

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Injectable – Programmed Death Receptor-1) – Opdualag Prior Authorization Policy
- Opdualag™ (nivolumab and relatlimab-rmbw intravenous infusion – Bristol-Myers Squibb)

REVIEW DATE: 03/30/2022

OVERVIEW

Opdualag, a combination of a programmed death receptor-1 (PD-1) blocking antibody and a lymphocyte activation gene-3 (LAG-3) blocking antibody, is indicated for the treatment of unresectable or metastatic **melanoma** in patients ≥ 12 years of age.¹

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for **cutaneous melanoma** (version 3.2022 – April 11, 2022) recommend Opdualag as a preferred first-line treatment option for patients with metastatic or unresectable disease.^{2,3}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Opdualag. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Opdualag as well as the monitoring required for adverse events and long-term efficacy, approval requires Opdualag to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Opdualag is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Melanoma.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
 - A) Patient is ≥ 12 years of age; AND
 - B) Patient is ≥ 40 kg; AND
 - C) Patient has unresectable or metastatic disease; AND
 - D) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Opdualag is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Opdualag intravenous infusion [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; March 2022.

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2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on April 11, 2022. Search term: nivolumab and relatlimab.
3. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 3.2022 – April 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>.

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