

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

## Opdualag<sup>TM</sup> (nivolumab/relatlimab-rmbw) (Intravenous)

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### I. Length of Authorization <sup>Δ 1</sup>

Coverage will be provided for six (6) months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [NDC Unit]:

- Opdualag 240 mg/80 mg in a 20 mL single-dose vial: 2 vials per 28 days

#### B. Max Units (per dose and over time) [HCPCS Unit]:

- 480 mg/160 mg (nivolumab/relatlimab) every 28 days

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided for the following conditions:

- Patient is at least 12 years of age; **AND**

#### Universal Criteria <sup>1-3</sup>

- Patient weighs at least 40 kg; **AND**
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, pembrolizumab, atezolizumab, durvalumab, dostarlimab, etc.), unless otherwise specified <sup>Δ</sup>; **AND**
- Patient does not have active or untreated brain or leptomeningeal metastases; **AND**

#### Cutaneous Melanoma † <sup>1,2,3</sup>

- Will not be combined with other therapies; **AND**

*\*Metastatic disease includes stage III unresectable/borderline resectable disease with clinically positive node(s) or clinical satellite/in-transit metastases, as well as unresectable local satellite/in-transit recurrence, unresectable nodal recurrence, and widely disseminated distant metastatic disease.*

*❖ If confirmed using an immunotherapy assay-<http://www.fda.gov/CompanionDiagnostics>*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); ◻ Orphan Drug

#### IV. Renewal Criteria <sup>Δ 1-3</sup>

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), severe immune-mediated adverse reactions (i.e., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, myocarditis, adverse skin reactions/rash, neurologic toxicities, etc.), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

##### Δ Notes:

- Patients responding to therapy who relapse  $\geq 6$  months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.
- Patients who complete adjuvant therapy and progress  $\geq 6$  months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

#### V. Dosage/Administration <sup>Δ 1</sup>

| Indication         | Dose   |
|--------------------|--|
| Cutaneous Melanoma | <u>Adult patients and pediatric patients 12 years of age or older who weigh at least 40 kg:</u> <ul style="list-style-type: none"><li>• Administer 480 mg nivolumab and 160 mg relatlimab (contents of 2 vials) intravenously over 30 minutes every 4 weeks until disease progression or unacceptable toxicity</li></ul> |

#### VI. Billing Code/Availability Information

##### HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drug

##### NDC(s):

- Opdualag 240 mg of nivolumab and 80 mg of relatlimab per 20 mL single-dose vial: 00003-7125-xx

## VII. References

1. Opdualag [package insert]. Princeton, NJ; Bristol-Myers Squibb Company; March 2022. Accessed March 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) nivolumab-relatlimab. National Comprehensive Cancer Network, 2022. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2022.
3. Tawbi HA, Schadendorf D, Lipson EJ; RELATIVITY-047 Investigators, et al. Relatlimab and nivolumab versus nivolumab in untreated advanced melanoma. *N Engl J Med.* 2022;386:24-34.

### Appendix 1 – Covered Diagnosis Codes

| ICD-10  | ICD-10 Description   |
|---------|--|
| C43.0   | Malignant melanoma of lip  |
| C43.10  | Malignant melanoma of unspecified eyelid, including canthus        |
| C43.11  | Malignant melanoma of right eyelid, including canthus              |
| C43.12  | Malignant melanoma of left eyelid, including canthus               |
| C43.111 | Malignant melanoma of right upper eyelid, including canthus        |
| C43.112 | Malignant melanoma of right lower eyelid, including canthus        |
| C43.121 | Malignant melanoma of left upper eyelid, including canthus         |
| C43.122 | Malignant melanoma of left lower eyelid, including canthus         |
| C43.20  | Malignant melanoma of unspecified ear and external auricular canal |
| C43.21  | Malignant melanoma of right ear and external auricular canal       |
| C43.22  | Malignant melanoma of left ear and external auricular canal        |
| C43.30  | Malignant melanoma of unspecified part of face                     |
| C43.31  | Malignant melanoma of nose   |
| C43.39  | Malignant melanoma of other parts of face                          |
| C43.4   | Malignant melanoma of scalp and neck                               |
| C43.51  | Malignant melanoma of anal skin                                    |
| C43.52  | Malignant melanoma of skin of breast                               |
| C43.59  | Malignant melanoma of other part of trunk                          |
| C43.60  | Malignant melanoma of unspecified upper limb, including shoulder   |
| C43.61  | Malignant melanoma of right upper limb, including shoulder         |
| C43.62  | Malignant melanoma of left upper limb, including shoulder          |

|        |   |
|--------|---|
| C43.70 | Malignant melanoma of unspecified lower limb, including hip |
| C43.71 | Malignant melanoma of right lower limb, including hip       |
| C43.72 | Malignant melanoma of left lower limb, including hip        |
| C43.8  | Malignant melanoma of overlapping sites of skin             |
| C43.9  | Malignant melanoma of skin, unspecified                     |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |   |   |
|---|---|---|
| Jurisdiction  | Applicable State/US Territory   | Contractor  |
| E (1)   | CA, HI, NV, AS, GU, CNMI  | Noridian Healthcare Solutions, LLC                |
| F (2 & 3)   | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ  | Noridian Healthcare Solutions, LLC                |
| 5   | KS, NE, IA, MO  | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6   | MN, WI, IL  | National Government Services, Inc. (NGS)          |
| H (4 & 7)   | LA, AR, MS, TX, OK, CO, NM  | Novitas Solutions, Inc.                           |
| 8   | MI, IN  | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9)   | FL, PR, VI  | First Coast Service Options, Inc.                 |
| J (10)  | TN, GA, AL  | Palmetto GBA, LLC                                 |
| M (11)  | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                                 |
| L (12)  | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc.                           |
| K (13 & 14)   | NY, CT, MA, RI, VT, ME, NH  | National Government Services, Inc. (NGS)          |
| 15  | KY, OH  | CGS Administrators, LLC                           |