

CLINICAL POLICY

Nivolumab and Relatlimab-rmbw



Clinical Policy: Nivolumab and Relatlimab-rmbw (Opdualag)

Reference Number: CP.PHAR.588

Effective Date: 08/2022

Last Review Date: 07/2025

Description

Nivolumab and relatlimab-rmbw (Opdualag™) is a fixed-dose combination of blocking antibodies against programmed death receptor-1 (PD-1) and lymphocyte activation gene-3 (LAG-3).

FDA Approved Indication(s)

Opdualag is indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Opdualag is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Melanoma (must meet all):

1. Diagnosis of melanoma and disease is one of the following (a or b):
 - a. Unresectable or metastatic;
 - b. Resectable or limited resectable (*off-label*);
2. Prescribed by or in consultation with an oncologist;
3. Age $\geq$ 12 years;
4. If age $\geq$ 12 years and $<$ 18 year, member's weight is $\geq$ 40 kg;
5. Request meets one of the following (a or b):
 - a. Dose does not exceed 480 mg of nivolumab and 160 mg of relatlimab every 4 weeks;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Melanoma (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;

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3. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 480 mg of nivolumab and 160 mg of relatlimab every 4 weeks;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

LAG-3: lymphocyte activation gene-3

PD-1: programmed death receptor-1

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Melanoma (unresectable or metastatic)	480 mg nivolumab with 160 mg relatlimab IV every 4 weeks	See dosing regimen

VI. Product Availability

Single-dose vial: 240 mg of nivolumab and 80 mg of relatlimab per 20 mL

VII. References

1. Opdualag Prescribing Information. Princeton, NJ: Bristol Myers Squibb; March 2024. Available at <https://www.opdualag.com>. Accessed May 13, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 13, 2025.

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3. National Comprehensive Cancer Network: Melanoma: Cutaneous Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 13, 2025.
4. Tawbi HA, Schadendorf D, Lipson EJ, et al. Relatlimab and nivolumab versus nivolumab in untreated advanced melanoma. N Engl J Med. 2022 January; 386(1):24-34. doi: <https://www.doi.org/10.1056/NEJMoa2109970>.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg

Reviews, Revisions, and Approvals	Date
Policy created	07/2022
Added HCPCS code [J9298].	01/2023
3Q 2023 annual review: removed expired HCPCS codes [C9399, J3590]; references reviewed and updated.	07/2023
3Q 2024 annual review: added off label indication for resectable or limited resectable melanoma per NCCN 2A recommendation; revised weight criteria to apply only to pediatric patients per PI; references reviewed and updated.	07/2024
3Q 2025 annual review: no significant changes; references reviewed and updated.	07/2025