

## Clinical Policy: Nivolumab and Relatlimab-rmbw (Opdualag)

Reference Number: LA.PHAR.588

Effective Date: 09.29.23

Last Review Date: 08.18.25

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**\*\*Please note: This policy is for medical benefit\*\***

### 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 Louisiana Healthcare Connections® 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 years, 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*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 6 months**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255

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2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53.

## II. Continued Therapy

### A. Melanoma (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Opdualag for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
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*).

*\*Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.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 policy LA.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

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#### 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/](https://www.nccn.org/professionals/drug_compendium/content/). Accessed May 13, 2025.
3. National Comprehensive Cancer Network: Melanoma: Cutaneous Version 2.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/cutaneous\\_melanoma.pdf](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     | LDH Approval Date |
|---|----------|-------------------|
| Policy created  | 05.01.23 | 08.28.23          |
| Annual review: removed expired HCPCS codes [C9399, J3590]; references reviewed and updated.   | 03.15.24 | 05.23.24          |
| 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. | 10.09.24 | 01.27.25          |
| Annual review: no significant changes; references reviewed and updated.   | 08.18.25 |                   |

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#### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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