ATRIO HEALTH PLANS

Chemotherapy: PD-1 Inhibitor

Keytruda (pembrolizumab) J9271 is non-preferred. The preferred product is Part D covered Keytruda. (May require PA)

Prior Authorization Step Therapy 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.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	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	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐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)**

☐ **Patient has tried / failed Humira under Medicare Part D - Billing Date: _____**
If not, please provide clinical rationale why member cannot Self-Administer
_____

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**
If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**

☐ 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.

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

- Carcinoma of urinary bladder, superficial, Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, with carcinoma in situ, with or without papillary tumors in patients ineligible for or have elected not to undergo cystectomy
- Cervical cancer, Recurrent or metastatic disease, on or after chemotherapy, in tumors that express PD-L1, as a single agent
- Cervical cancer, Persistent, recurrent, or metastatic disease in tumors that express PD-L1, in combination with chemotherapy, with or without bevacizumab
- Colorectal cancer, unresectable or metastatic, Microsatellite instability-high, Or mismatch repair deficient
- Endometrial carcinoma, Carcinoma, advanced disease, not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), in combination with lenvatinib in patients with disease progression following prior systemic therapy in any setting who are not candidates for curative surgery or radiation
- 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
- Esophagogastric cancer, Adenocarcinoma, locally advanced or metastatic, PD-L1 expression, after failure of 2 or more fluoropyrimidine- and platinum- containing therapies
- Esophagogastric cancer, Adenocarcinoma, locally advanced unresectable or metastatic, HER2-positive, first-line in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
- Esophagogastric 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-positive, first-line in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy
- 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
- High tumor mutational burden - Solid tumor, Unresectable or metastatic, progression following prior treatment
- Hodgkin's disease, Classical, refractory or relapsed
- Hodgkin's disease, Classical, refractory or relapsed after 2 or more prior lines of therapy
- Liver carcinoma, In patients previously treated with sorafenib
- Malignant melanoma, Adjuvant, with stage IIB, IIC, or III following complete resection
- Malignant melanoma, Unresectable or metastatic
- Merkel cell carcinoma, Recurrent, locally advanced or metastatic
- Metastatic urothelial carcinoma, Or locally advanced, in patients with not eligible for any platinum-containing chemotherapy regimen regardless of PD-L1 status
- Metastatic urothelial carcinoma, Progression during or after platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy
- Microsatellite instability-high, Or mismatch repair deficient - Solid tumor, Unresectable or metastatic, progressed following prior treatment and who have no satisfactory alternative treatment options
- 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, PD-L1 expression, first-line treatment, with no EGFR or ALK tumor aberrations and is metastatic or stage 3 where patients are not candidates for surgical resection or definitive chemoradiation
- 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
- Primary mediastinal (thymic) large B-cell lymphoma, Refractory or relapsed after 2 or more lines of therapy
- Renal cell carcinoma, Advanced, first-line therapy in combination with axitinib
- Renal cell carcinoma, Advanced, in combination with lenvatinib, first-line treatment
- 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
- 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 whose tumors express PD-L1, in combination with chemotherapy

Off-Label Uses:

- Anal cancer, Advanced or metastatic squamous cell disease, previously treated
- Malignant mesothelioma of pleura, Previously treated

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#