CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Bavencio (avelumab)
BILLING CODE	J9999
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 10 mg/kg every 2 weeks
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Bavencio (avelumab) 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.

METASTATIC MERKEL CELL CARCINOMA (MCC)

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Chart documentation confirming a diagnosis of metastatic MCC; AND
3. Medication must be prescribed by oncologist/hematologist; AND
4. Member does **not** have ANY of the following:
   a) Autoimmune disease;
   b) Medical conditions requiring, systemic immunosuppression;
   c) Prior organ or allogeneic stem cell transplantation;
   d) Prior treatment with anti-PD-1, anti-PD-L1, or anti-CTLA-4 antibodies;
   e) Central nervous system (CNS) metastases;
   f) Infection with HIV, hepatitis b or hepatitis c (lab results must be submitted with chart notes);
   g) Eastern cooperative oncology group (ECOG) performance score > 2; AND
5. Documentation in chart notes that member was instructed to practice effective contraception during therapy and for at least 1 month after stopping therapy (for female members only).
6. **Dosage allowed:** Administer 10 mg/kg as an intravenous infusion over 60 minutes every 2 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 initial criteria; AND
2. Member's serum creatinine is no more than 6 times the upper limit of normal; AND
3. Member's aspartate aminotransferase (AST) or alanine aminotransferase (ALT) are no more than 5 times the upper limit of normal or total bilirubin is no more than 3 times the upper limit of normal; AND
4. Member does not have Grade 4 diarrhea or colitis or recurrent Grade 3 diarrhea or colitis; AND
5. Member does not use prednisone (or other steroid) of 10 mg per day or greater for more than 12 weeks; AND
6. Member does not have persistent Grade 2 or 3 immune-mediate adverse reactions lasting 12 weeks or longer; AND
7. Member does not have Grade 3 or 4 pneumonitis or recurrent Grade 2 pneumonitis.

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

UROTHELIAL CARCINOMA (UrC)

For **initial** authorization:

1. Member 18 years of age and older and has diagnosis of advanced or metastatic UrC documented in chart notes; AND
2. Medication must be prescribed by oncologist/hematologist; AND
3. Member has disease progression during or following platinum-containing chemotherapy, or disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy; AND
4. Member does **not** have ANY of the following:
   a) Active or history of central nervous system metastasis;
   b) Other malignancies within the last 5 years;
   c) Organ transplant;
   d) Conditions requiring therapeutic immune suppression;
   e) Active infection with HIV, hepatitis B, or hepatitis C;
   f) Autoimmune disease (other than type 1 diabetes, vitiligo, psoriasis, or thyroid disease) that did not require immunosuppressive treatment.
5. **Dosage allowed:** Administer 10 mg/kg as an intravenous infusion over 60 minutes every 2 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 initial criteria; AND
2. Member's serum creatinine is no more than 6 times the upper limit of normal; AND
3. Member's aspartate aminotransferase (AST) or alanine aminotransferase (ALT) are no more than 5 times the upper limit of normal or total bilirubin is no more than 3 times the upper limit of normal; AND
4. Member does not have Grade 4 diarrhea or colitis or recurrent Grade 3 diarrhea or colitis; AND
5. Member does not use prednisone (or other steroid) of 10 mg per day or greater for more than 12 weeks; AND
6. Member does not have persistent Grade 2 or 3 immune-mediate adverse reactions lasting 12 weeks or longer; AND
7. Member does not have Grade 3 or 4 pneumonitis or recurrent Grade 2 pneumonitis.

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

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

DATE	ACTION/DESCRIPTION
08/02/2017	New policy for Bavencio created.

References:

1. Bavencio [package insert]. Rockland, MA; EMD Serono, Inc. and Pfizer Inc.: Revised March, 2017.

Effective date: 11/01/2017
Revised date: 08/02/2017