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: 03/27/2024

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 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 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 ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 12 years of age; AND
   - **B)** Patient is ≥ 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.

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.