis	

Social History

Socioeconomic History

• Marital status:	Married
Spouse name:	Not on file
• Number of children:	Not on file
• Years of education:	Not on file
• Highest education level:	Not on file

Occupational History
• Not on file

Social Needs

• Financial resource strain:	Not on file
• Food insecurity	
Worry:	Not on file
Inability:	Not on file