Nivolumab and relatlimab-rmbw (Opdualag™)	Place of Service Office Administration Infusion Center Administration Outpatient Facility Administration HCPCS: J9298 per 3 mg/1 mg

Condition(s) listed in policy (*see criteria for details*)

- Melanoma: cutaneous

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: PD-1–blocking antibody and lymphocyte-activation gene 3 (LAG-3)–blocking antibody

(1) Special Instructions and pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Opdualag™ (nivolumab and relatlimab-rmbw) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Melanoma: cutaneous

1. Disease is unresectable or metastatic, **AND**
2. Not being used in combination with other systemic therapy for melanoma

Covered Doses
Up to 480 mg nivolumab and 160 mg relatlimab IV every 4 weeks

Coverage Period
Indefinitely

ICD-10:
C43.0, C43.10 -C43.12, C43.111, C43.112, C43.121, C43.122, C43.20-C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59, C43.60-C43.62, C43.70-C43.72, C43.8, C43.9

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Opdualag™ (nivolumab and relatlimab-rmbw) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

240 mg of nivolumab and 80 mg of relatlimab per 20 mL (12 mg and 4 mg per mL) in single dose vials

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com
- Opdualag™ (nivolumab and relatlimab-rmbw) [Prescribing Information]. Princeton, NJ: Bristol-Myers Squibb Company; 3/2022.
- National Comprehensive Cancer Network. Melanoma: Cutaneous. (Version 2.2023). Available at: http://www.nccn.org.

(7) Policy Update

Date of last review: 2Q2023

Date of next review: 2Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee