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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/16/2026

Opdualag™ (nivolumab and relatlimab-rmbw)

HCPCS: J9298

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Treatment must follow the Food and Drug Administration (FDA) approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation
 - i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation
 - b. Must be prescribed by, or in consultation with, an oncologist or hematologist
 - c. No prior failure of a programmed death receptor-1 (PD-1 or PD-L1) inhibitor except when previous use was for neoadjuvant or adjuvant therapy and there was at least 6 months between the last dose of therapy and date of recurrence
 - d. No prior failure of a lymphocyte activation gene-3 (LAG-3) targeting agent
 - e. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant
 - f. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Align with FDA recommended dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Treatment may be continued until unacceptable toxicity or disease progression OR Not applicable as no further authorization will be provided.

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Opdualag is a combination PD-1 and LAG-3 blocking antibody indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.
- The National Comprehensive Cancer Network (NCCN) guidelines category 1 and 2A recommendations are based on uniform NCCN consensus that the recommendations are appropriate. Treatment regimens have been studied and shown to be efficacious when administered as listed in the guidelines. Category 2B and 3 recommendations do not have a high level of evidence to support use and also do not have a uniform consensus from the NCCN panel that the recommendations are appropriate.
- There are no studies to support use of Opdualag following failure. NCCN treatment guidelines also do not recommend use of Opdualag or other PD-L1 checkpoint inhibitors and LAG-3 blocking agents following a previous failure. The only time Opdualag has been shown to be effective following previous use with a PD-1/PD-L1 inhibitors is when the previous agent was used as neoadjuvant or adjuvant therapy and there was at least 6 months between the last dose of therapy and the date of recurrence. In these scenarios, use of Opdualag can be considered.
- Opdualag has not been studied in patients on chronic immunosuppressant therapy and therefore, should not be used in patients on chronic immunosuppressants.
- Opdualag has not been studied in patients with an ECOG performance status of greater than 1 and therefore, should not be used in patients with an ECOG score greater than 1.

References:

1. Opdualag [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; March 2024.
2. Tawbi HA, Schadendorf D, Lipson EJ, et al. Relatlimab and nivolumab versus nivolumab in untreated advanced melanoma. NEJM. 2022 Jan 6; 386 (1): 24 - 34.
3. National Comprehensive Cancer Network. Cutaneous melanoma (Version 1.2026). 2026 Feb 17. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed on February 23, 2026.

Policy History												
#	Date	Change Description										
1.5	Effective Date: 04/16/2026	Updated to include the trial and failure of preferred products statement										
1.4	Effective Date: 04/10/2025	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 04/11/2024	Updated to remove the ECOG score requirement										
1.2	Effective Date: 04/06/2023	Updated approval length to allow for no less than a 60 day approval duration										
1.1	Effective Date: 12/01/2022	UM medical management system update for BCBS, BCN, MAPPO, and BCNA <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.0	Effective Date: 06/09/2022	New policy										

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.