

**POLICY:** Oncology (Injectable – Programmed Death Receptor-1) – Opdualag Utilization  
Management Medical Policy

- Opdualag™ (nivolumab and relatlimab-rmbw intravenous infusion – Bristol-Myers Squibb)

**EFFECTIVE DATE:** 07/01/2022

**LAST REVIEW DATE:** 02/25/2026

**COVERAGE CRITERIA FOR:** All Aspirus Medicare Plans

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### **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  $\geq 12$  years of age.<sup>1</sup>

### **Dosing Information**

The recommended dose of Opdualag for patients  $\geq 12$  years of age and weighing  $\geq 40$  kg is 480 mg of nivolumab and 160 mg of relatlimab administered by intravenous infusion once every 4 weeks until disease progression or unacceptable adverse events occur.<sup>1</sup> The recommended dose for patients  $\geq 12$  years of age and weighing  $\leq 40$  kg has not been established.

### **POLICY STATEMENT**

Prior Authorization is recommended for medical benefit coverage of Opdualag. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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

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1. **Melanoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
  - A) Patient is  $\geq$  12 years of age; AND
  - B) Patient weighs  $\geq$  40 kg; AND
  - C) Patient meets ONE of the following (i or ii):
    - i. Patient has unresectable or metastatic disease; OR
    - ii. Medication is used for neoadjuvant therapy; AND
  - D) The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve 480 mg of nivolumab and 160 mg of relatlimab administered by intravenous infusion no more frequently than once every 4 weeks.

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### 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 2024.
2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 19, 2026. Search term: nivolumab and relatlimab.
3. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 1.2026 – February 17, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 19, 2026.

### HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/29/2023
Annual Revision	<b>Melanoma:</b> "Patient has unresectable or metastatic disease" was changed from a requirement to an option for approval. "Medication is used for neoadjuvant therapy" was added as an option for approval.	03/27/2024
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
Annual Revision	No criteria changes.	03/19/2025
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/15/2025
Annual Revision	No criteria changes.	02/25/2026