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: 09/16/2024

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

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]

Dosing Information

The recommended dose of Opdualag for patients ≥ 12 years of age and weighing ≥ 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.[1] The recommended dose for patients ≥ 12 years of age and weighing ≤ 40 kg has not been established.

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for **cutaneous melanoma** (version 1.2024 – February 12, 2024) recommend Opdualag as a preferred first-line treatment option for patients with metastatic or unresectable disease (category 1).[2,3] Opdualag is also recommended for second-line or subsequent treatment, and for re-induction therapy in patients with disease control with previous anti-PD-1/LAG-3 therapy and disease progression or relapse occurring > 3 months after treatment discontinuation (category 2A). In addition, Opdualag is recommended as primary treatment for neoadjuvant therapy for stage III clinically positive, resectable nodal disease; initial and/or subsequent treatment for limited resectable stage III disease with clinical satellite/in-transit metastases and limited resectable local satellite/in-transit recurrence; and treatment for resectable disease limited to nodal recurrence (category 2A).

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 ≥ 12 years of age; AND
- **B)** Patient weighs ≥ 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.

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. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 25, 2024. Search term: nivolumab and relatlimab.

3. The NCCN Melanoma: Cutaneous Clinical Practice Guidelines in Oncology (version 1.2024 – February 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 25, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/29/2023
Annual Revision	**Melanoma:** "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