Medical Policy

Opdualag™ (nivolumab/relatlimab-rmbw)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-124
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan*: ALL *Small Group:* ALL *Medicare Advantage*: ALL

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Opdualag™ (nivolumab/relatlimab-rmbw) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Opdualag will be provided for six months and may be renewed.

- Max Units (per dose and over time): 480 mg/160 mg (nivolumab/relatlimab) every 28 days

Initial

A. Patient is 12 years of age or older; **AND**
B. Patient weighs at least 40 kg; **AND**
C. Patient has a diagnosis of unresectable or metastatic melanoma; **AND**
D. Opdualag will be used as first-line therapy; **AND**
E. Opdualag will not be combined with other therapies; **AND**

F. 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*; **AND**
G. Patient does not have active or untreated brain or leptomeningeal metastases.

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. 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**
C. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

*- Patients responding to therapy who relapse ≥ 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 ≥ 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.

LIMITATIONS/EXCLUSIONS

1) Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. OPDUALAG™ (nivolumab and relatlimab-rmbw) injection, for intravenous use. Initial U.S. Approval: 2022
    a. OPDUALAG (nivolumab and relatlimab-rmbw) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution for intravenous use supplied in a single-dose vial containing 240 mg of nivolumab and 80 mg of relatlimab per 20 mL (12 mg and 4 mg per mL) per carton

CODING

Applicable NDC Codes	
00003-7125-11	Opdualag (nivolumab and relatlimab-rmbw) 12 mg/1 ml-4 mg/1 ml injection

Applicable Procedure Code	
J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg

Applicable ICD-10 Codes	
C43.0	Malignant melanoma of lip

Applicable ICD-10 Codes	
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

EVIDENCE BASED REFERENCES

1. Opdualag [package insert]. Princeton, NJ; Bristol-Myers Squibb Company; March 2022. Accessed July 2022.

Policy History

This policy has been approved by the approval body listed below or has received other necessary

approval pursuant to Brand New Day/Central Health Medicare Plan Care's policies on clinical criteria and policy development.

Approval Body	Pharmacy and Therapeutics Committee
Original Effective Date	July 26, 2022
Revision Date	February 28, 2023 – Annual review, Updated HCPCS for Opdualag (J9298) March 01, 2023 – Adopted by MA UMC January 01, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan