Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Opdivo (nivolumab)

Policy Number: 5.02.545
Origination: 10/2017
Last Review: 10/2018
Next Review: 10/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Opdivo when it is determined to be medically necessary because the following criteria have been met.

When Policy Topic is covered

Opdivo is considered **medically necessary** for the following indications:

FDA Approved Indications:
Age 18 years of age or older:

1. Unresectable or metastatic melanoma with ONE of the following:
    a. BRAF V600 mutation positive
    b. BRAF V600 wild-type
    c. Used in combination with ipilimumab

2. Adjuvant treatment of Melanoma post resection

3. Metastatic non-small cell lung cancer with ONE of the following:
    a. Disease must have progressed while on or after platinum-based chemotherapy
    b. If EGFR or ALK genomic tumor aberration, had disease progression on FDA approved therapy

4. Advanced renal cell carcinoma
    a. Prior treatment with anti-angiogenic therapy or
    b. In combination with ipilimumab for intermediate or poor risk, previously untreated

5. Relapsed or progressed classical Hodgkin lymphoma with ONE of the following:
    a. Patient has had autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation therapy with brentuximab vedotin (Adcetris)
    b. Patient has had 3 or more lines systemic therapy that includes autologous HSCT

6. Recurrent or metastatic squamous cell carcinoma of the head and neck
    a. Disease must have progressed while on or after platinum-based chemotherapy

7. Locally advanced or metastatic urothelial carcinoma with ONE of the following:
    a. Disease must have progressed while on or after platinum-based chemotherapy
    b. Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

8. Hepatocellular carcinoma
    a. Prior treatment with sorafenib (Nexavar)

9. Metastatic small cell lung cancer in patients with progression after platinum-based chemotherapy and at least one other line of therapy

Age 12 years and older:

9. Colorectal cancer, metastatic (microsatellite instability-high or mismatch repair deficient) in adult and pediatric patients 12 years of age and older
    a. Disease must have progressed following treatment with a fluoropyrimidine, oxaliplatin or irinotecan.

When Policy Topic is not covered

Opdivo is considered **investigational** in patients less than 18 years of age (except as noted above under colorectal cancer indication) and in patients with all other indications.

Considerations

Opdivo requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Background

Opdivo is a monoclonal antibody for the treatment of patients with unresectable (cannot be removed by surgery), metastatic (advanced) melanoma and metastatic non-small cell lung cancer, renal cell carcinoma, relapsed or progressed classical Hodgkin lymphoma, recurrent or metastatic squamous cell carcinoma of the head and neck or locally advanced or metastatic urothelial carcinoma who are no longer responding to other drugs. Opdivo works by inhibiting the PD-1 protein on cell surfaces, which blocks the immune system from attacking melanoma tumors. Opdivo is intended for patients who have been previously treated with ipilimumab and, for melanoma patients whose tumors express a gene mutation called BRAF V600, after treatment with ipilimumab and a BRAF inhibitor have lost effectiveness (1).

Clinically significant immune-mediated adverse reactions may occur with Opdivo therapy including pneumonitis, colitis, hepatitis, nephritis, renal dysfunction, hyperthyroidism, and hypothyroidism. Patients should be monitored for signs and symptoms of adverse reactions and based on the severity, Opdivo should be withheld or discontinued and corticosteroids administered. Opdivo may cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised of the potential hazard to a fetus. Opdivo is administered every 2 weeks until disease progression or unacceptable toxicity (1).

Safety and effectiveness of Opdivo have not been established in pediatric patients younger than 12 years (1).

Rationale

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Opdivo while maintaining optimal therapeutic outcomes.

References

1. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. December 2017.

Billing Coding/Physician Documentation Information

J9299	Injection, nivolumab, 1 mg

Additional Policy Key Words

5.02.545

Policy Implementation/Update Information

10/2017	New policy titled Opdivo (nivolumab)
06/2018	New indications added
10/2018	Metastatic small cell lung cancer added to list of approved indications