ATRIO HEALTH PLANS

# Chemotherapy: PD-1 Inhibitor
## Keytruda (pembrolizumab) J9271
### Prior Authorization Request
### Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

| | | | |
|---|---|---|---|
| ☐ | **NEW START - Start Date:**_____ | ☐ | **Continuation** (within 365 days)**:** Date of last treatment _____ |
| ☐ | Date Requested _____ | | |
| | Requestor _____ Clinic name: _____ Phone / Fax | | |

**MEMBER INFORMATION**

*Name:_____ *ID#:_____ *DOB:_____

**PRESCRIBER INFORMATION**

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

*Name:_____ Phone:_____

*Address:_____ Fax:_____

**PROCEDURE / PRODUCT INFORMATION**

| HCPC Code | Name of Drug ☐ Self-administered | Dose (Wt: _____ kg Ht:_____ ) | Frequency | End Date if known |
|---|---|---|---|---|
| | | | | |

☐Chart notes attached. **Other important information:**_____

**Diagnosis: ICD10**: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Biliary tract cancer** – ALL of the following:
- ☐ Age 18 years or older
- ☐ Locally advanced unresectable or metas
- ☐ Previously untreated disease, administered in combination with cisplatin and gemcitabine

☐ **Breast cancer** – ALL of the following:
- ☐ Age 18 years or older
- ☐ HER2-negative and hormone receptor-negative (triple-negative) disease
- ☐ *Treatment scenario* – 1 or more of the following:
  - ☐ **Locally recurrent unresectable or metastatic disease** – ALL of the following:
    - ☐ Administered with chemotherapy (carboplatin, paclitaxel, paclitaxe protein-bound, gemcitabine)
    - ☐ Tumor tissue expresses PD-L1 (combined positive score [CPS] ≥10) by FDA-approved test
  - ☐ **Perioperative therapy for nonmetastatic disease** – 1 or more of the following:
    - ☐ Administered with chemotherapy (eg, carboplatin, paclitaxel, doxorubicin, and epirubicin) as neoadjuvant therapy prior to surgery, with planned monotherapy for adjuvant therapy

☐ Administered as monotherapy for adjuvant therapy after neoadjuvant combination therapy and surgical resection

☐ **Cervical cancer – ALL of the following:**
- ☐ Age 18 years or older
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ FIGO 2014 stage III-IVA disease, in combination with chemoradiotherapy
  - ☐ Persistent, recurrent, or metastatic disease, and tumors express PD-L1 ≥1% by FDA- approved test, administered in combination with platinum-based chemotherapy with or without bevacizumab
  - ☐ Recurrent or metastatic disease, and tumors express PD-L1 ≥1% by FDA-approved test, with progression on or after chemotherapy, administered as monotherapy

☐ **Colorectal cancer – ALL of the following:**
- ☐ Age 12 years or older
- ☐ DNA mismatch repair-deficient or microsatellite instability-high colorectal cancer
- ☐ ECOG performance status of 0 to 2 (or equivalent)
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ Primary treatment for previously untreated, unresectable advanced or metastatic disease
  - ☐ Primary treatment for unresectable metachronous metastases
  - ☐ Subsequent therapy for unresectable advanced or metastatic disease following previous treatment with oxaliplatin, irinotecan, or fluoropyrimidine, administered as monotherapy
- ☐ No previous treatment with PD-1 agent (eg, nivolumab, atezolizumab)

☐ **Endometrial cancer – ALL of the following:**
- ☐ Age 18 years or older
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ Disease progression following prior chemotherapy – *ALL of the following:*
    - ☐ Administered in combination with lenvatinib
    - ☐ Patient is not a candidate for curative surgery or radiation therapy
    - ☐ Recurrent, advanced, or metastatic disease
  - ☐ Primary advanced or recurrent disease, administered in combination with carboplatin and paclitaxel, followed by pembrolizumab monotherapy

☐ **Esophageal cancer – ALL of the following:**
- ☐ Age 18 years or older
- ☐ Locally advanced unresectable or metastatic disease
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ Disease progression on or after one or more prior lines of therapy, and tumor tissue expresses PD-L1 ≥10% by FDA-approved test
  - ☐ First-line therapy in combination with platinum and fluoropyrimidine-based chemotherapy

☐ **Gastric or gastroesophageal cancer – ALL of the following:**
- ☐ Age 18 years or older
- ☐ Locally advanced unresectable or metastatic disease
- ☐ Previously untreated disease
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ HER2-negative disease, administered in combination with chemotherapy containing fluoropyrimidine and platinum
  - ☐ HER2-positive disease – *ALL of the following:*

☐ Administered in combination with trastuzumab and chemotherapy containing fluoropyrimidine and platinum
☐ Tumor tissue expresses PD-L1 ≥1% by FDA-approved test

☐ **Head and neck cancer (squamous cell carcinoma) – ALL of the following:**
- ☐ Age 18 years or older
- ☐ Patient not candidate for surgery or radiation therapy
- ☐ Recurrent, unresectable, or metastatic disease
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ First-line treatment – *1 or more of the following:*
    - ☐ Administered as monotherapy, and tumor tissue expresses PD-L1 ≥1% by FDA-approved test
    - ☐ Administered in combination with platinum (carboplatin or cisplatin) plus fluorouracil
  - ☐ Subsequent therapy – *ALL of the following:*
    - ☐ Administered as monotherapy
    - ☐ Disease progression on or after platinum-containing chemotherapy

☐ **Hepatocellular carcinoma – ALL of the following:**
- ☐ Age 18 years or older
- ☐ Child-Pugh class A liver disease
- ☐ Disease is secondary to hepatitis B infection
- ☐ Disease progression after previous systemic therapy other than PD-1 inhibitor (eg, nivolumab) or PD-L1 inhibitor (eg, atezolizumab, durvalumab)
- ☐ Unresectable disease

☐ **Hodgkin lymphoma (classical type) – ALL of the following:**
- ☐ Classical Hodgkin lymphoma
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ Adult patient with progression or relapse after autologous hematopoietic stem cell transplant
  - ☐ Pediatric patient – *1 or more of the following:*
    - ☐ Refractory disease
    - ☐ Relapsed disease after 2 or more prior lines of therapy

☐ **Melanoma – ALL of the following:**
- ☐ ECOG performance status of 0 to 2 (or equivalent)
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ Adjuvant therapy – *ALL of the following:*
    - ☐ Age 12 years or older
    - ☐ Administered following complete resection
    - ☐ Stage IIB, IIC, or III disease
  - ☐ Unresectable or metastatic disease – *ALL of the following:*
    - ☐ Age 18 years or older
    - ☐ Treatment scenario – *1 or more of the following:*
      - ☐ First-line therapy, administered as monotherapy
      - ☐ Second-line or subsequent therapy, administered as monotherapy, when patient has not had prior treatment with PD-1 inhibitor
      - ☐ Reinduction therapy for relapse after initial clinical response or disease progression after stable disease for >3 months, with no significant systemic toxicity during prior embrolizumab therapy

☐ **Merkel cell carcinoma (recurrent, locally advanced, or metastatic)**

☐ **Microsatellite instability-high, mismatch repair-deficient, or tumor mutational burden-high solid tumor – ALL of the following:**
- ☐ Cancer has progressed following prior treatment
- ☐ No satisfactory alternative treatment available
- ☐ Unresectable or metastatic disease

☐ **Non-small cell lung cancer – ALL of the following:**
- ☐ Age 18 years or older
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ First-line therapy as monotherapy – *ALL of the following:*
    - ☐ Advanced (stage IIIB or higher) or metastatic disease
    - ☐ Absence of EGFR or ALK genomic tumor aberrations (or unknown)
    - ☐ Tumor tissue expresses PD-L1 ≥1% by FDA-approved test
  - ☐ First-line therapy with platinum + pemetrexed – *ALL of the following:*
    - ☐ Advanced (stage IIIB or higher) or metastatic nonsquamous (large cell, adenocarcinoma, NSCLC NOS) NSCLC
    - ☐ Absence of EGFR or ALK genomic tumor aberrations (or unknown)
    - ☐ ECOG performance status of 0 to 1 (or equivalent)
  - ☐ First-line therapy with platinum + paclitaxel (or protein-bound paclitaxel) – *ALL of the following:*
    - ☐ Advanced (stage IIIB or higher) or metastatic squamous cell NSCLC
    - ☐ Absence of EGFR or ALK genomic tumor aberrations (or unknown)
    - ☐ ECOG performance status of 0 to 1 (or equivalent)
  - ☐ Perioperative therapy – *1 or more of the following:*
    - ☐ Adjuvant therapy as monotherapy – *ALL of the following:*
      - ☐ Administered following complete resection and platinum-based chemotherapy
      - ☐ Stage IB (tumor ≥4 cm), stage II, or stage III disease
    - ☐ Neoadjuvant therapy – *ALL of the following:*
      - ☐ Administered in combination with platinum-based chemotherapy for resectable disease (tumor ≥4 cm or node positive)
      - ☐ Continued as adjuvant monotherapy after surgery
  - ☐ Second-line therapy as monotherapy – *ALL of the following:*
    - ☐ Advanced (stage IIIB or higher) or metastatic disease
    - ☐ Disease progression on or after platinum-containing chemotherapy, or if EGFR/ALK aberrations present, progression on FDA-approved therapy for those aberrations
    - ☐ ECOG performance status of 0 to 2 (or equivalent)
    - ☐ Tumor tissue expresses PD-L1 ≥1% by FDA-approved test
    - ☐ No prior therapy with immune checkpoint inhibitor (eg, nivolumab, atezolizumab)

☐ **Primary mediastinal large B-cell lymphoma – ALL of the following:**
- ☐ Patient does not require urgent cytoreductive therapy
- ☐ Refractory or relapsed disease after 2 or more prior lines of therapy

☐ **Renal cell carcinoma – ALL of the following:**
- ☐ Age 18 years or older
- ☐ Clear cell histology
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ Adjuvant therapy after nephrectomy, or after nephrectomy and resection of metastatic lesions

☐ First-line treatment of advanced or metastatic disease, administered in combination with axitinib or lenvatinib

☐ **Squamous cell skin cancer – ALL of the following:**
- ☐ Curative surgery or radiation therapy not feasible
- ☐ Recurrent or metastatic disease

☐ **Urothelial (renal pelvis, ureter, bladder, or urethra) carcinoma – ALL of the following:**
- ☐ Age 18 years or older
- ☐ ECOG performance status of 0 to 2 (or equivalent)
- ☐ *Treatment scenario – 1 or more of the following:*
  - ☐ High-risk non-muscle-invasive bladder cancer with carcinoma in situ (with or without papillary tumors) unresponsive to treatment with BCG
  - ☐ Locally advanced or metastatic disease – *1 or more of the following:*
    - ☐ First-line therapy – *1 or more of the following:*
      - ☐ Administered as monotherapy, when patient not eligible for any platinum-containing therapy
      - ☐ Administered in combination with enfortumab vedotin
    - ☐ Second-line or subsequent therapy as monotherapy, when patient has disease progression during or following (or w/in 12 mos of neoadjuvant/adjuvant) platinum-containing chemotherapy
- ☐ No active autoimmune disease
- ☐ No active infection
- ☐ No concurrent use of systemic immunosuppressive therapy

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)
- ☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**
- ☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____
_____

**ACKNOWLEDGEMENT**

**Request 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. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

# Prior Authorization Group – Oncology: PD-1 Inhibitors PA

## Drug Name(s):

**KEYTRUDA** **PEMBROLIZUMAB**

## Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan, in accordance with the Label.

## Exclusion Criteria:

**Cannot be prescribed for experimental or investigational use.**

## Prescriber Restrictions:

**Oncologist or other cancer specialist**

## Coverage Duration:

**New Start: Approval will be for 6 months**
**Continuation: Approval will be for 12 months**

## FDA Indications:

**Keytruda**

- Biliary tract cancer, Unresectable, locally advanced or metastatic, in combination with gemcitabine and CISplatin
- Bladder cancer, Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive with carcinoma in situ, with or without papillary tumors in patients ineligible for or have elected not to undergo cystectomy, as monotherapy
- Bladder cancer, Muscle-invasive, as neoadjuvant therapy and then continued after cystectomy as adjuvant treatment, in combination with enfortumab vedotin, in patients who are ineligible for cisplatin-containing chemotherapy
- Cervical cancer, Locally advanced, involving the lower third of the vagina, with or without extension to pelvic sidewall, or hydronephrosis/non-functioning kidney, or spread to adjacent pelvic organs (FIGO 2014 Stage III to IVA), in combination with chemoradiotherapy (CRT)
- Cervical cancer, Persistent, recurrent, or metastatic disease in tumors that express PD-L1, in combination with chemotherapy, with or without bevacizumab
- Cervical cancer, Recurrent or metastatic disease, on or after chemotherapy, in tumors that express PD-L1, as a single agent
- Colorectal cancer, Unresectable or metastatic, MSI-H or dMMR
- Endometrial cancer, Advanced, dMMR or MSI-H, disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation, as a single agent
- Endometrial cancer, Advanced, pMMR or not MSI-H, disease progression following prior systemic therapy, in combination with lenvatinib
- Endometrial cancer, Advanced or recurrent disease, in combination with CARBOplatin and paclitaxel, followed by single-agent pembrolizumab therapy

- Esophageal cancer, Locally advanced or metastatic, not amenable to surgical resection or definitive chemoradiation, in combination with platinum- and fluoropyrimidine-based chemotherapy, or as a single agent after 1 or more prior lines of systemic therapy in PD-L1-expressing tumors of squamous cell histology
- Gastric cancer, Adenocarcinoma, locally advanced unresectable or metastatic, HER2-negative, in tumors that express PD-L1 (CPS 1 or greater); first-line in combination with fluoropyrimidine- and platinum-containing chemotherapy
- Gastric cancer, Adenocarcinoma, locally advanced unresectable or metastatic, HER2-positive, in tumors that express PD-L1 CPS 1 or greater, first-line in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
- Gastroesophageal junction cancer, Adenocarcinoma, locally advanced unresectable or metastatic, HER2-negative, in tumors that express PD-L1 (CPS 1 or greater); first-line in combination with fluoropyrimidine- and platinum-containing chemotherapy
- Gastroesophageal junction cancer, Adenocarcinoma, locally advanced unresectable or metastatic, HER2-positive, in tumors that express PD-L1 CPS 1 or greater, first-line in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
- Gastroesophageal junction cancer, Locally advanced or metastatic, not amenable to surgical resection or definitive chemoradiation, in combination with platinum- and fluoropyrimidine-based chemotherapy, or as a single agent after 1 or more prior lines of systemic therapy in PD-L1-expressing tumors of squamous cell histology
- Head and neck cancer, Metastatic or unresectable, recurrent squamous cell, first-line, with PD-L1 overexpression, as a single-agent
- Head and neck cancer, Metastatic or unresectable, recurrent squamous cell, first-line treatment in combination with platinum and fluorouracil
- Head and neck cancer, Recurrent or metastatic, squamous cell, with disease progression on or after platinum-based chemotherapy, as a single-agent
- Head and neck cancer, Resectable locally advanced, PD-L1 CPS 1 or greater, neoadjuvant as a single agent, continued as adjuvant treatment in combination with radiotherapy with or without cisplatin, then as a single agent
- Hodgkin's disease, Classical, refractory or relapsed
- Hodgkin's disease, Classical, refractory or relapsed after 2 or more prior lines of therapy
- Liver carcinoma, Secondary to hepatitis B, in patients who have received prior systemic therapy other than a PD-1/PD-L1-containing regimen
- Malignant mesothelioma of pleura, Previously untreated, unresectable advanced or metastatic, in combination with pemetrexed and platinum chemotherapy
- Melanoma, Adjuvant, with stage IIB, IIC, or III disease following complete resection
- Melanoma, Unresectable or metastatic
- Merkel cell carcinoma, Recurrent, locally advanced or metastatic
- Non-small cell lung cancer, Adjuvant therapy following resection and platinum-based chemotherapy, stage IB to IIIA, single agent
- Non-small cell lung cancer, Metastatic, PD-L1 expression, with disease progression on or after platinum-based chemotherapy; patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving pembrolizumab
- Non-small cell lung cancer, Metastatic disease, PD-L1 expression, with no EGFR or ALK tumor aberrations; first-line treatment
- Non-small cell lung cancer, Resectable, neoadjuvant therapy in combination with platinum-containing chemotherapy, then continued as a single agent as adjuvant therapy after surgery
- Non-small cell lung cancer, Stage 3, PD-L1 expression, with no EGFR or ALK tumor aberrations; first-line treatment in those ineligible for surgical resection or definitive chemoradiation
- Nonsquamous non-small cell lung cancer, Metastatic disease without EGFR or ALK aberrations, first-line treatment in combination with pemetrexed and platinum chemotherapy

- Ovarian cancer, Epithelial ovarian, fallopian tube, or primary peritoneal carcinoma, platinum-resistant, in patients whose tumors express PD-L1 (CPS 1 or greater), following 1 or 2 prior systemic treatment regimens, in combination with paclitaxel, with or without bevacizumab
- Primary mediastinal (thymic) large B-cell lymphoma, Refractory or relapsed after 2 or more lines of therapy
- Renal cell carcinoma, Adjuvant treatment, in patients with intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesion
- Renal cell carcinoma, Advanced, first-line therapy in combination with axitinib
- Renal cell carcinoma, Advanced, in combination with lenvatinib, first-line treatment
- Solid tumor, Unresectable or metastatic, high tumor mutational burden, with progression following prior treatment
- Solid tumor, Unresectable or metastatic, MSI-H or dMMR, progressed following prior treatment and who have no satisfactory alternative treatment options
- Squamous cell carcinoma of skin, Recurrent or metastatic or locally advanced, not curable by surgery or radiation
- Squamous non-small cell lung cancer, Metastatic, first-line treatment in combination with carboplatin and either paclitaxel or nab-paclitaxel
- Triple-negative breast cancer, High-risk early-stage, in combination with chemotherapy as neoadjuvant treatment, then continued as a single agent as adjuvant treatment after surgery
- Triple-negative breast cancer, Locally recurrent unresectable or metastatic disease, PD-L1 positive, in combination with chemotherapy
- Urothelial carcinoma, Metastatic or locally advanced, in combination with enfortumab vedotin
- Urothelial carcinoma, Metastatic or locally advanced, in patients not eligible for any platinum-containing chemotherapy
- Urothelial carcinoma, Metastatic or locally advanced, with progression during or after platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy, as monotherapy

## Off-Label Uses:

- Anal cancer, Advanced or metastatic squamous cell disease, previously treated
- Malignant mesothelioma of pleura, Previously treated
- Melanoma, Neoadjuvant, resectable stage III or IV disease
- Triple-negative breast cancer, Unresectable locally advanced or metastatic disease, PD-L1 positive, previously untreated, in combination with sacituzumab govitecan
- Urothelial carcinoma, Adjuvant treatment in those at high risk for recurrence

## Age Restrictions:

**N/A**

## Other Clinical Considerations:

Criteria as per NCCN or other FDA-approved cancer related guidelines.

## Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/B3282F/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/35839B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931040&contentSetId=100&title=Pembrolizumab&servicesTitle=Pembrolizumab&brandName=Keytruda&UserMdxSearchTerm=Keytruda&=null#