Reference number(s)
5326-A

STANDARD MEDICARE PART B MANAGEMENT

OPDUALAG (nivolumab and relatlimab-rmbw)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Opdualag is indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Melanoma
Authorization of 6 months may be granted for treatment of adult members and children 12 years of age and older weighing at least 40 kg, with unresectable or metastatic melanoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 6 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen AND
    2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Opdualag.
2. The available compendium

a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
b. Micromedex DrugDex
c. American Hospital Formulary Service- Drug Information (AHFS-DI)
d. Lexi-Drugs
e. Clinical Pharmacology

3. NCCN Guideline: Cutaneous melanoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Opdualag are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Opdualag [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2022.