Clinical Policy: Nivolumab and Relatlimab-rmbw (Opdualag)

Reference Number: CP.PHAR.588
Effective Date: 08/2022
Last Review Date: 01/2023

Coding Implications
Revision Log

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 unresectable or metastatic melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 12 years;
4. Weight ≥ 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.LTSS.PHAR.01) applies;
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*).

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.LTSS.PHAR.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 intravenously 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 2022. Available at https://www.opdualag.com. Accessed March 30, 2022.
2. Non-small Cell Lung Cancer (Version 3.2022). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed March 31, 2022.

3. 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
C9399, J3590	Unclassified drugs or biologicals
J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07/2022	
Added HCPCS code [J9298].	01/2023	