

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Keytruda (pembrolizumab)
BILLING CODE	J9271
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 200 mg every 3 weeks
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Keytruda (pembrolizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CLASSICAL HODGKIN LYMPHOMA (cHL)

For **initial** authorization:

1. Medication is being used for the treatment of adult and pediatric patients with refractory cHL, or who have relapsed after 3 or more prior lines of therapy; AND
2. Medication must be prescribed by oncologist/hematologist; AND
3. Member does **not** have ALL of the following:
 - a) Active, non-infectious pneumonitis;
 - b) An allogeneic hematopoietic stem cell transplantation (HSCT) within the past 5 years (or greater than 5 years but with symptoms of graft versus host disease (GVHD));
 - c) Active autoimmune disease;
 - d) A medical condition that required immunosuppression;
 - e) An active infection requiring systemic therapy.
4. **Dosage allowed:** 200 mg every 3 weeks for adults; 2 mg/kg (up to 200 mg) every 3 weeks for pediatrics.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved.

HEAD AND NECK SQUAMOUS CELL CANCER (HNSCC)

For **initial** authorization:

1. Member must be 18 year of age or older; AND
2. Medication is being used for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy; AND
3. Medication must be prescribed by oncologist/hematologist; AND
4. Member does **not** have ALL of the following:
 - a) Active autoimmune disease;
 - b) A medical condition that required immunosuppression;
 - c) Evidence of interstitial lung disease.
5. **Dosage allowed:** 200 mg every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved.

MELANOMA

For **initial** authorization:

1. Member must be 18 year of age or older; AND
2. Medication must be prescribed by oncologist/hematologist; AND
3. Member has unresectable or metastatic melanoma and **one** of the following:
 - a) Member is ipilimumab (Yervoy)-naïve (was not treated with ipilimumab) with ALL of the following:
 - i) Member had no more than one prior systemic treatment for metastatic melanoma; AND
 - ii) Member does **not** have ALL of the following:
 - (1) Autoimmune disease;
 - (2) A medical condition that required immunosuppression;
 - (3) Previous severe hypersensitivity to other monoclonal antibodies;
 - (4) HIV, hepatitis B or hepatitis C infection;
 - b) Member is ipilimumab (Yervoy)-refractory (i.e. refractory to two or more doses of ipilimumab (3 mg/kg or higher)) with ALL of the following:
 - i) Disease progression within 24 weeks following the last dose of ipilimumab is documented in chart notes; AND
 - ii) Member does not have uveal melanoma and active brain metastasis; AND
 - iii) Chart notes with documentation that member is refractory to a BRAF or MEK inhibitor (if BRAF V600 mutation-positive).
4. **Dosage allowed:** 200 mg every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved.

MICROSATELLITE INSTABILITY-HIGH CANCER

For **initial** authorization:

1. Member must be 18 year of age or older; AND
2. Medication is being used for the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient with:
 - a) Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, OR
 - b) Colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan; AND
3. Medication must be prescribed by oncologist/hematologist; AND
4. Member does not have active autoimmune disease or a medical condition that required immunosuppression.
5. **Dosage allowed:** 200 mg every 3 weeks for adults and 2 mg/kg (up to 200 mg) every 3 weeks for children.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved.

NON-SMALL CELL LUNG CANCER (NSCLC)

For **initial** authorization:

1. Member must be 18 year of age or older; AND
2. Medication must be prescribed by oncologist/hematologist; AND
3. Member has metastatic NSCLC whose tumors have high PD-L1 expression [(Tumor Proportion Score (TPS) $\geq 50\%$)] as determined by an FDA-approved test with **both** of the following:
 - a) Medication is being used in combination with pemetrexed and carboplatin, as first-line treatment of patients with metastatic nonsquamous NSCLC. Chart notes with length of chemotherapy cycle and the days of the cycle (on which chemotherapy will be administered) submitted with prior authorization request; AND
 - b) Member does **not** have ALL of the following:
 - i) Autoimmune disease that required systemic therapy within 2 years of treatment;
 - ii) A medical condition that required immunosuppression;
 - iii) Received more than 30 Gy of thoracic radiation within the prior 26 weeks;
 - iv) EGFR or ALK genomic tumor aberrations; OR
4. Member has metastatic NSCLC whose tumors express PD-L1 (TPS $\geq 1\%$) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy with **both** of the following:
 - a) Medication is being used as a single agent; AND
 - b) Members with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda with ALL of the following:
 - i) Member has documented in chart notes disease progression following treatment with platinum-based chemotherapy; AND
 - ii) Member does not have autoimmune disease or other medical conditions that required systemic corticosteroids or other immunosuppressive medication; AND
 - iii) Member did not received more than 30 Gy of thoracic radiation within the prior 26 weeks were ineligible.
5. **Dosage allowed:** 200 mg every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved.

UROTHELIAL CARCINOMA (UrC)

For **initial** authorization:

1. Member must be 18 year of age or older; AND
2. Medication must be prescribed by oncologist/hematologist; AND
3. Member does **not** have autoimmune disease or medical conditions that required systemic corticosteroids or other immunosuppressive medications; AND
4. Medication is being used for the treatment of patients with locally advanced or metastatic UrC who are not eligible for cisplatin-containing chemotherapy (i.e. impaired renal function (creatinine clearance of < 60 mL/min), Class III heart failure, Grade 2 or greater peripheral neuropathy, and Grade 2 or greater hearing loss); OR
5. Medication is being used for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
6. **Dosage allowed:** 200 mg every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

If member meets all the reauthorization requirements above, the medication will be approved.

CareSource considers Keytruda (pembrolizumab) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/20/2017	New policy for Keytruda created.

References:

1. Keytruda [package insert]. Whitehouse Station, NJ; Merck Sharp & Dohme Corp: May, 2017.
2. ECOG Performance Status. ECOG-ACRIN Cancer Research Group. <http://ecog-acrin.org/resources/ecog-performance-status>.

Effective date: 09/01/2017

Revised date: 06/20/2017